

# CORPORATE SOCIAL RESPONSIBILITY REPORTING 2011



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## OUR VISION

Corporate Social Responsibility (CSR) lies at the core of Sanofi's business activities. As a global healthcare partner focused on patients and their needs, we pay careful attention to the social, environmental and economic consequences of all our activities. Our commitment to act ethically and responsibly is fundamental to how we conduct our business each day.

Sanofi implements our CSR approach across four key areas:  
Patient, Ethics, People and Planet.

### Listed on the DJSI World Index for the 5th year running

Sanofi was listed on the Dow Jones Sustainability World Index (DJSI World) for the fifth consecutive year for our CSR and sustainability performance. In 2011, the Group was one of only eight pharmaceutical companies selected from among 56 applicants.



### A stronger CSR Network

#### Growth of our CSR Network in 2011

- Over 80 CSR correspondents
- representing all affiliates, regions and corporate functions worldwide
- working on over 200 CSR projects to date
- overseen by the CSR Excellence Team

### Ongoing stakeholder dialogue

In France, the Group has created a panel of internal and external experts to support us as we define the Group's CSR commitments and address our CSR challenges.

- [Our vision / Our stakeholder / Ongoing stakeholder dialogue](#)

## BUSINESS CASES



Our CSR initiatives impact our business. In addition to bringing benefits to patient, the environment, our employees and other stakeholders, our commitment to CSR principles has a positive effect on our bottom line.

- [Our vision / Our report overview / The business case approach](#)



## Message from Senior management

Interview with Christopher A. Viehbacher and Gilles Lhernould



**Christopher A. Viehbacher**

Chief Executive Officer

**Gilles Lhernould**

Senior Vice President  
Corporate Social Responsibility



### What CSR challenges is the Group facing?

**Christopher A. Viehbacher (CV):** Corporate Social Responsibility is a subject that is complex, encompasses many aspects of our business and ultimately affects the lives of people around the world. The primary area where we can and do have an impact is in healthcare. We have the expertise and resources to make a real difference. We have, as in some other companies, a comprehensive access to medicines department but we go much further. The real challenge of our time is access to healthcare itself – improving the infrastructures, the health policies, the pricing programs and boosting the local economy are all areas where we have seen we can make a change and therefore where we will continue to concentrate our efforts.

The effect we have on the environment is another key challenge. We need to have the most positive and the least negative effect. To this end, we have put in place a number of teams to

ensure we do not just meet standards, but go beyond them. A particular focus is to reduce the consumption of gas and oil in our sites, increase the use of greener technologies and reduce the environmental footprint and costs.

**Gilles Lhernould (GL):** As part of our commitment to acting ethically and to supporting employees during the Group's transformation, we support our people in every way we can to best manage any impact that is caused and to help them through the process and beyond. An example of this includes the provision of outplacement opportunities, training programs and various measures to help employees impacted by change. For example, Sanofi's business "start-up" unit in France assists employees who wish to create their own business.

## What are the areas where you feel Sanofi's CSR approach is making the greatest impact?

**CV:** Simply put, in healthcare. Over the years we have developed deep partnerships with key stakeholders to improve access to healthcare for the poorest of populations. We have significant drug and vaccine donation programs for example through our Sanofi Espoir Foundation, our commitment to the Polio Eradication Initiative and vaccination programs for yellow fever with GAVI. We work with individual countries to support access through tiered pricing programs such as we have in Africa for malaria.

Our partnership with the WHO is one I am particularly proud of. We established this in 2001 and it has evolved over the years to include Buruli Ulcer, Chagas disease and leishmaniasis. But the main focus has been sleeping sickness and the results speak for themselves. Since 2001, we have screened over 2 million patients for the disease, which is usually fatal if left untreated. We have diagnosed and treated 170,000 patients. Early in 2012, we reconfirmed our commitment to WHO and the Bill & Melinda Gates Foundation in Neglected Tropical Diseases with a primary goal to eliminate Sleeping Sickness by 2020. We are on track to achieve this.

In 2011, we also signed a 3-year research agreement with DNDi for nine NTDs and we signed up to the WIPO Consortium (World Intellectual Property Organization). Through these partnerships we will share valuable intellectual property and expertise to enable faster development of more effective treatments in NTDs.

But where we further differ from others is the work we do in the broader healthcare arena. We have been present in over 100 countries for many decades and we provide our expertise and resources to advise on and support better health infrastructure. For example, we have worked with some African governments and agencies on developing specific health policies for their country. Equally, training and compliance has become a focus. A good example is our work in TB, where completing treatment is vital to a full recovery. In South Africa, we have trained healthcare physicians and nurses on how to diagnose and treat, we have set up clinics to

ensure patients are monitored correctly and we provide the educational resources to ensure patients understand the importance of completing treatment.

Supporting the local economy by manufacturing locally where possible is also a focus. We have 7 manufacturing sites in Africa which produce 60% the Group's needs for the continent. We also have a vaccines plant in India, Shantha, which means we can produce our vaccines at a lower price for the developing markets.

In terms of our progress environmentally, we are in good shape. We reduced our CO<sub>2</sub> emissions by 15%, two years ahead of plan. We just signed a 3-year partnership with Cofely, GDF SUEZ group, covering the construction of energy production and distribution facilities for all our manufacturing sites in continental Europe. It will use innovative technologies and work towards developing renewable energy. In 2007 we installed solar panels in Ambares and in 2009, in Quetigny, a French site. This program was extended in 2011 and once completed will mean 22,000m<sup>2</sup> of solar panels on 5 sites in France.

**GL:** Our CSR approach also makes a difference when it comes to diversity, which is a source of strength and is critical to performance and innovation – this is why diversity and equal opportunity are included in the Sanofi Code of Ethics. As part of our commitment to promoting gender balance, the Group was once again a premium sponsor of the Women's Forum for the Economy and Society. Today 45% of Sanofi managers are women, and the percentage of women on the Board of Directors has increased to 20%.

Our attention to ensuring employees' health and safety also paid off, because we lowered our lost time injury frequency rate for the sixth consecutive year, reaching a record low of 1.8.

Currently, we are preparing the global CSR correspondents convention for our CSR correspondent networks: we'll continue to provide in-depth information about the Group's CSR priorities and the sharing of best practices, so that our CSR strategy is implemented in every Sanofi organization across the globe. We are also very proud of the launch of the Sanofi Global CSR Awards in 2012.

## What about the future?

**CV:** There is still a lot of work to do to ensure we leave this planet in good shape for future generations and improve the health of as many as we can reach.

In each of the four pillars, we have new initiatives for 2012 and beyond. For example, we now have a 2020 goal to reduce our CO<sub>2</sub> emissions by 20%; we have a new five-year HSE plan to ensure high standards and guidelines for continuing improvements and we are developing Key Performance Indicators to assess implementation of the Group's CSR strategy.

We will continue to work tirelessly on improving access to healthcare building on all our successes, experiences and expertise. And, as an innovation-based biopharmaceutical player, we will do our utmost to continue to innovate for patients, wherever they may be.

**GL:** In 2012, we will continue to focus on the Group's 12 CSR priorities by integrating CSR even more solidly into our strategy and by spreading the word. The Key Performance Indicators will help us better identify areas for improvement so we can focus our efforts where they will make the most impact. These will not only help us assess our performance; they will help us to better respond to stakeholders' needs.

**For more information.:**

- [Our 12 key CSR priorities](#)

## The Group's profile

Sanofi is a diversified global healthcare company engaged in the research, development, manufacturing and marketing of healthcare products. Our business includes pharmaceuticals, comprising prescription drugs, consumer healthcare and generics; vaccines and animal health.

### ▼ Sanofi Key Activities

#### ▼ Pharmaceuticals

#### ▼ Human Vaccines

#### ▼ Animal Health

#### ▼ Geographic Presence

**A diversified global healthcare leader, discovers, develops and delivers healthcare solutions focused on patients' needs**



- Zoom: A diversified global healthcare leader, discovers, develops and delivers healthcare solutions focused on patients' needs

## Sanofi Key Activities

Our business includes three main activities: Pharmaceuticals, Human Vaccines through Sanofi Pasteur and Animal Health products through Merial Limited (Merial).

For more information:

 [Annual Report on Form F-20 2011](#) (PDF, 1289Kb)

## Pharmaceuticals

- **2011 net sales of the pharmaceuticals business:** €27,890 million, +6.7% at Constant Exchange Rate (CER)

Sanofi's pharmaceuticals business notably focuses on diabetes, oncology, and other flagship products in thrombosis, cardiovascular, central nervous system, internal medicine areas. Since April 1st 2011, Sanofi's pharmaceuticals business also includes Genzyme products.

Sanofi also has a significant presence in Consumer Health Care, in various product categories.

- **2011 net sales of Consumer Health Care:** €2,666 million, +22.8% at CER

In addition, our pharmaceuticals portfolio comprises other prescription drugs including Generics.

- **2011 net sales of Generics:** €1,746 million, +16.2% at CER

For more information:

- [en.sanofi.com / Investors / Key facts and figures](http://en.sanofi.com/Investors/Key_facts_and_figures)

## Human Vaccines

- **2011 net sales of the vaccines business:** €3,469 million, - 5.5% at CER, +7.2% excluding A/H1N1 vaccines sales.

Sanofi Pasteur, the fully integrated vaccines business of Sanofi, is a world leader in the vaccines industry offering a large range of vaccines covering 20 different infectious diseases.

For more information:

- [en.sanofi.com / Investors / Key facts and figures](http://en.sanofi.com / Investors / Key facts and figures)

## Animal Health

- **2011 sales of Merial:** €2,030 million, +4.3% at CER

Merial, a wholly owned subsidiary of Sanofi since September 18, 2009, is one of the world's leading animal health companies dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners.

For more information:

- [en.sanofi.com / Investors / Key facts and figures](http://en.sanofi.com / Investors / Key facts and figures)

## Geographic Presence

Sanofi has commercial presence in more than 100 countries, and our products are available in more than 170 countries.

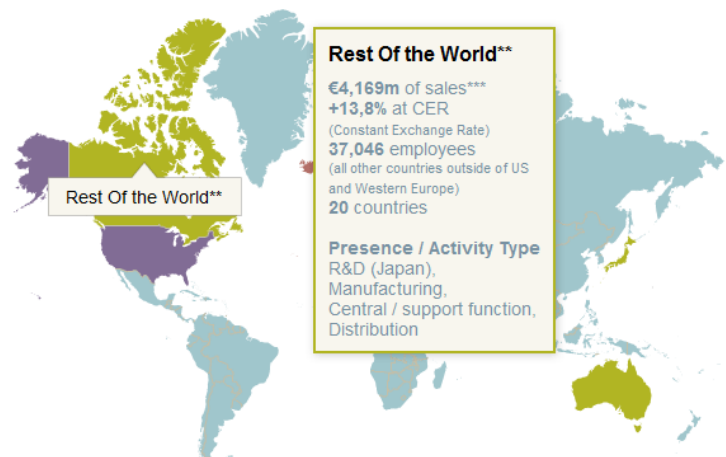
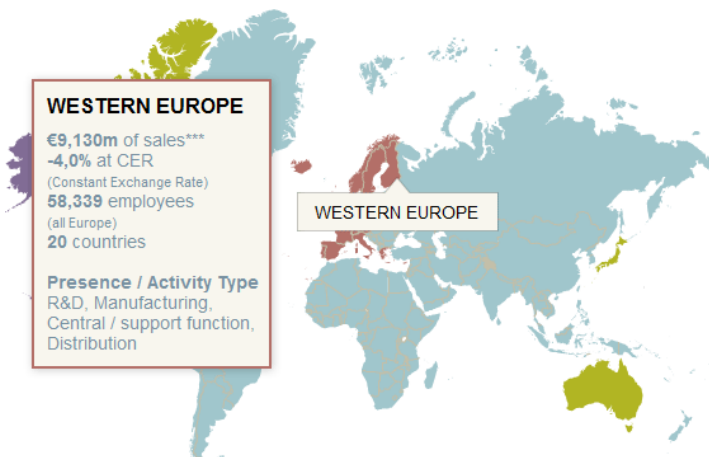
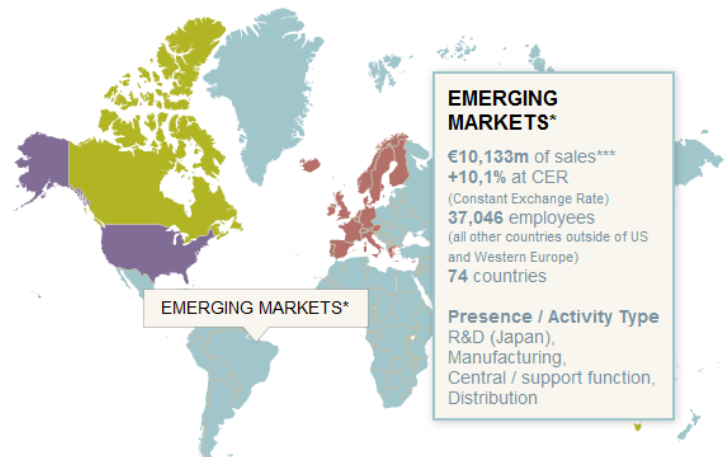
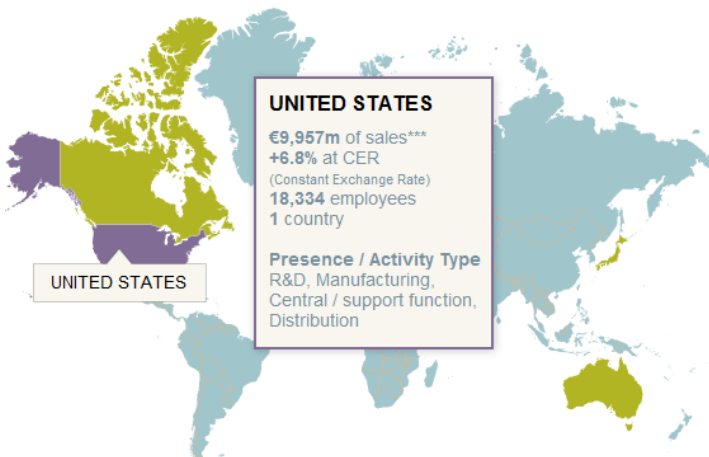
For more information:

- [en.sanofi.com / Investors / Key facts and figures](http://en.sanofi.com / Investors / Key facts and figures)

Sanofi is the established leader in pharmaceuticals in Emerging Markets, holding top positions in the main countries. In 2011, Emerging Markets totaled €10,133 million, an increase of 10.4% (excluding Genzyme and A/H1N1 vaccines sales of €361 million booked in 2010). Emerging Markets sales contribute to 30.3% of the Group sales and become the most important contributors to the region sales. In 2011, Emerging Markets sales recorded double digit growth (up 12.4% to €507 million) accounting for 25.0% of total Merial sales.

## Sanofi accross the world

## By geographical areas



- **\* Emerging Markets:** World less North America (USA, Canada), Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Holland, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark), Japan, Australia and New Zealand.
- **\*\*ROW:** Japan, Canada, Australia and New Zealand.
- **\*\*\* Sales:** Sales growth excluding A/H1N1 and Genzyme is:  
-5.7% for U.S., -10.5% for Western Europe, +10.4% for Emerging Markets, +6.3% for ROW.



By Presence / Activity type



*4. Home / Our vision / Our CSR Approach*

## Our CSR Approach

## Strategy and approach

Corporate Social Responsibility encompasses a broad array of issues. This year, our CSR Report addresses 48 topics in our key areas of Patient, Ethics, People and Planet.

Each CSR challenge is important. To avoid a situation where we cannot see the forest for the trees, Sanofi has developed a sound CSR organization and applies sophisticated methods to manage the CSR approach across entire the Group.

The CSR approach places the patient at the center of the Group's business. Woven into the fabric of Sanofi's values and our strategy, CSR principles provide a vision for the future and foster sustainable growth.

Sanofi's CSR approach focuses on four pillars:

- Patient: The patient at the center of the Group's business
- Ethics: Ethics in action
- People: Employees and local communities
- Planet: Environmental performance

As part of the process to identify Sanofi's CSR challenges within each of these four pillars, the Group has established the following 12 key CSR priorities:

|   |                |   |
|---|----------------|---|
|    | <b>PATIENT</b> | <ul style="list-style-type: none"> <li>• Access to healthcare</li> <li>• Product risk management</li> <li>• Innovation for patients</li> </ul>            |
|    | <b>ETHICS</b>  | <ul style="list-style-type: none"> <li>• Ethics in R&amp;D</li> <li>• Business ethics</li> <li>• Human rights</li> </ul>                                  |
|    | <b>PEOPLE</b>  | <ul style="list-style-type: none"> <li>• Occupational health, safety and well-being</li> <li>• Diversity</li> <li>• Workforce development</li> </ul>      |
|  | <b>PLANET</b>  | <ul style="list-style-type: none"> <li>• Energy and carbon footprint</li> <li>• Water management</li> <li>• Pharmaceuticals in the environment</li> </ul> |

## How we identified our 12 CSR priorities for action

Our 12 priorities for action were determined by applying a careful analytical process, the materiality test. The purpose of this analysis is to identify our most “material” challenges, i.e., those that are most critical for the Group because they entail significant financial, business or reputational risks if Sanofi fails to respond to them. Because we are convinced that wherever there is risk, there is also opportunity, finding effective responses to these challenges allows Sanofi to make the most of opportunities to improve our performance – from both a CSR and a business perspective.

For more information:

- [Our Vision / Our CSR Report: an overview / Materiality Test](#)

## CSR governance

Today CSR is strongly linked with Group's business strategy. Our CSR governance is part of Sanofi's corporate governance approach, which is implemented at all Group levels. *A part of the Board's time is dedicated to issues of Corporate Social Responsibility related to Group's strategy, including sustainable development and workforce diversity* \*.

**For more information:** [Sanofi's Corporate Governance](#)

- [Ethics section of the 2011 Report](#)



[Directors, Senior Management and Employees \(extract from 2011 Form 20-F\)](#) (PDF, 173Kb)

## Spearheading the approach: The CSR Direction

Sanofi's Corporate Social Responsibility Direction was created in late 2009 to establish a CSR organization at the highest level of the Group. Sanofi's Senior Management entrusted the CSR Direction with:

- Managing and integrating the Group's CSR approach throughout Sanofi entities
- Bringing together all major initiatives in connection with economic, social and environmental responsibility

Given the strategic importance of ensuring consistency throughout all the Group's CSR initiatives, the CSR Direction reports directly to the CEO. In addition, the Senior Vice President of CSR, Gilles Lhernould, is a member of the Sanofi Global Leadership Team.

The CSR Direction coordinates all our initiatives through four departments: CSR Excellence, Access to Medicines, Diversity / Disability and Childhood Mission, which was created to support employees and their families.

## Sanofi Espoir Foundation

The aim of the foundation, with a strong link to the CSR direction because of several Top Management individuals of the board: see the information below, is to complement the Sanofi Access To Healthcare initiatives from Sanofi as follows: "the Foundations' mission is to

contribute to reducing health inequalities, particularly among the most needy, by focusing on key issues in prevention, training and access to care.”

The College of the Founder’s Representatives:

- [www.fondation-sanofi-espoir.com](http://www.fondation-sanofi-espoir.com) / *The Board of Directors*

## Valuable leadership: The CSR Excellence Team

The CSR Excellence Team plays a key role by organizing initiatives and implementing our CSR practices Group-wide. Created in 2010, the CSR Excellence Team:

- Proposes the CSR strategy for the Group
- Implements the CSR strategy across all Sanofi entities
- Provides CSR expertise (CSR watch, in-house working groups)
- Organizes initiatives to increase awareness about CSR challenges
- Promote CSR both inside and outside the Group
- Engages in ongoing dialogue with our stakeholders to define the Group’s commitments and draw up action plans to address Sanofi’s CSR challenges

## Our 2011 CSR achievements

The CSR Excellence Team achieved successes in many areas in 2011. In-house, we strengthened our functional, country and regional [CSR networks](#). We strengthened our dialogue with stakeholders and continued to develop communications on key CSR issues for the Group. We also developed a wide variety of communications tools to improve awareness and highlight CSR initiatives across the Group, focusing particular attention on improving employees’ understanding of CSR priorities and good practices. For this purpose, we made use of tools such as the CSR Blog, the CSR Brochure, videos and the Group intranet. [Our CSR initiatives: spreading the word](#).

Some of our new and ongoing actions in 2011 included:

- Organizing special events (CSR convention, training programs, and the CSR Awards to be inaugurated in 2012)
- Identifying and monitoring CSR indicators with the relevant Group functions

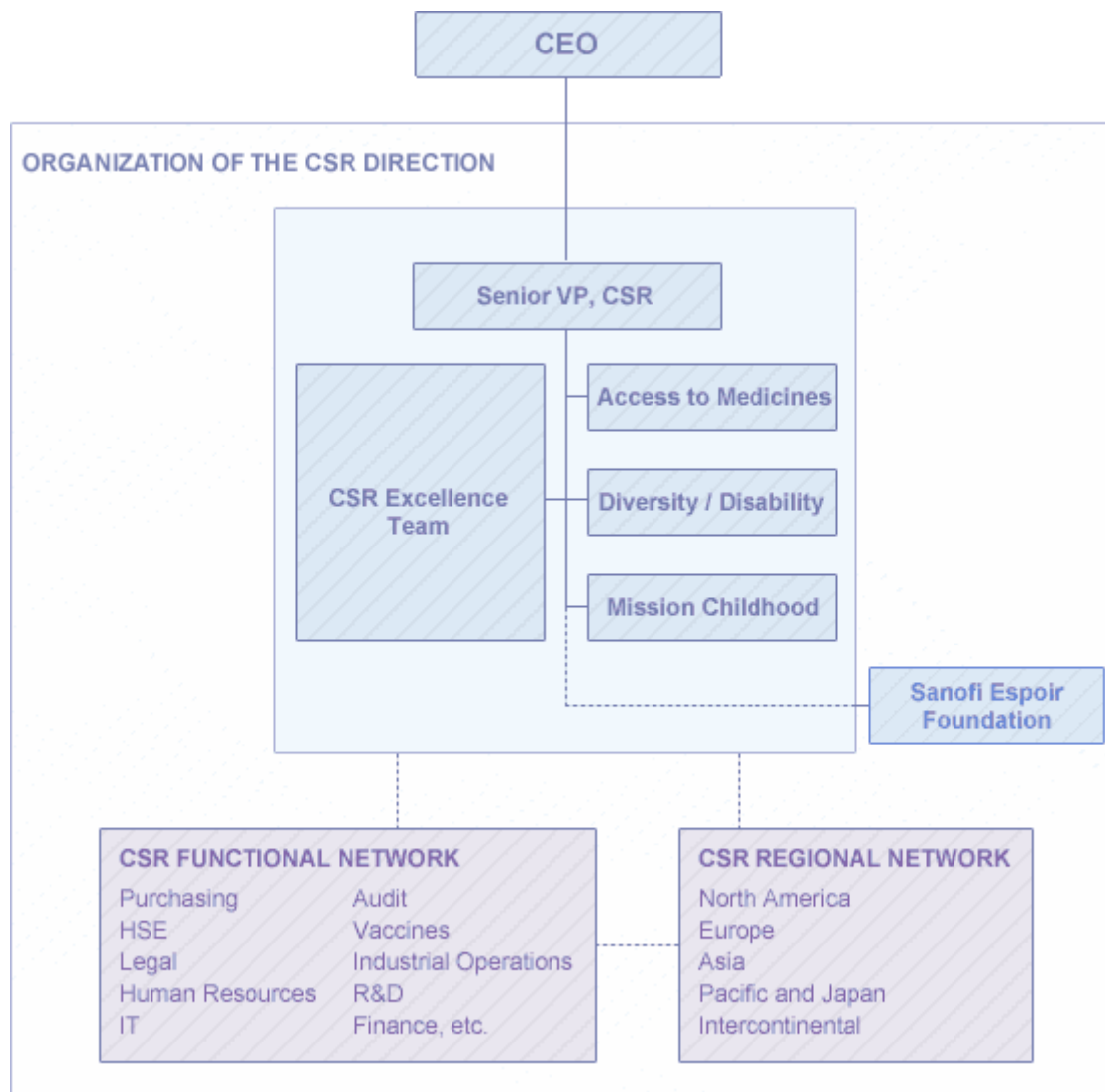
- Supporting our regions and affiliates as they organized strategic CSR initiatives



Our cross-functional team oversees the implementation of the CSR approach across all Group entities.

**Didier Terrolle**  
Director, CSR Excellence

## Sanofi's CSR organization



## A corporate foundation to coordinate solidarity initiatives



The role of the **Sanofi Espoir Foundation**, created in late 2010, is to facilitate access to healthcare and reduce health inequalities, especially for those in need.

● [www.fondation-sanofi-espoir.com](http://www.fondation-sanofi-espoir.com)

\* The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

● [\*Vision / CSR performance / Statutory auditors' review report\*](#)



## CSR networks

As the Group's source of CSR expertise, the CSR Direction Excellence Team proposes the Group's CSR strategy to the Management Committee. It also implements this strategy at every level of Sanofi's organization – locally, regionally and globally.

A strong network of over 80 CSR correspondents across all Group regions and functions, on all continents.

In 2011, the CSR Excellence Team pursued its work via the CSR functional and regional networks, which play a vital role by ensuring we are present and receive feedback from our sites on all continents.

- The CSR Functional Network represents all the Group's corporate functions (i.e., Industrial Affairs, R&D, Commercial Operations, etc.) The purpose of the functional network is to better integrate the global CSR strategy into Sanofi's business activities.
- The CSR Regional Network is made up of CSR correspondents from the regions and countries where the Group operates. The purpose of this network is to implement, adapt and develop the Group's global CSR strategy locally and regionally.

Two conventions were organized for CSR correspondents in 2011 and a global convention is being planned for 2012.

To build on the momentum of our 2010 successes and further strengthen our networks, the CSR Excellence Team organized two conventions for our network correspondents in 2011.

- In May 2011, an inaugural CSR convention in Paris brought together over 25 correspondents representing more than 40 countries. Also in attendance were the regional CSR correspondents, the CSR Excellence Team, and representatives from functions such as Access to Medicines, Diversity, Childhood Mission, HSE, Communications and the Sanofi Espoir Foundation. This two-day event provided a comprehensive look at the Group's CSR strategy and highlighted key CSR messages and objectives.
- In December 2011, in the Paris area (France) site, over 50 participants attended a convention for Sanofi's CSR functional and regional correspondents. The convention aimed to reinforce the network and provide in-depth information about the Group's CSR activities.

In addition to giving participants an opportunity to share knowledge and best practices, these encounters provide important information and practical tools to all members of our CSR networks, who return to their home countries and affiliates with new ideas about how to promote CSR and build on the Group's collective CSR expertise.

The Group also invites independent CSR specialists as guest speakers. Their insights and knowledge help enlarge our field of vision, provide up-to-date information about CSR trends and address CSR topics from a perspective that differs from our own.

The CSR Excellence Team is planning a global convention in June 2012 for all CSR correspondents at all levels of the organizations: central functions, regions and countries. We expect over 100 people to attend.

## A new CSR e-learning tool for employees

As of late 2011, Sanofi employees in France have access to an educational "e-learning" tool about the fundamentals of CSR. This interactive tool, designed to raise CSR awareness among all employees of pharmaceutical companies, was developed by LEEM (the French Pharmaceutical Companies Association) for use by its member companies. In 2011 Sanofi was part of the working group that developed the e-Learning tool, which consists of three training modules:

- The challenges of sustainable development
- Pharmaceutical companies' social responsibility
- How individuals can make a difference each day when it comes to CSR

In agreement with the LEEM, Sanofi decided to translate the modules into other languages so that employees worldwide can use this tool. The English version is already available to Group employees and translations into other languages are underway.

Users of this e-learning tool work through the modules and learn at their own pace. In a video clip shown on the Sanofi intranet to launch the program, Gilles Lhernould, Senior Vice President of CSR, encouraged employees to find out more about the basics of CSR and how social responsibility affects their life and work each day.

## CSR initiatives

In 2011, the CSR Excellence Team organized many in-house initiatives to increase awareness about Corporate Social Responsibility challenges among all Group employees, focus on key messages and receive feedback at every level of the Group.

In-house, we made extensive use of web-based communication tools to share CSR best practices.

Since its launch in July 2009, over **360** initiatives have been published on the CSR Blog.

The CSR Blog is an internal collaborative communication platform to promote CSR initiatives worldwide, allowing employees to share ideas and experiences. Since the Blog was launched in July 2009, over 360 initiatives have been published on this Group-wide platform.

In addition to updating Sanofi's CSR website and intranet, we improve awareness inside and outside the Group thanks to internal and external communication tools:

- **The 2011-2012 CSR Brochure**, "Acting Ethically and Responsibly for the Patient," was published in mid-October 2011 in English, French and Spanish. In addition to the printed format, it is available on the Sanofi CSR website [2011-2012 CSR Brochure](#). The brochure was written for Sanofi employees as well as stakeholders outside the Group and was widely publicized through our CSR networks, the CSR Blog, and the Group's intranet.

The 2012-2013 CSR Brochure will be tablet-optimized and make use of **Flashcode** technology so that

- **The 2012-2013 CSR Brochure** will be tablet-optimized to keep pace with the latest technological innovations. The CSR Excellence Team wished to capitalize on the growing use of mobile devices, which are powerful new platforms for communication. Not only will users be able to read the brochure on their tablets, but the Flashcode

readers can go directly to the Sanofi CSR website for more in-depth information.

- technology integrated into the brochure will take them directly to the Sanofi CSR website for more in-depth information on any topic.

### “Spreading the word through out affiliates”

In 2011 many other country CSR initiatives demonstrate that the approach is fully integrated at the operational levels. Below are a few examples from the countries.

#### United States

Watch a video clip of how our site in Bridgewater, New Jersey, celebrated CSR Day in 2011:



#### Turkey

Members of the CSR Excellence Team frequently travel to other countries to support Sanofi affiliates during initiatives to implement the CSR strategy at the local level. Most often these events are associated with raising CSR awareness at Group sites. In October 2011, a Town Hall meeting was held in Istanbul, Turkey, followed by a visit to the Zentiva manufacturing site at Lüleburgaz. This two-day encounter highlighted good CSR practices at Sanofi Turkey and the strong link between CSR and business.

## Taiwan

In October 2011, Sanofi's CSR Steering Committee for Taiwan organized a two-week CSR awareness campaign, "It's Everyone's Responsibility" to improve employees' understanding of the importance of CSR-related work at local level. All members of the management executive team took part in filming a comedy video shown at CSR Town Hall Meetings held for staff at Taiwan's three sites. A follow-up event, "Give CSR a Good," invited employees to send prose, poems and short messages in support of CSR initiatives, via internal emails, SMS, and even a Taiwan CSR Facebook fan page. The top ten "Give CSR a Good" messages were published in Taiwan Zoom.

## CSR Awards



The Global CSR Awards aim to recognize the best CSR projects led by functions or affiliates across all Sanofi divisions in our four pillars of Corporate Social Responsibility: Patient, Ethics, People and Planet.

The CSR Excellence Team wished to launch these awards to stimulate creative ideas among employees worldwide. Another aim of this contest, which potentially targets over 110,000 people worldwide, is to gain a better understanding of how the CSR approach impacts the Group from top to bottom, by reaching each individual employee, regardless of functional or geographical location.

Panels of Sanofi experts will evaluate submissions and select the best projects based on several criteria, such as innovativeness, business rationale and benefits to stakeholders. Winners will be announced in late April 2012 and invited to attend a special awards ceremony during the second Global CSR Convention in June 2012.

### **The CSR Awards, a catalyst for creative ideas**

- 9 winning projects
- Each winning team will receive €2,000 to be donated to the charitable organization of their choice in their home country
- The jury will confer the Grand Prix (€4,000) to the most outstanding charitable organization

The Sanofi CSR Excellence Team began communicating Group-wide about this initiative via many different channels in late 2011. A dedicated website has been created especially for the CSR Awards.

## Our report overview

### Who reads our report

Each year, Sanofi's CSR Excellence Team produces an annual report for use by experts in the field of CSR, including rating agencies, investors and shareholders.

Our CSR Report also speaks to a wide range of other stakeholders – from patient groups to employees, NGOs and healthcare professionals. We comply with accessibility rules concerning both content and structure so that the report can be read using vocal browsers by individuals with visual impairment or other disabilities, as well as readers with limited software and computer tools. In addition, pdf files enable content access for all readers.

#### WHO ARE OUR STAKEHOLDERS?

Patients, employees, shareholders, suppliers, competitors, local communities, public authorities, healthcare professionals, consumers, NGOs, the media, and the list goes on.

- [Our stakeholders](#)

### What you will find in our report

With each year's CSR Report, we seek to continuously improve the information we provide. We are committed to ensuring that our data are as reliable, comprehensive and representative as possible. We are also intent on continuously improving and enriching the contents of the CSR Report – which since 2009 has been a web-based CSR report – by providing more indicators ([Indicators scorecards](#)), more illustrations and more examples of how CSR has a positive impact on Sanofi's business.



## Our method

In terms of methodology, two valuable approaches help ensure we remain grounded in reality while striving to meet ambitious goals. First, the materiality test helps us determine which priorities are most material to our activities. Next, the Business Case approach provides concrete examples of how Sanofi teams have found solutions to very specific CSR challenges.

- [Materiality test](#)
- [Business Case approach](#)

In addition, we go one step farther to strengthen the quality of our CSR Report: we voluntarily submit it to the scrutiny of external statutory auditors who carry out a review of selected data and information in order to provide assurance that they are accurate. We have made this a practice since 2007.

Moreover, for the past three years, we have asked CSR experts from outside the Group (i.e., CSR Europe) to provide an independent assessment of our CSR Report.

## Materiality test

The materiality test is a methodical approach designed to identify the many CSR challenges that the Group must address and prioritize. It determines with precision those issues that are most “material” (i.e., the most critical) to our ongoing business so that Sanofi can assess, prioritize and address the CSR challenges that are identified by the Group and our stakeholders.

The materiality test is a key part of the Group’s CSR reporting strategy. This approach is very important for two reasons:

- It encourages the communication of relevant information that is meaningful for stakeholders.
- It helps us analyze the Group’s current and future performance.

In preparing our 2011 CSR Report, we made use of the findings of the materiality test performed in 2010, but with a shift in focus so that we could meet new challenges that have taken center stage over the past year.

At the same time, we continued to concentrate on our 12 priorities, which correspond to areas where our stakeholders have specific expectations. This focus in turn allows us to improve our CSR reporting methods.

### For more information:

- [Our 12 CSR priorities for action](#)

## Materiality analysis process

Sanofi's process for analyzing the materiality of CSR challenges is based primarily on the recommendations outlined in the GRI (Global Reporting Initiative) G3 Guidelines and the AA1000 (AccountAbility Principles) standard.

### For more information:

- [\*Global Reporting Initiative\*](#)

Materiality analysis is carried out using a list of CSR challenges that was initially developed to help define the Group's CSR strategy. It utilizes extensive analyses of internal and external information sources.

After selecting and categorizing our CSR challenges (organized into the four pillars of Patient, Ethics, People and Planet), priorities are determined based on two types of parameters:

- The significance level for these challenges based on external information sources
- The Group's internal business strategy

### Assessing CSR challenges based on the significance of their impact for stakeholders

The materiality test first takes into account parameters related to external pressures with the aim of prioritizing the significance for stakeholders of all identified CSR challenges. This assessment also includes benchmarking of a selection of companies.

- **Stakeholder consultation**

In 2010, Sanofi surveyed a sample of over 20 stakeholders. Our sampling included 15 stakeholders of six nationalities (American, Belgian, Brazilian, Chinese, French and Hungarian) representing patient organizations, healthcare professionals, NGOs, universities, investors, Group employees and the media. They were questioned on a range of topics.

- **Benchmarking CSR practices among international groups**

Benchmarking is a method to identify the CSR challenges of various international groups, the commitments they have made, their good practices and how they communicate on CSR issues. Our review included nine pharmaceutical and non-pharmaceutical companies.

- **Analyzing external questionnaires**

External questionnaires from extra-financial rating agencies, non-profit CSR organizations and investors were also analyzed in depth. This process helped identify the challenges they consider to be important and defined the level of information they require.

- **Media reviews**

Media reviews helped identify key topics as well as emerging CSR issues and trends.

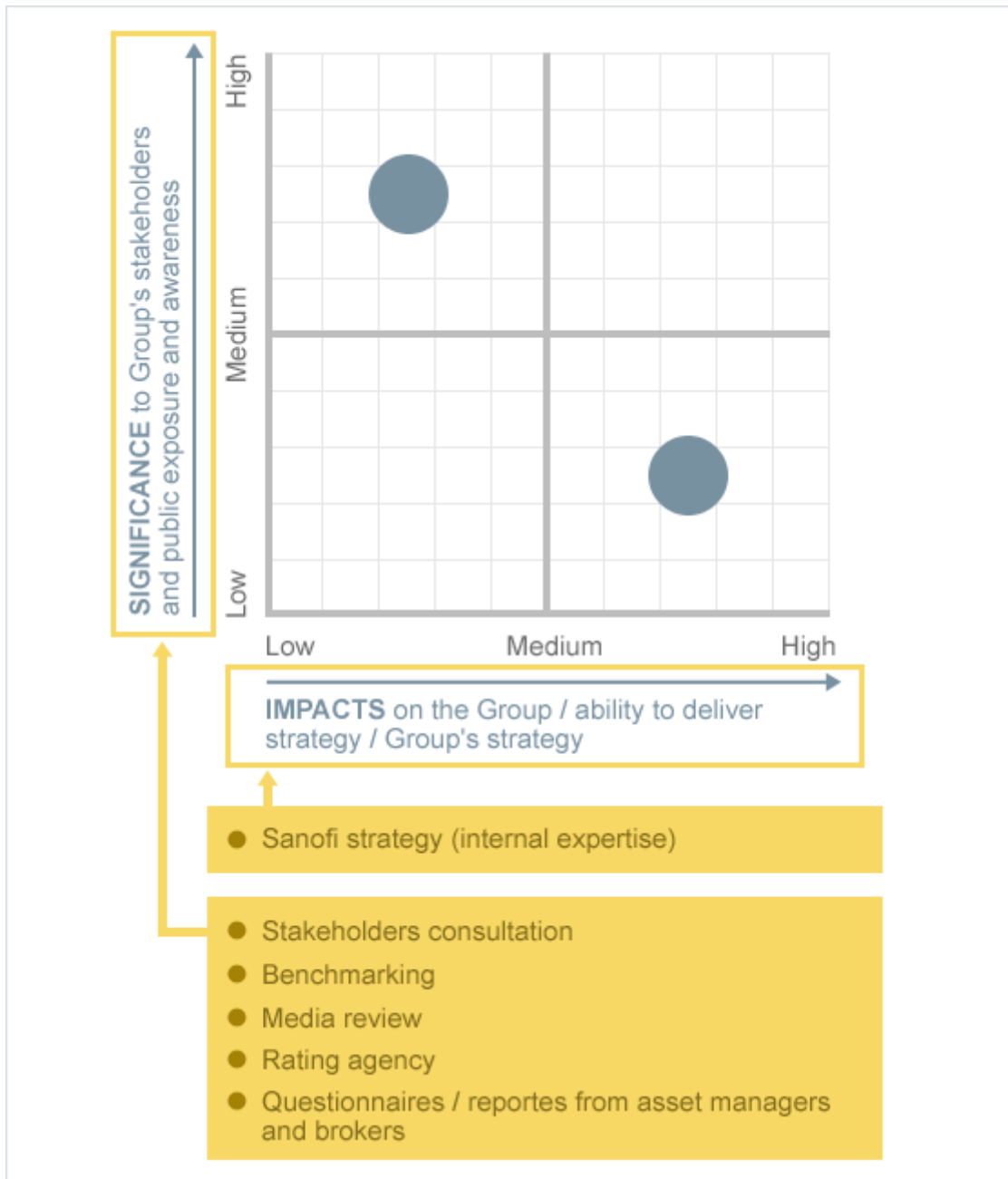
- **CSR watch**

### Assessing CSR challenges relative to internal strategy

At the same time, Sanofi's management assessed the Group's CSR challenges to determine priorities based on their relevance and how they influence Sanofi's strategy.

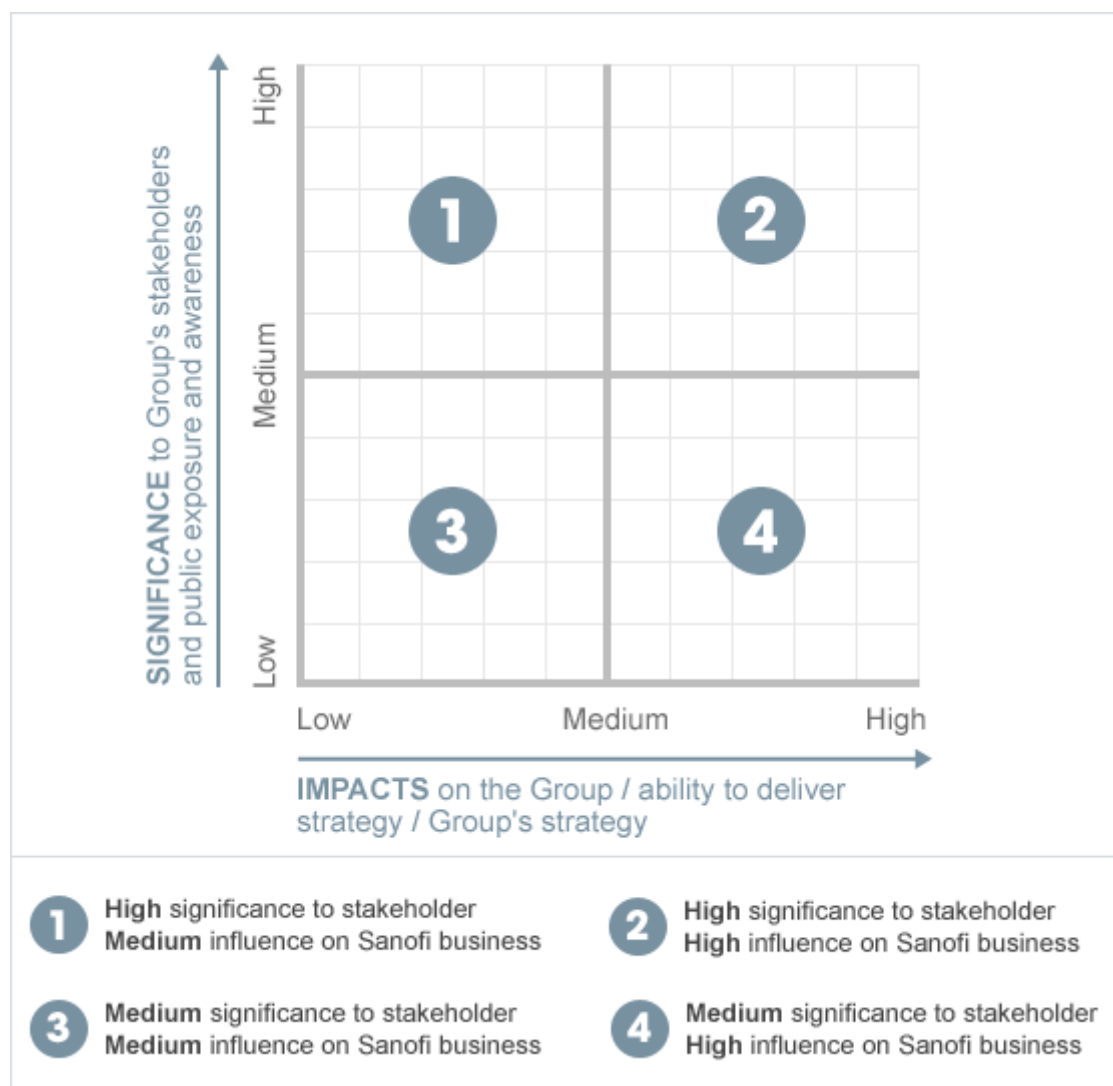
The chart below illustrates the general approach used for the materiality test:

## Materiality test

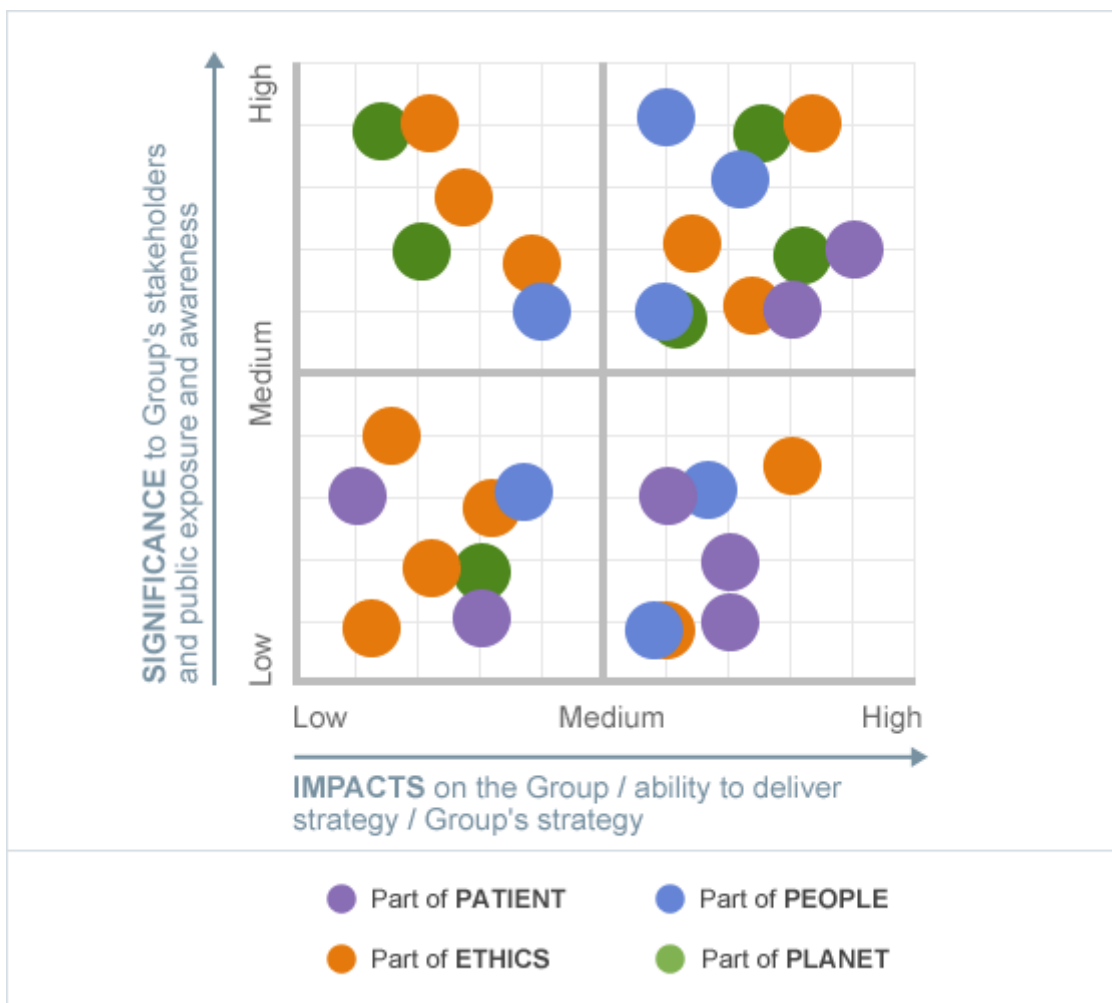


## Materiality analysis results

After all the CSR challenges are assessed, they are placed on a matrix in order to categorize them based on their level of importance for external stakeholders and how relevant they are to Group's overall strategy.



Each challenge is positioned on the matrix. The chart below positions the challenges based on a color code that corresponds to each of the key areas of the Group's CSR strategy: PATIENT, PEOPLE, ETHICS and PLANET.



See the details:

▼ Part of **PATIENT**

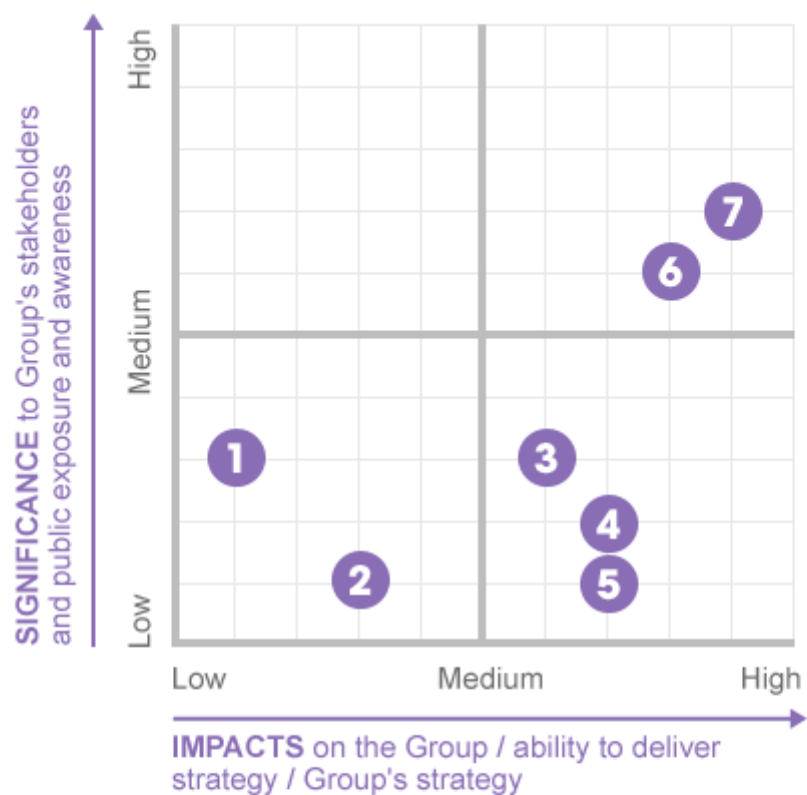
▼ Part of **ETHICS**

▼ Part of **PEOPLE**

▼ Part of **PLANET**

Finally, in addition to the raw results of the materiality analysis represented in the matrix above, the diagrams below provide a clear view of the four focus areas, the various Group CSR challenges, their relevance and degree of priority relative to one another.

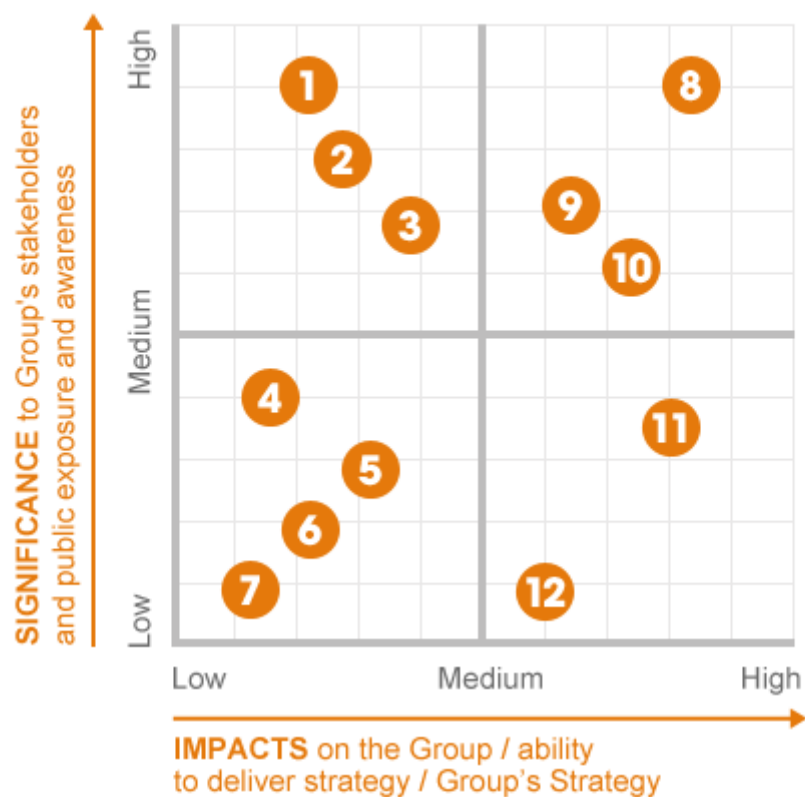
## Part of PATIENT



- |  |                            |
|--|----------------------------|
| <b>1</b> The fight against counterfeit drugs | <b>5</b> Innovation        |
| <b>2</b> Business and Supply Continuity      | <b>6</b> Pharmacovigilance |
| <b>3</b> Information and patient education   | <b>7</b> Access to health  |
| <b>4</b> Quality of group products           |                            |

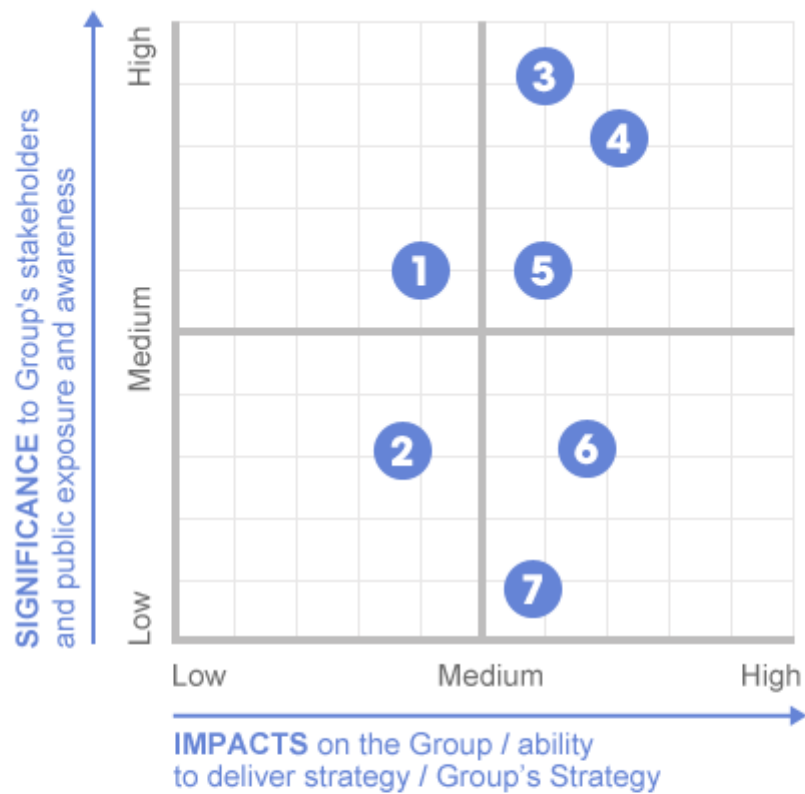


## Part of ETHICS



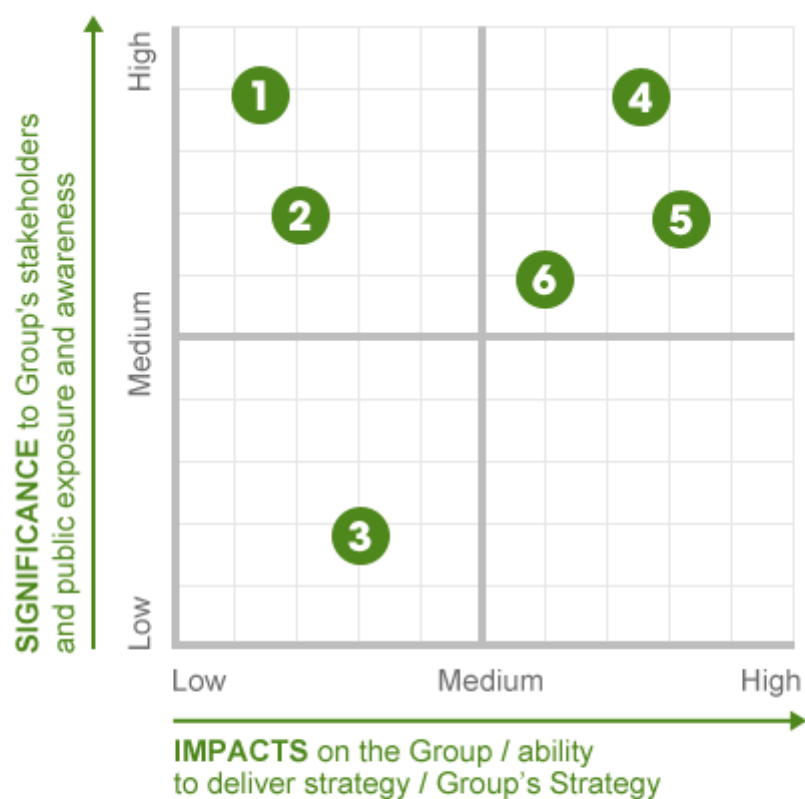
- |  |                                    |
|--|------------------------------------|
| <b>1</b> Responsible marketing   | <b>7</b> Biopiracy                 |
| <b>2</b> Responsible purchasing  | <b>8</b> Ethics in clinical trials |
| <b>3</b> Institutional relations   | <b>9</b> Corporate governance      |
| <b>4</b> Use of laboratory animals for research and genetically modified animals | <b>10</b> Human rights             |
| <b>5</b> Protection of personal data   | <b>11</b> Bioethics                |
| <b>6</b> Free competition  | <b>12</b> Fighting corruption      |

## Part of PEOPLE



- |  |   |
|--|---|
| <b>1</b> Employee representation and information | <b>5</b> Diversity                                  |
| <b>2</b> Compensation & social benefits          | <b>6</b> Restructuring                              |
| <b>3</b> Safety and health in the workspace      | <b>7</b> Contribution to local economic development |
| <b>4</b> Workforce development                   |   |

## Part of PLANET



**1** Limiting local environmental impacts

**2** Products and packaging life cycle management

**3** Biodiversity

**4** Climate change and energy

**5** Water management

**6** Pharmaceuticals in the environment

## The Business Case Approach

- ▼ [How we respond to very specific CSR challenges](#)
- ▼ [How Business Cases are presented](#)

### How we respond to very specific CSR challenges

One of the highlights of the 2011 CSR Report is our expanded coverage of Business Cases, which describe how, through Sanofi initiatives, we integrate CSR practices at all levels of the Group, with clear benefits for Sanofi's business and for our stakeholders.

Each Business Case illustrates how we respond to CSR challenges that arise in our day-to-day work across all Sanofi functions and geographies – from retaining valuable employees in China, to reducing the use of solvents in the manufacture of Plavix® by applying the principles of Green Chemistry, to helping healthcare professionals in Africa conduct clinical trials effectively and ethically.

As we develop innovative responses to these challenges – very often by engaging in teamwork and pooling valuable expertise from within the Group – we also improve our business.

Every time we respond to a challenge, we seize an opportunity: indeed, we mitigate risks (i.e., to our business continuity or to our reputation) and find solutions that improve our CSR performance and our bottom line.

#### 17 new business cases in 2011

Our CSR initiatives impact our business. In addition to bringing benefits to patient, the environment, our employees and other stakeholders, our commitment to CSR principles has a positive effect on our bottom line.

### How Business Cases are presented



The logo appears each time a Business Case is featured in the CSR Report. Each one describes the CSR challenge facing the Group, our response, benefits for stakeholders, opportunities for Sanofi, and what we may expect in the future.

Benefits for our stakeholders and for the Group are numerous. Some examples:

- Establishing Sanofi as a leader in finding innovative solutions for patients
- Preserving the environment by promoting biodiversity
- Improving the Group's image and reputation
- Guaranteeing the continuity of our Supply Chain
- Strengthening trust in Sanofi's products
- Attracting, retaining and motivating talented employees
- Protecting the Planet by reducing CO2 emissions
- Establishing the Group as a preferred employer
- Respecting Human Rights and promoting ethical conduct in R&D
- Contributing to the elimination of a devastating neglected tropical disease

The following table presents the 18 Business Cases featured in the 2011 CSR Report.

| Pillar         | Business cases list  |
|----------------|--|
| <b>PATIENT</b> | <ul style="list-style-type: none"> <li>● <b>Continuity of supplies</b><br/><i><u>Guaranteeing the delivery of Sanofi products to hospitals: Innovation at the Marly-La-Ville distribution center</u></i></li> <li>● <b>Access to Healthcare / Neglected tropical diseases</b><br/><i><u>Sanofi makes a front-line contribution to help combat sleeping sickness</u></i></li> <li>● <b>Innovation for patients</b><br/><i><u>Valuable progress in dengue fever vaccine program in 2011</u></i></li> <li>● <b>Innovation for patients</b><br/><i><u>The Aging Patient</u></i></li> <li>● <b>Pharmacovigilance</b><br/><i><u>New pharmacovigilance monitoring system enhances worldwide compliance</u></i></li> </ul> |
| <b>PEOPLE</b>  | <ul style="list-style-type: none"> <li>● <b>Compensation &amp; Employee Benefits / Diversity</b><br/><i><u>Helping employees' children prepare to study at Brazil's leading universities</u></i></li> <li>● <b>Workforce Development</b><br/><i><u>Retaining valuable employees thanks to the China Talent Center</u></i></li> <li>● <b>Health and Safety</b><br/><i><u>Continued success of the Safety Game in Suzano, Brazil</u></i></li> </ul>  |

| Pillar | Business cases list   |
|--------|---|
| ETHICS | <ul style="list-style-type: none"> <li>● <b>Responsible Procurement</b><br/><u><i>Socially responsible Purchasing benefits the environment and creates business value</i></u></li> <li>● <b>Human Rights</b><br/><u><i>Innovative ways to increase awareness and incorporate human rights into our business activity</i></u></li> <li>● <b>Personal Data Protection</b><br/><u><i>An imaginative campaign to promote information protection</i></u></li> <li>● <b>Ethics in clinical trials</b><br/><u><i>Conducting clinical trials in Africa without compromising global standards</i></u></li> </ul>   |
| PLANET | <ul style="list-style-type: none"> <li>● <b>Biodiversity</b><br/><u><i>Producing semisynthetic artemisinin and preserving biodiversity where wormwood grown: 2011 update</i></u></li> <li>● <b>Green Chemistry</b><br/><u><i>“Greener” processes reduce environmental footprint and costs</i></u></li> <li>● <b>Water management</b><br/><u><i>Successful water reduction program at Genzyme’s Waltham facility</i></u></li> <li>● <b>CO<sub>2</sub> emissions and energy</b><br/><u><i>Good for the Planet and for the business: Genzyme meets CO<sub>2</sub> emissions reduction target two years early and receives Climate Leadership Award</i></u></li> <li>● <b>Packaging</b><br/><u><i>Smaller box design for SoloSTAR® pens optimizes transport, storage and waste reduction</i></u></li> </ul> |

## Our Stakeholders

A company's ability to respond to stakeholders' expectations is a measure of its credibility and sustainability.

As a diversified global healthcare leader operating in more than 100 countries, Sanofi is well aware of the importance of providing concrete responses to the needs and expectations of a wide variety of stakeholders, particularly those in the healthcare field.

In our day-to-day interactions with stakeholders, we seek to deliver appropriate responses whenever we are called upon – for example, to provide reliable and factual information, to participate in constructive dialogue, to form partnerships, to support patient associations, to provide humanitarian assistance, to find innovative solutions for patients and to answer many other needs.

### Ongoing stakeholder dialogue

In the past, we have consulted our in-house and external stakeholders on many occasions with a precise purpose in mind – such as for the materiality test.

However, starting in 2011, Sanofi's CSR Direction decided to pursue a more pro-active strategy and establish a dedicated structure to ensure continuous, formal interaction with our external stakeholders. A stakeholder panel was created in late 2011 in France. The first stakeholder meeting will be organized in Q1 of 2012.

This new development, one of Sanofi's 2011 CSR milestones, is supported by leading CSR rules and guidelines (e.g., Global Reporting Initiatives, ISO 26000). Ensuring stakeholder engagement and dialogue on a regular basis will allow us to constantly gain new insights about the CSR landscape and benefit from outside expertise on the CSR challenges facing the Group.

*Regular contacts with large or small investors are ensured by the Board or company employees acting on its behalf on questions of corporate governance through various channels and events such as Salon Actionaria organized in France, the establishment of a minority shareholder committee, the maintenance of an award winning Investor Relations and Individual Shareholder department, interactions with Proxy Agencies and Social Rating Agencies, and individual outreaches. \**

### For more information:

- [Corporate Governance](#)

We are exploring approaches to expanding our ongoing dialogue with stakeholders and expect to see exciting developments in this area in 2012.

## Different stakeholder relationships correspond to different needs

Our interactions with stakeholders necessarily require differing degrees of involvement – from promoting awareness and communications, to dialogue and consultation, partnerships and collaboration. The following table outlines our primary stakeholder relationships. These stakeholder relationships are managed on a daily basis worldwide and the stakeholder process is a complementary process.

The different sections of our CSR Report provide an in-depth account of how these interactions with our many stakeholders have produced results through specific initiatives and actions.

| Stakeholders | Communication   | Dialogue / Consultation   | Collaborations  |
|--------------|---|---|---|
| Employees    | <ul style="list-style-type: none"><li>● In-house communication tools (intranet, Internet, CSR blog, CSR events)</li><li>● Awareness-raising initiatives (training, CSR report, brochures)</li></ul> | <ul style="list-style-type: none"><li>● Dialogue with employees, employee representatives and trade unions</li><li>● Direct expression forum</li><li>● Raising awareness about sustainable development</li><li>● Satisfaction surveys</li></ul> | <ul style="list-style-type: none"><li>● Support for employees' individual projects (spin-offs, NGOs, etc.)</li><li>● Calls for CSR projects</li></ul> |
| Patients     | <ul style="list-style-type: none"><li>● Dedicated internet sites</li><li>● CSR brochures and reports</li><li>● Communication about product safety information</li></ul>                             | <ul style="list-style-type: none"><li>● Dialogue / consultation panels with patients and patient organizations</li></ul>  | <ul style="list-style-type: none"><li>● Information (prevention, screening, education, treatments) and support for</li></ul>                          |



| Stakeholders                        | Communication   | Dialogue / Consultation  | Collaborations  |
|-------------------------------------|---|--|---|
|                                     | <ul style="list-style-type: none"> <li>● Communication about proper use of products</li> <li>● Communication about clinical trials</li> </ul>   |  | <ul style="list-style-type: none"> <li>● patients and their families</li> <li>● Support for recycling programs for unused medicines where available</li> </ul>                      |
| Citizens                            | <ul style="list-style-type: none"> <li>● CSR Internet site</li> <li>● CSR brochures and reports</li> <li>● Communication about product safety information</li> <li>● Communication about clinical trials</li> </ul>                   | <ul style="list-style-type: none"> <li>● Forums for dialogue and consultation</li> </ul>   | <ul style="list-style-type: none"> <li>● Information on healthcare prevention, screening and education</li> <li>● Support for recycling unused medicines</li> </ul>                 |
| Healthcare professionals            | <ul style="list-style-type: none"> <li>● Dedicated Internet sites</li> <li>● Scientific publications</li> <li>● Communication about product safety and efficacy information</li> <li>● Communication about clinical trials</li> </ul> | <ul style="list-style-type: none"> <li>● Working groups</li> <li>● Scientific meetings</li> <li>● Development expertise</li> <li>● Satisfaction surveys</li> </ul>             | <ul style="list-style-type: none"> <li>● Clinical trials</li> <li>● Training</li> </ul>   |
| Regulatory authorities and agencies | <ul style="list-style-type: none"> <li>● Pharmacovigilance</li> <li>● Communication about the Group's corporate strategy and policy</li> </ul>  | <ul style="list-style-type: none"> <li>● Compliance with standard practice (e.g., registration dossier assessment and inspections)</li> <li>● Development expertise</li> </ul> | <ul style="list-style-type: none"> <li>● Research partnerships</li> <li>● Providing medicines and vaccines at no cost / low cost for populations in developing countries</li> </ul> |

| Stakeholders                | Communication  | Dialogue / Consultation   | Collaborations  |
|-----------------------------|--|---|---|
|                             |  | <ul style="list-style-type: none"> <li>● Prescription guidelines, negotiating prices and reimbursements</li> </ul>  | <ul style="list-style-type: none"> <li>● Prevention and management of health crises</li> </ul>  |
| Other pharmaceutical groups |  | <ul style="list-style-type: none"> <li>● Representation on pharmaceutical industry organizations</li> </ul>   | <ul style="list-style-type: none"> <li>● Research partnerships</li> <li>● Joint ventures</li> </ul>   |
| Suppliers                   | <ul style="list-style-type: none"> <li>● Suppliers Code of Conduct</li> </ul>  | <ul style="list-style-type: none"> <li>● Raising awareness about human rights, working conditions and respect for the environment</li> <li>● Evaluation</li> </ul>                        | <ul style="list-style-type: none"> <li>● Improvement plans</li> </ul>   |
| NGOs                        | <ul style="list-style-type: none"> <li>● Brochures, reports, Internet site</li> <li>● Customized information sessions</li> </ul> | <ul style="list-style-type: none"> <li>● Multi-stakeholder associations</li> <li>● Answering questionnaires</li> <li>● Participating in forums</li> <li>● Satisfaction surveys</li> </ul> | <ul style="list-style-type: none"> <li>● Providing medicines and vaccines at no cost / low cost or selling at differential prices</li> <li>● Awareness-raising, prevention and training initiatives for NGOs</li> </ul> |
| Rating agencies             | <ul style="list-style-type: none"> <li>● Brochures, reports, Internet site</li> </ul>  | <ul style="list-style-type: none"> <li>● Answering questionnaires / occasional requests</li> </ul>  |   |

| Stakeholders            | Communication  | Dialogue / Consultation   | Collaborations   |
|-------------------------|--|---|--|
| Investors               | <ul style="list-style-type: none"> <li>● Quarterly financial results</li> <li>● Annual and half-year reports</li> <li>● Internet site</li> <li>● Group CSR performance</li> </ul>                        | <ul style="list-style-type: none"> <li>● Financial events / meetings of analysts</li> <li>● Special meetings</li> <li>● Answering questionnaires / occasional requests</li> <li>● Roadshows</li> <li>● Salon Actionaria organized in France</li> <li>● interactions with Proxy Agencies and Social Rating Agencies</li> </ul> | <ul style="list-style-type: none"> <li>● Conferences for the financial community</li> <li>● establishment of a minority shareholder committee</li> </ul> |
| Individual shareholders | <ul style="list-style-type: none"> <li>● Letter to shareholders</li> <li>● Individual shareholder handbook</li> <li>● Annual review</li> <li>● Internet site</li> <li>● Group CSR performance</li> </ul> | <ul style="list-style-type: none"> <li>● Individual shareholders' advisory committees</li> <li>● Specific meetings in France</li> <li>● General Meeting</li> <li>● Individual shareholder fairs in France and the United States</li> </ul>  |  |
| Local communities       | <ul style="list-style-type: none"> <li>● Brochures and reports</li> <li>● Open houses</li> <li>● Special events</li> </ul>   | <ul style="list-style-type: none"> <li>● Panels of local residents</li> <li>● Dialogue with local authorities</li> </ul>  | <ul style="list-style-type: none"> <li>● Local development initiatives (humanitarian sponsorship, governments, NGOs, etc.)</li> </ul>                    |

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Vision / CSR performance / Statutory auditors' review report*

## Policies and management systems

Sanofi' CSR approach is based on internal policies and tailored management systems that make it possible to integrate this CSR approach throughout the entire Group. Risk management is also a key part of the Sanofi CSR approach.

## Internal policies

Sanofi has established many documents to structure the Group's CSR approach. The Group has developed internal codes, charters, policies and other tools that are aligned with the Code of Ethics and the Social Charter. The following internal policies apply to the entire Group.

▼ Code of Ethics

▼ Social Charter

▼ Other internal policies

## Code of Ethics

### General principles

Sanofi is committed to compliance and ethics in every country where Sanofi does business. Because regulations are constantly evolving, there is a genuine need to explain the minimum rules and ethical standards that apply in a global company, in particular when all employees do not share the same legal system and where cultural differences may arise with respect to certain issues.

In 2011, the Global Compliance Department undertook a comprehensive update of the Sanofi Code of Ethics. This Code was designed as a guide for all employees. Furthermore, the Code is intended to protect employees by helping them recognize situations that may not be easily identifiable in which they may put themselves and the company at risk.

Ethical conduct is essential both within the Group and outside the Group. All Sanofi employees, regardless of where they work or the job that they do, must uphold the principles and values referred to in the Code of Ethics so that these principles and values serve the Group and all our partners. Sanofi aims to:

- Combine economic and social performance by reaffirming our commitments to the Group's values.
- Enhance health and safety in the workplace by encouraging dialogue within the Group, providing training, ensuring respect for privacy, etc.

- Carefully maintain a climate of mutual respect with employees and external partners in the fields of medicine, science and business. The Group attaches great importance to providing information to the medical and scientific community, especially about clinical trial results for drug development and post-marketing studies.
- Preserve life and health. Sanofi pursues ambitious programs and actions to protect and ensure the safety of our industrial sites and to protect the environment.
- Apply the principles of good corporate governance and encourage transparency. In accordance with relevant regulations, the Group has a duty to provide our shareholders and the market with timely, regular, trustworthy and relevant information concerning our activities, financial performance and economic results.
- Respect the cultural and legal environment of the countries in which we operate:
  - By objecting to all forms of corruption
  - By complying with the rules of free competition
  - By adhering to the principles of the Universal Declaration of Human Rights
  - By supporting the principles of the International Labor Organization (ILO) and the guidelines issued by the Organization for Economic Cooperation and Development (OECD) geared to multinational enterprises
  - By promoting various international initiatives that forge links between the business sector and society.

Sanofi is a member of the United Nations Global Compact and is committed to supporting and applying the key principles of the UN Global Compact concerning human rights, labor, the environment and anti-corruption.

#### Distributing and understanding the Code of Ethics

As of April 2011, an updated version of the Code of Ethics was introduced globally. In order for all Sanofi employees to better understand the new Code of Ethics, in their native language, it was translated into many different languages as possible and can be found on Sanofi's intranet and the Group's website. As of late 2011, the Sanofi Code of Ethics is available in 31 languages. Additional languages will be available in 2012. The updated Code of Ethics was presented to the Sanofi European Works Council.

**For more information:** Code of Ethics

- [en.sanofi.com / Responsibility / Code of Ethics](http://en.sanofi.com / Responsibility / Code of Ethics)

To coincide with the launch of the Code of Ethics, related training programs Code were organized globally. E-learning modules were provided to employees who have access to a computer and face-to-face meetings were held for employees who do not have access to a computer (e.g., those who work in factories). This course is available in 26 languages. As of mid-February 2012, more than 76,000 employees have received training about the Code of Ethics in 98 countries.

## Social Charter

The Social Charter outlines the principles that form the common core for human relations within the Group in terms of social dialogue, employee benefits, occupational health and safety, working conditions, professional training and non-discrimination within the Group. It was distributed to all employees in some 20 languages. It contains important sections on human rights and the principles of the UN Global Compact, particularly in the field of labor relations:

- Freedom of association and recognition of the right to collective bargaining
- The abolition of child labor
- The elimination of discrimination in employment

It also addresses all the topics in International Labor Organization Conventions 138 and 182 with respect to children's safety and physical and moral health.

**For more information:**

 [Sanofi Social Charter](#) (PDF, 298Kb)

## Other internal policies

In addition to the Code of Ethics and the Social Charter, Sanofi has defined a set of CSR-related principles and policies. The table below lists the corresponding documents (codes, charters, policies, etc.) that are applicable to the entire Group.

| Internal Policies | Principles  |
|-------------------|---|
| Code of Ethics    | The purpose of the Code of Ethics is to demonstrate the Group's continued responsibility and commitment towards employees and |



| Internal Policies              | Principles   |
|--------------------------------|--|
|                                | <p>external stakeholders (e.g. patients, suppliers, healthcare professionals, etc.).</p> <p>This Code is a guide for all employees. It is intended to protect employees by helping them recognize situations that may not be easily identifiable in which they may put themselves and the company at risk.</p>   |
| Anti-corruption Policy         | In 2010, Sanofi established an anti-corruption policy, which was provided to all Group employees, via the Group's intranet. This policy describes Sanofi's commitment to fighting all forms of corruption by making employees aware of anti-corruption laws and regulations so that they can apply them within the scope of their work.  |
| Conflict of Interest Directive | In 2011, Sanofi issued a Conflict of Interest directive for employees to enable the early detection of conflict of interest situations for Sanofi employees across the Group and to provide a methodology to follow in such situations.  |
| Risk Committee Charter         | The Risk Committee Charter describes the Sanofi Risk Committee mission, scope of accountability, interactions with other committees, organization and authority regarding risk management.   |
| Code of Financial Ethics       | <p>In accordance with U.S. securities law, Sanofi has adopted a Code of Financial Ethics that applies to the Chief Executive Officer, the Executive Vice-President Chief Financial Officer and the Vice-President Corporate Accounting. The Chief Financial Officers of Group entities are also required to sign up each year to the code in recognition of their adherence to its principles.</p> <p>Principles guaranteeing the exhaustive, accurate and objective nature of financial information published by the Group in compliance with regulations issued by the relevant administrative authorities or any other public or private body with regulatory powers regardless of where they are located in the world.</p> |
| Internal Audit Charter         | This Charter describes the responsibilities and goals of internal audit as well as the related professional and ethical rules intended to provide Senior Management with reasonable assurance concerning the level of control over Group operations.   |
| IT Audit Charter               | This charter outlines the IT Audit Department's responsibilities and objectives within the sanofi Group. In coherence with Internal Audit Charter, it covers the specificities of IS dimensions. It establishes the professional and ethical rules that IT system auditors must follow. It   |

| Internal Policies                         | Principles  |
|---|---|
|   | <p>also defines the methodological framework for IT audit and serves as a key communication tool.</p>   |
| Code of Internal Control Principles       | <p>This code presents key principles in terms of governance and internal control. It forms a foundation for initiating monitoring at the local level of the effectiveness and the relevance of controls in place.</p>   |
| Good Promotional Practices                | <p>Sales representatives apply rules when dealing with prescribing physicians or patients to ensure that the Group provides them with all necessary information about the proper use of a medicine. These rules comply with the requirements of the World Health Organization (WHO) and the IFPMA (International Federation of Pharmaceutical Manufacturers &amp; Associations).</p> <ul style="list-style-type: none"> <li>● <a href="#"><i>Ethics / business ethics / responsible marketing</i></a></li> </ul>  |
| Good Marketing and scientific information | <p>In 2011, Sanofi created an internal directive in connection with good practices when it comes to scientific information and marketing. This was the first time common requirements have been provided on investigational medicinal products, vaccines, medical devices, cosmetics and nutraceuticals, applying to scientific information (promotional and non-promotional information; inquiries about medical information; complaints, gifts &amp; other items, patient support programs, samples and hospitality).</p> <ul style="list-style-type: none"> <li>● <a href="#"><i>Ethics / business ethics / responsible marketing</i></a></li> </ul> |
| Supplier Relationships Charter            | <p>The Sanofi Supplier Relationships Charter, distributed to the entire Sanofi procurement organization in September 2011, sets out the rules of conduct that must be respected by all Group employees in their relations with suppliers and governs issues relating to invitations, gifts, meetings and correspondence.</p> <ul style="list-style-type: none"> <li>● <a href="#"><i>Suppliers Relationship Charter</i></a></li> </ul>  |

| Internal Policies   | Principles  |
|---|---|
| Suppliers Code of Conduct   | <p>The Sanofi Suppliers' Code of Conduct, which is distributed to all suppliers, was developed to ensure that all suppliers respect and are aware of the Group's CSR principles. The Code describes the conditions that Group suppliers must respect in terms of human rights, labor practices, the environment and the fight against corruption. Suppliers' compliance with this code is decisive in their commercial relationships with Sanofi.</p> <ul style="list-style-type: none"> <li>● <a href="#">Suppliers Code of Conduct</a></li> </ul> |
| Charter on the Ethical Principles Governing Scientific / Medical Publications for the Group's Techniques / Compounds / Vaccines | <p>For all types of scientific publications on the Group's compounds, vaccines and techniques (concerning both pre-clinical and clinical trial results), this charter describes the principles to be followed as regards quality, transparency, respect for copyright and good publishing practices. The principles set out in this charter also apply to all publication authors, i.e., regardless of whether or not they are Sanofi employees.</p>  |
| Charter on the Humane Care and Use of Laboratory Animals  | <p>This charter outlines rules governing the conditions for using laboratory animals. They include seeking alternative methods as well as the routine implementation of the best standards by the Group, our partners and subcontractors.</p>   |
| Data Protection Charter   | <p>Internal rules concerning the collection, processing, utilization, distribution, transfer and storage of individual data are set out in this charter to ensure an adequate level of protection.</p> <ul style="list-style-type: none"> <li>● <a href="#">Ethics / Data protection</a></li> </ul>   |
| Quality Policy  | <p>These principles ensure patient safety by implementing a Quality management system incorporated into all the Group's activities. The principle of continuous improvement – a key concept of this policy – is shared with all employees. This policy establishes a high Quality standard worldwide to provide effective and safe products that are developed, manufactured, distributed and marketed in full compliance with regulatory requirements and the Group's corporate values.</p>  |
| Health, Safety and Environment Policy (HSE)   | <p>The HSE Policy contains guidelines outlining the Group's scope of action to safeguard the health and safety of employees and outside partners, and to protect natural resources and the environment.</p> <ul style="list-style-type: none"> <li>● <a href="#">Health and Safety</a></li> </ul>   |

## Management systems

- [Standards and controls: A fully integrated CSR approach](#)
- [HSE](#)
- [Quality](#)
- [Pharmacovigilance](#)
- [Compliance](#)
- [Internal Control and Audit](#)

## Standards and controls

The Sanofi CSR approach is based on a cross-functional method designed to ensure full integration at every level in order to further minimize risk:

- The Group complies with widely recognized international CSR standards.
- Additionally, documents such as guidelines, codes, charters and procedures are developed and implemented throughout the Group to integrate various external standards and laws that apply to Sanofi activities. Sanofi monitors the implantation of such documents.

Sanofi adopts procedures that make it possible to share and ensure proper application of policies that the Group has undertaken to follow. Various management systems establish a framework for monitoring the application of these procedures and implementation of action plans.

The Group's management systems related to CSR includes the following areas:

- HSE
- Quality
- Pharmacovigilance
- Compliance
- Internal Control and Audit

## HSE

▼ Background

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▼ Policy

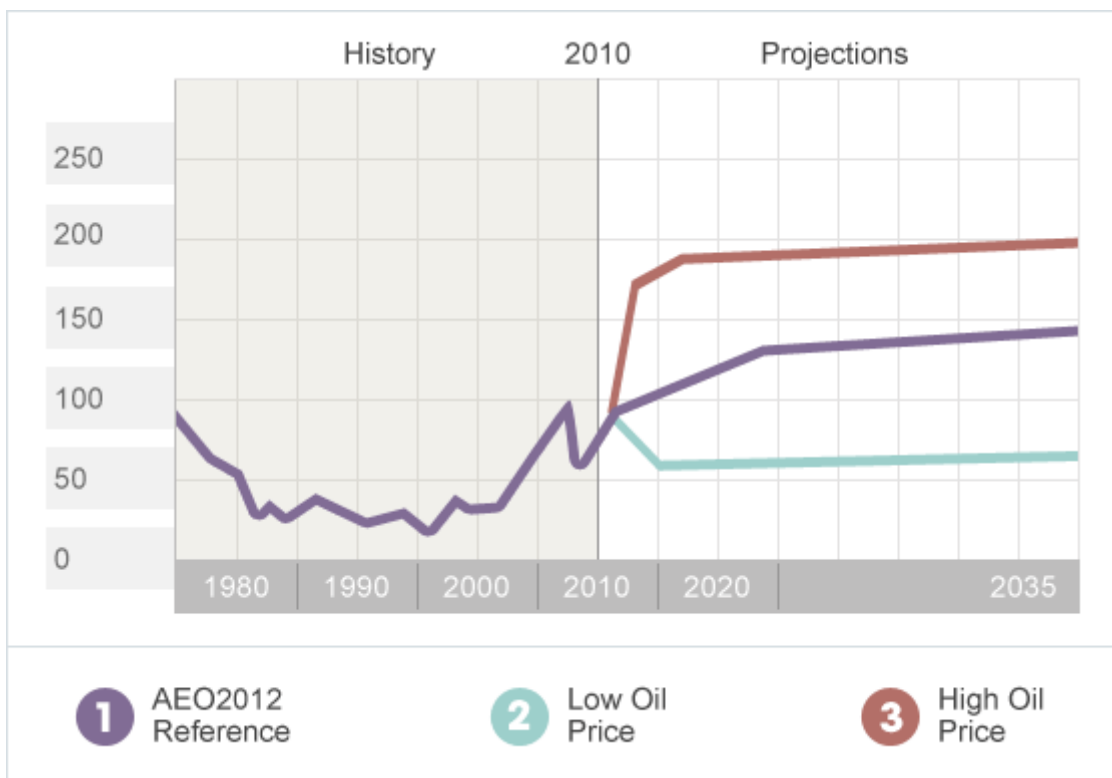
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### Background

Sanofi has implemented an HSE management system encompassing all operational levels. This system is designed to protect the health and safety of each employee, develop and utilize safe industrial processes, and limit the environmental impact of the Group's activities.

Sanofi's HSE management system covers all Sanofi activities and sets goals for the Group to reach.

One of the main responsibilities of the HSE Department is to ensure these goals are attained. It also oversees compliance with regulations by defining an internal framework based on the policy and internal requirements, rules and procedures developed by the Group. Many training programs are set up to fully implement this framework and involve employees and managers. HSE performance is measured using reporting tools, self-inspections and audits to evaluate the system's effectiveness and review the goals and methods used as part of a continuous improvement approach.



The HSE department has a network of nearly 700 individuals that support the implementation of policy and requirements.

## Policy

### New requirements and a new HSE policy

The HSE management system is continuously being improved. As we do each year, in 2011, Sanofi issued a new integrated policy that encompasses the Group's new and existing entities. The HSE Policy was signed by Christopher A. Viehbacher, Chief Executive Officer, demonstrating the Group's strong commitment to addressing HSE issues.

In addition, in 2011 we added a new requirement regarding well-being in the workplace. A total of 78 HSE requirements now support Sanofi's HSE policy, focusing on all areas of HSE. They are supported by a set of standards and guidelines that provide further guidance for implementation of the management system.

For more information:

 [HSE Policy](#) (PDF, 523Kb)

## Goals

In order to solidly root this HSE policy within the Group's activities and sectors, the HSE Committee developed a five-year strategic plan – HSE 2015 – in 2010. At the end of 2011, a new HSE progress action plan (PASS) was released to complement the previous five-year plan. This PASS includes:

- a review of objectives for indicators in the HSE 2015 strategic plan
- new objectives for new indicators
- new orientations for progress regarding training, programs, support to new entities, feedback on experience and HSE communications.

This new HSE progress action plan was presented to the HSE Network and distributed to all the Group's affiliates including Merial and Genzyme. It was endorsed by the Sanofi's Vice President for HSE.

Some examples of objectives contained in the progress action plan:

### For Health and Safety (2015)

- 30% reduction in LTIR (Lost Time Injury Rate)
- 25% total car accident reduction (in absolute figures)

### For Environment (2020)

- 20% reduction for CO2 emissions (in absolute figures)
- 25% reduction for water consumption (in absolute figures)

**For more information:** Our goals and related actions

- [People / Health and Safety](#)
- [Planet / Energy and carbon footprint / Actions](#)
- [Planet / Local environmental impact / Water management](#)
- [Planet / Waste management](#)



## Actions

- ▼ Developing an HSE culture
- ▼ Assessing compliance
- ▼ Learning from experience
- ▼ Providing support to new entities
- ▼ Broadening environmental and safety certification

### Developing an HSE culture

Offering HSE culture training to managers is an important part of the HSE Department's role. When managers receive training, they acquire knowledge and skills in order to properly control the risks that employees are exposed to in their work environment. This program aims to raise managerial awareness of HSE issues by emphasizing the role and responsibilities of managers.

Sanofi introduced the HSE Culture training program in 2005 at the Group's chemical sites in France and in 2007 expanded it to R&D sites, as a pilot. The program was implemented outside France in 2010 and continued further expansion in 2011.

Brazil, the Czech Republic, Germany, Hungary, Italy, South Africa and the United Kingdom initiated the program in 2010. The training program was rolled out in Middle East Africa and in China, among other countries.

Since 2005, 6,000 Group managers have received HSE Culture training. The program now covers 109 sites including Industrial Affairs, Merial, Sanofi Pasteur and Genzyme, located in 32 countries worldwide. Training modules have been adapted and translated into 14 different languages.

For example, in 2011, at Casablanca (Morocco), nearly 22 industrial site managers in Africa met for two days to focus on the HSE Culture program. The same year, 50 HSE managers from all Industrial Operations in China, including Merial and Sanofi Pasteur, came together for the Group's HSE Culture training.

In addition to these training programs, each manufacturing site organizes an HSE Week to increase awareness among all employees about different HSE issues.

In Cali, Columbia, the 11th HSE week was held in 2011 to address accident prevention, healthcare and the environment.

Sanofi's "HSE Academy" will be launched in 2012 to improve expertise among the HSE function and facilitate a strong business partnering culture. In the long run, this approach is expected to facilitate best practice sharing and networking. The Academy's primary objectives are to:

- Develop HSE technical and "soft" skills required for current and future success
- Share best practices and experiences
- Facilitate and foster networking
- Determine a common framework of references: roles, skills and knowledge within the HSE family
- Provide an overall skills development offer
- Streamline training and learning programs on offer

#### Assessing compliance

The HSE Department relies on audits to correct any failures to comply with the policy and minimize non-compliance. HSE audits are divided into three categories:

- Management audits aimed at ensuring compliance with the Group's HSE rules
- Specialized audits that target a specific area, for example "outside service providers" or "biosafety"
- Technical visits focusing on protecting property that are carried out with insurance adjusters

Sanofi carried out a total of 213 audits in 2011:

- 24 HSE management audits throughout the Group's sites or pharmaceutical operations headquarter offices
- 17 specialized audits
- 172 technical visits, including Genzyme and Merial

Working in coordination with the various training programs organized by the HSE Department, the Group performs these audits with the primary goal of fostering genuine behavioral change among line managers whose operations are being audited, as opposed to reacting to issues found after an audit. This is a sign of growing maturity within the HSE system.

As part of the HSE program described in the PASS, one of the Group's priorities is to reinforce audit programs concerning the management of outside service providers.

## Learning from experience

To promote health, safety and environment at Sanofi, various programs make it possible to report safety events, share and recognize best practices, and provide training about health and safety standards.

- ***“Prevention par le Retour d’Expérience dans Sanofi”*** (PRESS) is a publication that includes an analysis of the key safety and environmental events and immediate corrective actions, as well as recommendations for improving safety.
- **The HSE Awards** were launched in 2011 to recognize best practices at all Sanofi entities. Participants submitted applications about projects demonstrating efficiency, innovation and risk reduction as well as other criteria. Some 70 applications were received worldwide, and ten winners will be announced at the awards ceremony. The winners will be selected in the following categories: the environment, hygiene, safety and a special *“prix du Coeur”*.
- **Posters and communication tools that can be used by** industrial or R&D sites, subsidiaries’ offices and Group businesses to raise awareness about safety and the environment at workplace.

Example of a poster used for internal communication: “Think the risk is a key step”



- *Zoom: Example of a poster used for internal communication: “Think the risk is a key step”*
- **Learning Experience (LEX) Days** are one-day seminars to promote interaction among sites. The seminar focuses on avoiding recurrence of health, safety and environmental events and prevention through widespread application of best practices. In 2011, two LEX days were organized, bringing together more than 140 people. These LEX days provided an opportunity to share about:
  - Micropollutants in waste water.
  - The lock out / tag out (LOTO) system, which is a procedure to ensure that all sources of hazardous energy or products are locked out in order to protect employees and outside service providers during maintenance operations.



According to the new HSE progress action plan, the next Learning Experience Days will tackle emergency management and especially in natural disasters, biosafety and machine safety.

## Providing support to new entities

The strategic HSE plan describes the HSE integration process for new entities, such as Genzyme and Merial, and other future acquisitions by the Group, which means harmonizing documentation, standards and ways of working with these new entities.

This process entails the following steps:

- Implementing priority HSE processes (e.g., crisis management)
- Assessing the HSE situation and establishing action plans
- Providing support for and monitoring action plans
- Using a general HSE audit for final validation of the process

New entities will receive this specific HSE support for approximately 30 months. After this time, they will be fully integrated into the Group's HSE management system.

## Broadening environmental and safety certification

Sanofi seeks to highlight the progress the Group has made in health, safety and environmental management and promote our achievements with third parties by encouraging certification. Production sites are key priorities. ISO 14001 and OSHAS 18001 standards focus on the principle of continuous improvement of performance related to health, safety and the environment.

Today, out of 100 industrial and R&D Sanofi sites worldwide, 50 are ISO 14001 certified and 24 are OSHAS 18001 certified. A specific certification program was implemented for sites in the intercontinental region.

Out of 23 industrial and R&D Merial sites, five are ISO 14001 certified and one is OHSAS 18001 certified.

Out of 11 industrial and R&D Genzyme sites, three are ISO 14001 certified and four are OHSAS 18001 certified.

## Quality

Sanofi's approach consists of implementing guidelines for quality and continuous improvement to cover each phase of the product's life cycle, as well as all related services. Sanofi's Senior Management is firmly committed to providing effective and safe products worldwide that are developed, manufactured, distributed and marketed in full compliance with regulatory requirements and the Group's corporate values.

Quality Managers are appointed in each operating entity and each site or affiliate involved in activities that may impact product quality, patient safety or data integrity. They conduct and coordinate quality and compliance activities, and they contribute to compliance with regulatory requirements and continuous improvement of the Group's performance.

Since 2009, a Global Quality organization has brought together existing Quality teams and ensured the consistent implementation of the Quality Policy throughout the product's life cycle.

**For more information** on the development of Quality Systems, Quality risk management, audits and inspections, see the section on Global quality:

- [Patient / Quality](#)

## Pharmacovigilance

Sanofi's Pharmacovigilance organization at all affiliates and at the Group level, in charge of ensuring the safety and quality of our products, plays a vital role in patient safety by monitoring the risks associated with the use of our products.

The Pharmacovigilance organization seeks to constantly optimize a product's benefit / risk ratio by monitoring prescription practices to prevent and/or reduce treatment risks, propose training programs to healthcare professionals as well as Sanofi employees and alert patients about safety issues. To promote safe and quality products as well as product prescription good practices, we work in close collaboration with healthcare professionals, relevant health authorities and the patient community. This mission, which involves Sanofi's responsibility to patients, applies to products under development as well as marketed products.

The purpose of Pharmacovigilance is three-fold:

- To detect, evaluate and monitor risks related to the use of all Sanofi medicines and vaccines
- To seek and implement measures to reduce such risks as well as to prevent adverse events
- To promote the proper and safe use of medicines

### For more information:

- [\*Patient / Pharmacovigilance\*](#)

## Compliance

As enhancing compliance has become a real challenge for all global companies, Sanofi has made the decision to reinforce the compliance function at corporate, region, country and functional level.

The mission of the Global Compliance Organization at Sanofi is to shape an environment and build processes to instill ethical values and articulate clear standards of compliant behavior so that the Group and our external stakeholders view Sanofi as a global leader in upholding its ethical values.

At Global level, a Global Compliance Organization is headed by the Global Compliance Officer having direct access to the Group's Chief Executive Officer. Furthermore, the Global Compliance Officer meets twice a year with the Audit Committee.

In order to carry out the Global Compliance program, the Global Compliance Officer is leading a Global Compliance team which is responsible for designing process and policies but also training and communication tools around Compliance matters covered by the Code of Ethics. In addition, Regional Compliance Officers are in place in order to ensure that all compliance obligations are implemented and applied in their area of responsibility in a consistent and homogenous manner. Moreover, Sanofi has a network of local Compliance officers who ensure Group rules and trainings are properly implemented within their local organization.

### Warning system

Since 2006, a warning system has been in place to allow early detection and handling of non-compliant behaviors. The Code encourages employees who believes in good faith that a rule or one of the principles laid down in the Code of Ethics has been or is about to be violated, to inform his or her superior or Global Compliance of his or her concerns regarding possible illegal practices or ethical violations.

Moreover, an alert procedure has been established in order for Sanofi to comply with the Sarbanes-Oxley Act in the United State. This procedure can be used by any employee who has any doubt or suspicion relating to potential illegal or unethical practices in finance, accounting, internal control, in the respect of free competition or the fight against corruption.

In such cases, an employee may anonymously, if he/she wishes, contact Global Compliance based at corporate headquarters in France, where a dedicated, secured communication system (telephone, fax and e-mail) has been set up specifically for use by employees.



In the United States, in accordance with local regulations and practices, a toll-free external Compliance Helpline has been set up for company employees, who may call it at any time.

Early warnings involving the areas of financial or accounting audit are reported to the Audit Department and the Finance Department.

In 2011, the total number of calls received on Sanofi hotlines worldwide was 388. Of these matters, 167 met the Group's definition of a potential violation and were investigated and/or are still under investigation; 15 % of these alerts led to sanctions that ranged from warning letters to contract termination.

For more information:

- [Ethics / Fight against corruption](#)

## Executive Compliance Committee

Furthermore, an Executive Compliance Committee, which is chaired by the CEO, is responsible to facilitate and ensure the effectiveness of all components of Sanofi's compliance program and to foster the continued commitment to the Group values. In order to do so, the Executive Compliance committee is the forum that gathers all functions entrusted with compliance to focus attention on enterprise-wide compliance objectives. Moreover countries are encouraged to establish local Compliance Committees to oversee the country's compliance with the Group's Code of Ethics, policies and procedures, applicable legal and regulatory requirements and industry standards. Best Practices and Recommendations for Model Compliance Committee Charter were distributed to the affiliates in 2011.

## Internal audit

The Internal Audit and Control Department uses a systematic and methodological approach to ensure effective internal control in all countries. It seeks to promote safety, reliability and ethics through the Group's various activities. It is also committed to ensuring compliance with regulations and new constraints related to financial transparency and corporate governance.

The Internal Audit and Control Department is responsible for providing Senior Management with assurance on the level of control of its operations and providing guidance to improve operations and help create added value. Internal audit helps the Group reach goals by using a systematic and methodological approach to assess our risk management, control and corporate governance processes. It also makes recommendations to improve the effectiveness of these processes. Internal audit is responsible for identifying good practices and proposing areas for improvement or progress. Internal audit is responsible for oversight of compliance with anti-fraud and anti-corruption regulations, and verifies that the Group's activities are carried out within an ethical professional framework. Lastly, the department assesses the reliability, integrity and safety of the Group's IT applications, infrastructure and networks.

In terms of internal control, the department is responsible for compliance with the U.S. Sarbanes-Oxley Act and French law (Section L. 225-37 of the French Commercial Code).

Internal audit is also committed to implementing a quality approach to ensure compliance with standards that regulate its activity. In November 2006, Internal Audit received certification from IFACI (the French Institute of Audit and Internal Control). This certification has been renewed in 2010.



In January 2012, Sanofi's Information Systems Audit team was awarded the 2011 Hintze Prize by IFACI for its work on the "Audit of Information Systems Governance" in collaboration with two industry associations (CIGREF, AFAI).

This work included among other contributions a publication of a guide "Governance of the Information System" and the online publication of a downloadable tool to help with the implementation of program to evaluate the efficiency of the Information System Governance.

### Hintze 2011 award

## Hintze 2011 award



- [Zoom: Hintze 2011 award](#)

For more information:

- [www.ifaci.com \(in French\)](http://www.ifaci.com)
- [www.ifaci.com / Actualités \(in French\)](http://www.ifaci.com/Actualités)

## Risk management

 [Form 20-F 2011](#) (PDF, 1289Kb)

### Background

Sanofi main mission is to address the growing public health challenges, while ensuring the safety of its patients and employees. To achieve this mission, the Group must develop high standards practices in the control of the risks inherent to our activities.

The evaluation of opportunities and risks is affected by continual new developments. To strengthen our excellence in this area, the Sanofi Corporate Management acknowledges the need to promote and circulate a responsible risk culture within the Group to identify, assess and proactively manage the transversal and emerging risks within our organizations.

Over the last ten years, increasing attention has focused on topics relating to businesses' corporate social responsibility. Analysts are beginning to assess the financial impact of corporate social responsibility and environmental performance in certain key areas. Businesses are also trying to measure the return on investment associated with their CSR policy.

## Managing risks

The Group's organizational structure is geared to managing the risks and opportunities associated with the Sanofi's activities. The corporate, operational and support teams involved in internal control contribute to the overall risk control system by conducting control processes within their areas of responsibility.

The Executive Committee, chaired by the Chief Executive Officer implements the Group's overall strategy and oversees arbitration between departments and allocates resources, in furtherance of its high-level management role. It leans on its experiment to anticipate and pilot the risks and the opportunities bound to the evolutions of the Group and to the pharmaceutical sector. The Executive Committee meets according to a frequency favoring the fast decision-making.

A Risk Committee was created in late 2010 to assist the Executive Committee in fulfilling its corporate governance responsibilities by implementing an enterprise risk management framework to provide reasonable assurance on the effectiveness of the Group's risk management processes. The Risk Committee, co-chaired by the Senior Vice President Corporate Social Responsibility and the Senior Vice President Audit and Internal Control Assessment, meets quarterly. The Risk Committee defines the Group's risk monitoring strategy, including critical risk identification, evaluation and management.

The Risk Committee also reports on risk, ensures that actions plans are in place for critical risks, with clear ownership and / or responsibility for their execution, and capitalizes on lessons learned. It reports to the Executive Committee on the consistency and quality of critical risk management processes in place. More generally, the Risk Committee supports and promotes a responsible risk culture within the Group.

Major risks identified are reviewed on a regular basis and presented to the Board of Directors' Audit Committee.

The Group is currently establishing a Global Enterprise Risk Management Framework (ERM), which provides the fundamental principles underlying the management of Group's critical risks through detailed Directives and Standards.

As part of this framework, a new "risk" function will be created at the corporate level, will report directly to the Senior Vice President Corporate Social Responsibility, Chairman of the Risk Committee.

The Group also has a crisis management procedure designed to anticipate, insofar as possible, the potential consequences of a crisis, via management principles and early warning systems covering all Group activities.

For more information:

## 2011 Form 20-F



[Directors, Senior Management and Employees, beginning \(extract from 2011 Form 20-F\)](#)

(PDF, 173Kb)



[Risk factors, Environmental risks of our industrial activities, beginning\(extract from 2011 Form 20-F\)](#)(PDF, 173Kb)



[\(extract from 2011 Form 20-F\)](#)(PDF, 117Kb)



[Annual Report on Form 20-F 2011](#)(PDF, 1.25Mo)

## Risk factors

In addition to market-related risks, risks may concern corporate social responsibility and environmental issues such as certain legal risks, certain risks related to activities or environmental risks.

### Risks relating to legal matters

Thanks to its patents and other intellectual property rights, Sanofi has exclusive rights over various products created from the Group's research. Nonetheless, patent protection varies depending on the product and the country. Sanofi's operations and results could be adversely affected if the Group is unable to defend its intellectual property rights. Therefore, the Group's success depends on effectively protecting our intellectual property rights and our patents.

Product liability represents a risk for the pharmaceutical industry's activity insofar as product liability claims may be introduced, such as class action lawsuits in the United States.

The pharmaceutical industry is under increasing scrutiny by United States and European authorities, which accentuates the Group's exposure to what may be significant risks. For example, the marketing of our products is heavily regulated, and alleged failures to comply with applicable regulations could incur fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs.

The relevant authorities may conduct inquiries or investigations, or private parties could initiate litigation concerning adherence to applicable rules for antitrust, particularly regarding competition, marketing practices and pricing.

### Risks relating to Sanofi's business

These risks include:

- The difficulty of renewing our product portfolio in order to replace products whose patents or regulatory exclusivity are due to expire
- The diversification of our business
- Our notably increasing presence in emerging markets

In addition, the Group must anticipate risks concerning product manufacturing and distribution, those relating to counterfeit products, and risks related to reimbursement policies that are determined by governments or payers.

Worldwide, the pharmaceutical industry faces changes in the regulatory framework and increasing wariness on the part of consumers who want more guarantees regarding the safety and efficacy of medicines and healthcare products. Moreover, incentives for research are limited. Healthcare authorities have imposed more stringent requirements, especially in terms of the quality and quantity of data required, in order to establish that a product is effective and safe. Marketed products are reassessed on a regular basis to evaluate the risk / benefit ratio after they have been approved. These reassessments can give rise to marketing restrictions, product suspensions / recalls and an increased risk of legal disputes.

A pharmaceutical company's performance depends in part on the conditions for drug reimbursement. Governments and the public expect businesses to bring to market innovative products that meet major public health needs. They also depend on marketing medicines at reduced prices and generic products to help maintain the economic balance of healthcare systems. The pharmaceutical industry has been criticized for taking an incremental approach to innovation, producing neither major therapeutic improvements nor healthcare savings. In light of this situation, there is growing pressure concerning pricing and reimbursement due to the following: cost controls imposed in many countries, reduction of reimbursement for certain products and increasing difficulty in obtaining a satisfactory reimbursement rate.

To meet these challenges and expectations today, the Group offers a broad portfolio of prescription, generic and over-the-counter (OTC) products, which help to control healthcare system costs.

In addition, Sanofi has a specific approach to production and commercialization for emerging markets.

### Industrial risks relating to the environment

This area focuses on the utilization of hazardous substances, site remediation and compliance costs.

As a result of its chemicals activities, the Group may have risks related to accidental emissions or industrial incidents that could lead to damages, fines and operating losses. Unexpected soil contamination may be discovered at an industrial site, leading to environmental liability. This situation may concern sites that the Group has owned for many years or sites that were acquired or sold, for which the question of liability may lead to disputes.



Lastly and more generally speaking, when it comes to monetary investments, it is important to be prepared to react in response to rapidly changing environmental regulations.

For more information:



*Risk factors, Environmental risks of our industrial activities (extract from 2011 Form 20-F)*

(PDF, 117Kb)

## Our challenges

Sanofi must maintain its right to operate among the local communities where Group sites are located. To this end, the Group must control its direct corporate social responsibility and environmental impact (making the most positive and the least negative impact), respect ethical rules and create employment opportunities.

The Group actively monitors new developments connected with its environmental and corporate social responsibilities, even in areas where financial analysts have not established a direct link to the Group's financial performance.

**The information below presents an example for each of the four key areas of the Group's CSR approach.**

### Patient: Respecting human rights and the right to health

Respect for human rights forms the foundation upon which a corporate social responsibility policy is built. Both international regulations and voluntary initiatives alike have made human rights a key issue for companies.

This is particularly true for international groups like Sanofi that operate in countries where the risk of human rights violations can be significant.

The Group has thus put in place an ambitious policy involving self-assessment of its practices as well as training to ensure that human rights are respected throughout the Group.

One aspect of this challenge is the right to health, and specifically low-income populations' right to healthcare and treatments. The World Health Organization (WHO) recommends promoting access to pharmaceutical products worldwide, under certain conditions, by demonstrating flexibility regarding intellectual property rights. This major issue offers an important opportunity for the sector to develop in new markets, yet it also poses the risk of criticism for not responding fast enough. In this field, the Group has established specific programs targeting major diseases that affect developing countries and in which the Group has therapeutic expertise. These programs include specific R&D investments to develop adapted and non-patented products, sales at differentiated prices and drug and vaccine donations.

#### For more information:

- [Ethics / Human rights](#)
- [Patient / Access to healthcare](#)
- [Ethics / Responsible lobbying](#)

#### Ethics:

##### Marketing practices

Healthcare professionals and other stakeholders expect pharmaceutical companies to provide reliable product information, while facilitating competition without promoting the overuse of medicines. Some observers and patient organizations denounce certain marketing practices utilized by pharmaceutical companies. Beyond risk to the sector's reputation, this pressure is increasing due to the current trend among governments to promote generics and discontinue reimbursements for certain medicines. In this context, the implementation of "responsible marketing" rules such as those established by Sanofi provides an opportunity to maintain a climate of trust with the authorities, prescribing physicians and patients.

#### For more information:

- [Ethics / Responsible Marketing](#)

#### Information protection

Sanofi know-how, expertise and achievements all represent valuable strategic assets that must be preserved for the benefit of the Group.

Regardless of whether this involves industrial espionage or not, above all, we must ensure the sustainability of our projects and our investments by protecting them from intrusions, wherever they may come from. The risk of information leakage increases as communication technologies develop, building invisible bridges to the outside world. To address this issue, the Group has set up a broad program in order to protect its assets including dedicated awareness tools, IS tools and audits.

#### People: Employees' health

Employees' health risks represent a potential basis for legal action in the United States and Europe. The relationship between chronic disease and the occupational environment has become an important issue. In light of this situation, protecting and monitoring employees'

health is not only a matter of preventing absenteeism and demonstrating concern for employees; it is also a way to prevent financial and legal risks.

For more information:

- [\*People / Occupational health and safety\*](#)

## Planet: Combating climate change

Various risks related to evolving environmental regulations are analyzed in the 2011 Document de Référence and 2011 20F Form. The “risk factors” section includes some risks related to environment, such as natural disasters prevalent in certain regions in which we do business and that could affect our operations.

In the environmental field, greenhouse gas emissions represent an emerging issue. At the end of 2008, the European Council adopted the “Climate and Energy Package,” setting new quotas by sector, which will have a financial impact on businesses. In fact, this emerging issue goes beyond the European regulatory framework because other countries could adopt more restrictive regulations. The Group’s sound performance with respect to greenhouse gas emissions gives it a quota surplus.

For more information:

- [\*Planet / Energy and carbon footprint\*](#)



[\*Natural disasters prevalent in certain regions in which we do business could affect our operations \(extract from 2011 Form 20-F\)\*](#) (PDF, 38Kb)

## Protecting against risks

The Sanofi Insurance Department develops solutions to limit certain random risks and offset these risks either partially or completely over time through financial means.

The following risks are considered insurable: traditional risks, such as shipping by sea or land, liability for operations and delivered products, fire and related operating losses; as well as risks specific to the pharmaceutical industry, including those inherent to clinical trial management throughout the world, cold chain management for the transport of medicines and vaccines and production line management, and medicines and vaccines packaging developed in many different languages for use worldwide.

Establishing insurance programs to cover these risks depends on actions taken at every level, from the early stages of research and development, through manufacturing and distribution:

- Protection of goods management, regardless of the amounts and types of protection, makes it possible to limit the impact of an incident by protecting investments made within a company. The direct financial consequences of such an incident are therefore reduced and the related operating loss is largely offset by insurance coverage.
- Risk prevention management, whether or not it can be insured, makes it possible to limit the risk impact and to integrate all actions coordinated within the company.

Insurance plays a catalyst's role to finding solutions by taking into account the portion of transferred risk that may or may not be borne by the company. When insurance policies are negotiated, the terms and conditions of coverage offered by insurers and the quality of protection and prevention are important and decisive factors.

For more information:



[Information on the Company B. Business Overview Insurance and Risk Coverage \(extract from 2011 Form 20-F\)](#) (PDF, 42Kb)

## Standards and memberships

Sanofi addresses issues identified as being important for the pharmaceutical sector through a series of policies, procedures and initiatives that respect cultural and legal environments in the countries where the Group operates.

- [Complying with standards](#)
- [Memberships and partnerships](#)

## Complying with standards

Sanofi addresses issues identified as being important for the pharmaceutical sector through a series of policies, procedures and initiatives that respect cultural and legal environments in the countries where the Group operates.

### Respecting human rights

For human rights, the Group adheres to the Universal Declaration of Human Rights (UDHR) principles as well as other individual rights established by organizations in accordance with the United Nations system.

The principles set forth in universal human rights documents apply to people and organizations, and consequently, to businesses. Sanofi plays an active role in the public debate on human rights. The Group is a founding member of the EDH initiative, among the eight CAC 40 companies that are members. EDH is inspired by the work carried out since 2003 by the Business Leaders Initiative on Human Rights (BLIHR) to promote human rights in companies and aims to complement its work with contributions from French-speaking countries.

The Group adheres to several international codes, rules and principles such as principles of the International Labor Organization (ILO), the United Nations Global Compact, and the directives issued by the Organization for Economic Cooperation and Development (OECD).

### Adhering to international rules regarding the Group's area of business

Sanofi respects the international rules specific to the pharmaceutical industry, in particular with regard to:

- Clinical trials and animal testing, in particular rules developed by professional associations (European, American and Japanese) concerning clinical trial transparency, as well as ILAR (Institute for Laboratory Animal Research) and UFAW (Universities Federations for Animal Welfare) guidelines on animal testing
- Promotional practices such as Organization for Economic Cooperation and Development (OECD) directives geared to multinational firms and particularly concerning good business practices, anti-corruption and preventing illegal payments, as well as "ethical criteria" of the

- World Health Organization (WHO) with regard to drug promotion and codes from the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) concerning good commercial practices
- WHO recommendations for drug donations

In addition to these external codes and standards, a set of principles and policies that applies to the entire Group was defined. The most important of these are listed in Internal Policies section.

For more information:

- *Policies and management systems*



## Memberships and partnerships

Sanofi is committed to complying with CSR standards, and the Group is a member of the following organizations

### Organizations working in the field of CSR

#### **Global Compact**

- [www.unglobalcompact.org](http://www.unglobalcompact.org)

#### **CSR Europe**

- [www.csreurope.org](http://www.csreurope.org)

#### **CSR Asia**

- [www.csr-asia.com](http://www.csr-asia.com)

#### **CSR Middle East**

- [csrmiddleeast.org](http://csrmiddleeast.org)

#### **Entreprises pour les droits de l'homme**

#### **EPE – Entreprises pour l'Environnement**

- [www.epe-asso.org](http://www.epe-asso.org)

#### **IMS – Entreprendre pour la Cité**

- [www.imsentreprendre.com](http://www.imsentreprendre.com) (in French)

#### **ORSE (Observatoire sur la Responsabilité Sociale des Entreprises)**

- [www.orse.org](http://www.orse.org)

## **BSR (Business for Social Responsibility)**

- [www.bsr.org](http://www.bsr.org)

## **WEC (World Environmental Center)**

- [www.wec.org](http://www.wec.org)

## **Pharmaceutical industry associations**

### **International**

#### **International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)**

- [www.ifpma.org](http://www.ifpma.org) / *International Federation of Pharmaceutical Manufacturers and Associations*

#### **Influenza Vaccine Supply International Task Force (IFPMA/IVS)**

- [www.ifpma.org](http://www.ifpma.org) / *Influenza Vaccines*

### **Europe**

#### **European Federation of Pharmaceutical Industry Associations (EFPIA)**

- [www.efpia.eu](http://www.efpia.eu) / *European Federation of Pharmaceutical Industries and Association*

#### **European Vaccine Manufacturers (EVM)**

- [EVM website](#)

#### **Association British Pharmaceutical Industries (ABPI) in the UK**

- [www.abpi.org.uk](http://www.abpi.org.uk)

#### **Les Entreprises du Médicament (LEEM) in France**

- [www.leem.org](http://www.leem.org)

## **Verband Forschender Arzneimittelhersteller (VFA) in Germany**

- [www.vfa.de](http://www.vfa.de)

## **United States**

**Pharmaceutical Research-based Manufacturers Association (PhRMA) – Board Chaired by Christopher A. Viehbacher, Sanofi, Chieve Executive Officer**

- [www.phrma.org](http://www.phrma.org)

## **Biotechnology Industry Organization (BIO)**

- [www.bio.org](http://www.bio.org)

## **Japan**

**Japan Pharmaceutical Manufacturers Association (JPMA)**

- [www.jpma.or.jp](http://www.jpma.or.jp)

## **Other professional organizations in France**

**MEDEF (Mouvement des Entreprises de France)**

- [www.medef.com](http://www.medef.com)

**Association Française des Entreprises Privées(AFEP)**

- [www.code-afep-medef.com](http://www.code-afep-medef.com)

## CSR performance

## GRI



The Global Reporting Initiative (GRI) is an organization that aims to provide standardized performance indicators to be applied globally for corporate sustainability reporting of companies' economic, environmental and social performance.

Begun in 1997, the GRI is a joint initiative by the American Non-Governmental Organization CERES (Coalition for Environmentally Responsible Economies) and UNEP (United Nations Environment Program) with the mission of improving the quality, rigor and utility of sustainable development reporting.

Corporations, NGOs, consulting firms and academic institutions all participate in this international initiative. The GRI provides reporting guidelines to help interested companies to provide sustainability reporting of their economic, environmental and social initiatives.

Sanofi currently develop the G.R.I.-Index, which will be soon available on this page of the site.

## Recognition and awards

In 2011 Sanofi received numerous awards in recognition of our global CSR performance as well as our affiliates' achievements in the field of social responsibility.

In the following table, our 2011 awards are classified according to our four CSR key focus areas (Patient, Ethics, People, Planet).

- ▼ CSR Recognition
- ▼ Investor Relations Awards
- ▼ Affiliate Awards
- ▼ Awards Organized by CSR Pillars
- ▼ CSR awards highlight our affiliates' accomplishments

## CSR Recognition

- **Sanofi Achieves Dow Jones**

**Sustainability Index Listing for the Fifth Consecutive Year.** One

of Only Eight Pharmaceutical Companies - The index assesses the world's 2,500 largest companies from 57 different industry sectors, and companies are asked to report on their corporate social responsibility and sustainability performance. This year, Sanofi was one of only eight pharmaceutical companies selected from 56 applicants.



- **FTSE4Good**
- **ASPI**
- **Ethibel Excellence**

## Investor Relations Awards

- **Sanofi's Investor Relations ranked first** in France and also in the European pharmaceutical sector according to Extel 2011 Investor Relations Ranking - Christopher A. Viehbach and Jérôme Contamine come in first as “CEO” and “CFO”, respectively, for both France and the European pharmaceutical sector, and Sébastien Martel, Vice President Investor Relations, is ranked first and second, respectively, in the “IR Officer” category for both France and the European pharmaceutical sector.
- **2011 IR Magazine Award for Best Investor Relations by a French Company** - The IR Magazine Awards are the benchmark of excellence in investor relations. Analyst research is carried out year-round, and awards events are held in key global financial centers.
- **Best Investor Relations and best IR Web site** - Awarded by The 4th edition of the French Investor Relations Forum
- **Agefi awards ceremony for the Grands Prix de l'Analyse Financière** - hosted in association with the Extel Survey, the Investor Relations team took home three trophies (see second picture).

## Affiliate Awards

### Sanofi Russia

- Winner of “The Company of the Year” in the subcategory “International Pharmaceutical Manufacturer”.
- Winner of “Project of the Year” in the subcategory “Business-Project” – “Insulin Production Localization”.
- The most prestigious reward in the Russian pharmaceutical market “Platinum Ounce- 2011”. Platinum Ounce is the open competition for professionals in the pharmaceutical industry.

## Sanofi Brazil

Brazil one of the best companies to work for - For the sixth consecutive year, Sanofi is elected one of Brazil's best companies to work for by the Guide of Você S/A and Exame magazines, of Editora Abril

Named most admired pharmaceutical company in Brazil - The award, based on Fortune Magazine's "The Most Admired Companies" model, is granted to the most recognized companies in the country's main economic sectors. The aim is to better understand and celebrate the key factors that contribute to building their image and reputation, including innovation, ethics, customer care, management quality, corporate social responsibility, and commitment to society and the country as a whole.

## Sanofi Mexico

**For third year in a row, Sanofi México was recognized with the SRE (Socially Responsible Company) award presented by the Mexican Philanthropy Center** - the award which allows us to use freely the official logo created by Cemefi (The Mexican Center of Philanthropy), in order to increase and strengthen a culture of social responsibility in Mexican industries.

The criterion to give this award is based on the strategic principles of environmental care and preservation, linking the industry with the community and improving their quality of life.

## Sanofi Hungary

**Sanofi Hungary received an award on the best sustainability report in the country** - Sanofi as being member of the "Good CSR program" won the best sustainability report award.

## Sanofi Australia - New Zealand

**Sanofi ANZ recognized for their commitment to Sustainability** - The Australia New Zealand affiliate is proud to celebrate their sustainability efforts as the NSW State Government recently recognized Sanofi as a Bronze Partner of their environmental impact program for businesses.

## Sanofi United States

**Sanofi US was awarded by the Sustainable Raritan River Initiative** - Sanofi US is a member of the Sustainable Raritan River Business Roundtable. In June, the company was presented with a "Certificate of Appreciation" award for our achievement in sustainable business practices and our active support of the Sustainable Raritan River Business Roundtable.



## Sanofi Pasteur Malaysia

**ASEAN Dengue Day 2011 Celebration in Malaysia sees Sanofi Pasteur receiving special recognition by Deputy Prime Minister of Malaysia** - was accorded a token of appreciation for their contributions and ongoing commitment towards raising awareness on dengue as well as on public health in the country.

## Sanofi Hong Kong

**Sanofi Hong Kong was awarded manpower development “Grand Prize”** - Sanofi Hong Kong has recently received the “Manpower Developer 1st – Grand Prize Award” by Employee Retraining Board (ERB) in recognition of our commitment and outstanding performance in manpower training and development. Hong Kong office was the only pharmaceutical company received such honor.

In January 2012, Sanofi’s Information Systems Audit team was awarded the 2011 Hintze Prize by IFACI for its work on the “Audit of Information Systems Governance” in collaboration with two industry associations (CIGREF, AFAI). This work included among other contributions a publication of a guide “Governance of the Information System” and the online publication of a downloadable tool to help with the implementation of program to evaluate the efficiency of the Information System Governance.

## Awards Organized by CSR Pillars

| Pillar        | Topic                           | Award   | About the award   |
|---------------|---------------------------------|---|---|
| <b>Vision</b> | Risk Management                 | <i>"Risk Management Honor Roll"</i> awarded to Sanofi's, Vice President, Insurance (Françoise Carli)                                    | this distinction at the yearly ceremony hosted by the trade magazine Business Insurance   |
| <b>Vision</b> | Policies and Management Systems | Hintze Prize by IFACI (institute francias de l'audit et du controle internes) ( <i>French institute of audit and internal control</i> ) | In January 2012, Sanofi's Information Systems Audit team was awarded the 2011 Hintze Prize by IFACI for its work on the “Audit of Information Systems Governance” in collaboration with two industry associations (CIGREF, AFAI). This work included among other contributions a publication of a guide “Governance of the Information System” and the online publication of a downloadable tool to help with the |

| Pillar         | Topic                | Award  | About the award  |
|----------------|----------------------|--|--|
|                |                      |  | implementation of program to evaluate the efficiency of the Information System Governance.   |
| <b>Patient</b> | Access to Healthcare | Communiqué Awards for 'the tireless fight of Sanofi against sleeping sickness'   | The award was given in recognition of the company's work with partners including the World Health Organization (WHO) and Drugs for Neglected Diseases Initiative (DNDI) to combat sleeping sickness (Human African Trypanosomiasis), direct recognition for the outstanding work of Robert Sebbag, Benedict Blayney and the 'Access to Medicines' team.  |
| <b>Patient</b> | Access to Healthcare | Sanofi scoops Corporate Responsibility Award at Pharmaceutical Marketing Excellence Awards 2011 for second successive year | At the Pharmaceutical Marketing Excellence Awards ceremony in London late november, leading pharmaceutical company Sanofi was presented with the Corporate Responsibility Award for the second successive year. The Award recognizes pharmaceutical companies that have demonstrated an outstanding contribution to society through responsible marketing activities. Sanofi won the award for an entry entitled 'Human African Trypanosomiasis -Not neglected by Sanofi'. |
| <b>Patient</b> | Innovation           | Transatlantic Innovation Leadership Award awarded to Dr. Elias Zerhouni Receives Prestigious                               | The European Institute's prestigious Transatlantic Innovation Leadership Award on December 5. The award, which recognizes <i>"uncommon commitment to the renewal of the transatlantic relationship,"</i> was presented during the Ambassadors' Gala Dinner in Washington, D.C.   |
| <b>People</b>  | Diversity            | Turkey Medical Director (Dr. Edibe Taylan) is awarded for the Stevie Award for Women in Business                           | The Stevie Awards are among the most prestigious awards in the international business world.   |

| Pillar        | Topic                      | Award   | About the award  |
|---------------|----------------------------|---|--|
| <b>People</b> | Diversity                  | Sanofi recognized for promoting the interests of women within the workplace | Challenges magazine placed Sanofi in joint fourth position in a list of companies on the CAC 40 - the French stock market index of the 40 most valuable companies in the country for its success in furthering the interests of women. The magazine judged each company on its gender composition and highlighted the important strides forward that the Group has made in increasing the proportion of women in its most senior positions. The article notes that women now make up 45% of the Group's Managers and Engineers, 30% of its Board and 16% of its Executive Committee. |
| <b>People</b> | Workforce Development      | Sanofi Vietnam is honored to receive Grand Prix V.I.E 2011                  | For the 2nd consecutive year, V.I.E (International Corporate Volunteer Program) at Sanofi in Vietnam once again, won the Grand Prix V.I.E. The new formula for VIE (Voluntary International Enterprise), born in 2001, is increasingly successful. In Vietnam, there are now 77 VIE working in 47 companies.   |
| <b>People</b> | Local Economic Development | Sanofi Receives the 8th "French-Japanese Investment Awards"                 | for its contributions to Japan's economic development through investment in the country The French-Japanese Investment Awards launched in 2004 honor businesses which made significant contributions to the two countries' economic progress by making direct investments, and this year's Japanese Investor in France Award was given to Canon Inc., a global leader in office and business equipment.  |

## CSR awards highlight our affiliates' accomplishments

Sanofi Mexico received the Socially Responsible Company Award from the Mexican Philanthropy Center for the 3rd year in a row.

Sanofi Australia's sustainability efforts were commended with recognition as a Bronze Partner of a local environmental impact program for businesses.

Sanofi Hong Kong was awarded the Manpower Development Grand Prize for their outstanding performance in workforce training and development.

Sanofi was listed on the Dow Jones Sustainability World Index (DJSI World) for the fifth consecutive year for our CSR and sustainability performance. In 2011, the Group was one of only eight pharmaceutical companies selected from among 56 applicants.

## Methodological note

- ▼ Scope of consolidation
- ▼ Changes in scope
- ▼ Reporting guidelines
- ▼ Additional information and methodological limits

### Scope of consolidation

Social data are consolidated for all Group companies worldwide that are fully consolidated, regardless of their activity (industrial or research sites, commercial affiliates, administrative headquarters). However, while HR data for Genzyme is consolidated with Sanofi, Environment data for Genzyme is consolidated separately and Safety data for Genzyme is not consolidated with Sanofi nor separately.

At the end of 2011, health and safety data (occupational accidents and injuries) covered the same scope. Environmental data (including spending and investments) are consolidated for all industrial and research sites. Environmental impact measured as CO2 emissions from all company vehicles includes all Pharmaceutical Operations affiliates. The environmental impact of administrative headquarters locations is not included within this scope.

Social, health, safety and environmental data are wholly integrated into the scope of consolidation (full data integration).

Assets and liabilities of Merial are no longer destined to be sold, so data has been consolidated with Sanofi's as of December 31, 2011 (see D.8.1 to the consolidated financial statements, page 224 of the 2011 Document de Référence), Merial has 16 industrial sites, nine research and development sites and a number of administrative offices including its headquarters located in Lyon (France) and Duluth (Georgia, U.S.).

**For more information:** [2011 Document de Reference](#)

 [2011 Document de Reference](#) (PDF, 1826Kb)

### Changes in scope

Within the Group, changes in scope (new sites, site closings, transfers of activity) between 2010 and 2011 were analyzed according to predefined rules in order to assess Group performance on a scope that is comparable from one period to the next.

## Reporting guidelines

In order to ensure the uniformity and reliability of indicators used for all entities, the Group implemented standard reporting guidelines covering social factors as well as safety and environmental factors. These documents specify the methodologies to be used for indicator reporting for the entire Group: definitions, methodological principles, calculation formulas and emission factors. In addition, Sanofi adopted standard data collection tools:

- **Social data:** In 2011, Convergence, a single HR data platform for the entire Sanofi group was launched to facilitate managing personnel, implementing processes, and providing managers and employees with access to a wide array of HR information and tools.
- **Safety data:** The MSRS system makes it possible to collect safety data for Sanofi for the entire scope. Material data was consolidated through another tool (IRS) and then implemented in the MSRS tool.
- **Environment:** The GREEN tool enabled the consolidation of all Sanofi data contained in the report. Material sites' reporting has been transmitted to Sanofi through an excel file which has been consolidated with an extract from GREEN's data.

These tools and guidelines are updated and improved on a regular basis.

## Additional information and methodological limits

The methodological principles for certain HSE and social indicators may have limits due to:

- The absence of definitions recognized on a national and / or international level, in particular concerning the different types of employment contracts
- The necessary estimates and the representative nature of the measurements taken, or the limited availability of external data required for calculations
- The practical methods used for data collection and entry
- As a result, we make every effort to list the definitions and methodology used for the following indicators and, where appropriate, the confidence limits involved.

## Safety indicators

### **Occupational injury with lost time frequency rate <sup>(1)</sup>**

The frequency rate of occupational lost time injuries is defined as the number of accidents resulting in lost time of one day or more within a 12-month period, per million hours worked.

For non-mobile personnel, accidents occurring during the home-workplace commute are not included in this indicator. However, they are included for medical sales representatives, in accordance with the reporting rules defined by the Group.

In the event that additional accidents have not yet been recorded at the close of the financial year, or if changes in the qualification of accidents are observed after the financial year has ended, the frequency rate is subsequently corrected.

### **Motor vehicle accidents <sup>(1)</sup>**

Accidents are considered to be motor vehicle accidents if they occur when the driver is at the wheel of the vehicle (driving or parking the vehicle).

This concerns all traffic accidents occurring with vehicles owned or leased by the Group or owned by the employee if the vehicle is driven on a regular basis for professional purposes (medical sales representatives).

## Environmental Indicators

### **CO<sub>2</sub> emissions <sup>(1)</sup>**

Direct emissions are calculated on the basis of data from the Greenhouse Gas Protocol Initiative in relation to fuel emission factors. Indirect emissions resulting from other energy sources purchased off-premises and taken into account are the following:

- Emissions in connection with electricity production evaluated based on International Energy Agency (IEA) emission factors (available by country, and updated annually in the GREEN tool)
- Emissions in connection with the production of steam caused by site-specific factors.
- Those resulting from drug product transport are reported separately through the weight of CO<sub>2</sub> emitted for each pallet transported, the Truck Occupation Rate (TOR) which is the

- average number of pallets loaded in a truck compared to the theoretical maximum capacity and the Weight By Sea (WBS) which is the percentage of weight shipped by sea compared to the total weight shipped.

Emissions resulting from pharmaceutical sales fleet vehicles (medical representatives) were estimated on the basis of fuel consumption using a reporting system that distinguishes the emission factor specific to the type of fuel consumed (gasoline or diesel).

### **Percentage of renewable electricity <sup>(1)</sup>**

The percentage of renewable electricity compared to total electricity purchased is calculated using data on the source of electricity in each country where the Group operates, based on U.S. Energy Information Administration data.

### **Volatile Organic Compound emissions (VOCs) <sup>(1)</sup>**

VOCs are estimated either on the basis of mass balance or by direct measurement; the uncertainty resulting from these estimates is of the order of 10%.

### **Wastewater discharge <sup>(1)</sup>**

Data corresponds to waste after internal or external treatment. In the event of a lack of information about external treatment, a purification rate of 50% is assumed.

### **Waste <sup>(1)</sup>**

The distinction between hazardous and non-hazardous waste corresponds to that used in European regulations for European Union member countries (Decision 2000/532/EC of May 3, 2000) and that used in local regulations for other countries. It is noted that waste from remediation activities is not included in the published operational total.

### **Consolidation and internal controls**

The Corporate HR and HSE Departments are responsible for ensuring that all data are consolidated on the basis of information provided by the industrial and research sites and Group affiliates or administrative headquarters throughout the world.

When sites include more than one function, either environmental impact is attributed to the one with the greatest impact, or impact is shared among the functions. HSE coordinators for each



activity perform an initial validation of safety and environmental data prior to their consolidation. Corporate HR and HSE also verify data consistency during consolidation.

These validations include data comparisons from previous years as well as careful analysis of any significant discrepancies.

Social data regarding the workforce are compared with consolidated data in the management control database.

To ensure that site representatives have properly understood the HSE indicators, and to ensure that the data reported correspond with those requested, HSE data verification is carried out during in-house audits conducted at Group sites.

## External controls

In order to obtain an external review of our data's reliability and the thoroughness of our reporting procedures, we asked our Statutory Auditors to perform specific verification of certain CSR information and data, identified by an asterisk and available on the Group's CSR website. Since 2009, the review performed by the Statutory Auditors encompasses information concerning the implementation of the Group's CSR approach, with particular focus on the following areas: fighting corruption, responsible procurement, human rights, ethics in clinical trials, corporate governance, , pharmacovigilance, fight against counterfeit drugs, innovation, rare diseases, diversity, health and safety, workplace development, water management, and pharmaceuticals in the environment. The information covered by this work is also identified by an asterisk and may be found on the Group's CSR website.

The Statutory Auditors' review report, describing the work they performed as well as their comments and conclusions, appears on this website.

### For more information:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

Selected HSE and social data published in this CSR report were specifically reviewed by the Statutory Auditors in accordance with the relevant legislation and French professional practice to ensure that this information is consistent with the management report ("environmental data" and "social data" paragraph in the management report).

### For more information:

- [\*Social indicators\*](#)
- [\*Environmental indicators\*](#)

(1) Data available on the Sanofi Corporate Social Responsibility website.

## Statutory auditors' report



[Rapport d'examen des commissaires aux comptes](#) (PDF, 171Kb)

*This is a free translation into English of the Statutory Auditors' review report issued in French and is provided solely for the convenience of English speaking readers. The review report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.*

Review report from statutory auditors on a selection of corporate responsibility (CSR) information and data

Further to the request received and in our capacity as sanofi's statutory auditors, we have performed a review to enable us to provide limited assurance on a selection of information and data related to the fiscal year 2011 published on the Corporate Social Responsibility website (hereafter called "CSR website") of sanofi, and identified in the text by the sign "\*" (hereafter the "Information" and "the Data").

All the information and data published on the CSR website have been prepared under the supervision of the Corporate Social Responsibility Excellence Division, in accordance with the with the Group's reporting procedures applicable during 2011. These procedures are available at the Group's headquarters and summarized in the section "How data are reported: Methodological note" of the CSR website.

It is our responsibility to express conclusion on the selection of Information and Data based on our review

### Nature and scope of our review

We conducted our work in accordance with applicable auditing standards established in France by the Compagnie Nationale des Commissaires aux Comptes.

We planned and performed the procedures described below to provide limited assurance that the Information and Data are free of material misstatements. A higher level of assurance would have required more extensive procedures.

For the CSR Information covered by our procedures:

- We reviewed the content of the elements described on the CSR website in order to identify information related to the Group's accomplishments in the implementation

- of its CSR approach, in particular concerning the following areas: fighting corruption, ethics in R&D, human rights, diversity, workforce development, access to healthcare, innovation, pharmacovigilance, the fight against counterfeit drugs, health & safety,, pharmaceuticals in the environment, water management, responsible procurement and corporate governance.
- We conducted interviews with:
  - The CSR Excellence Division, which is in charge of elaborating and implementing the CSR approach
  - Individuals in operational divisions that are involved in implementing the approach such as Access to Medicines, Pharmacovigilance, R&D, Environment, Legal.
  - Individuals involved in implementing the approach in cross-functional departments such as human resources, global compliance, procurement, stakeholders relations
- We obtained supporting documentation such as internal procedures, minutes of committee meetings and other meetings, training materials, studies and survey findings that made it possible to support the selected information.

For the Data covered by our procedures:

- We assessed Group reporting procedures with regard to their consistency, relevance, reliability, objectivity and understandability.
- At Group level, we performed analytical procedures and verified, on a sample basis, the calculations and data consolidation. This work mainly relied on interviews with the members of EHS Department responsible for the preparation and application of the reporting procedures as well as for data consolidation.
- We selected a sample of seven industrial and research sites (Vitry, Marcy l'Etoile, Vertolaye, Swiftwater, Ujpest, Frankfort R&D and Frankfort Chimie) and Pharmaceutical Operations in 5 countries (USA, France, China, Italy and India).

- This selection was made on the basis of quantitative and qualitative criteria applied to the data (such as their relative contribution, geographic area and function) and on the basis of work conducted in prior years. Based on interviews with the individuals responsible for data preparation and reporting at the selected sites and units, we verified the proper understanding and application of procedures and carried out detailed tests to verify the calculations made and reconcile the data with the substantiating documents.

The contribution of these entities to the Group's consolidated total is:

- 33% of Volatile Organic Compound (VOC) emissions
- 41% of Nitrogen Oxide emissions (NO<sub>x</sub>) and 16% of Sulfur Oxide emissions (SO<sub>x</sub>),
- 30% of direct CO<sub>2</sub> emissions and 25% of indirect CO<sub>2</sub> emissions from energy,
- 26 % of total hazardous waste produced,
- 44% of total water used,
- 24% of hours worked as of December 31, 2011 and 33% of lost time injuries (to calculate the lost-time injury frequency rate).

#### Information on procedures

The Group presented detailed information on the methodologies used for reporting Information and Data in the section entitled "How data are reported: Methodological note" and in the comments on the published information and data. Methodological limits inherent to the reporting of certain indicators have been therefore disclosed.

#### Conclusions

Based on our review, no material misstatement has come to our attention that causes us to believe that:

- The selected Information is not consistent with the collected substantiating documents;
- The selected Data have not been prepared, in all material respects, in accordance with the Group's reporting procedures applicable during the 2011 fiscal year.

Neuilly-sur-Seine (France), April 23 2012

The Statutory Auditors

PricewaterhouseCoopers Audit ERNST & YOUNG Audit

Xavier Cauchois

Partner

Statutory Auditor

Jacques Pierres

Partner

Statutory Auditor

Thierry Raes

Partner

Sustainability Department

Eric Duvaud

Partner

Sustainability Department

Note concerning the publication of information on the internet

The maintenance and integrity of the information contained on this Corporate Social Responsibility website are the responsibility of sanofi; the reviews performed by the Statutory Auditors to provide limited assurance on the Information and Data did not involve a review of these matters. Our assurance statement only concerns a selection of Information and Data related to fiscal year 2011 as available on the date our report was issued. Our procedures did not include any review of information that was updated after the original date of publication of this information

## Social indicators

- ▼ Workforce data
- ▼ Workforce distribution
- ▼ Consolidated frequency rate for accidents by function
- ▼ Occupational diseases reported in 2011

### Workforce data

|                       | Definition                                       | Unit of measure   | 2008   | 2009    | 2010    | 2011           | Variation<br>2010/2011 |
|-----------------------|--|---|--------|---------|---------|----------------|------------------------|
| Total workforce       | Workforce as of December 31                      | Total number of permanent contract (PC) and fixed-term contract (FTC) employees | 98,213 | 104,867 | 101,575 | <b>113,860</b> | +12.10%                |
| PC workforce          | Group employees with a permanent contract (PC)   | Total number of PC employees  | 94,448 | 97,736  | 94,385  | <b>105,612</b> | +11.90%                |
| FTC workforce         | Group employees with a fixed-term contract (FTC) | Total number of FTC employees   | 3,765  | 7,131   | 7,190   | <b>8,248</b>   | +14.70%                |
|                       |  | % of PC employees in total workforce  | 4.00%  | 7.30%   | 7.10%   | <b>7.20%</b>   | +1.40%                 |
| Workforce by category | Group employees                                  | % of executives   | 24.30% | 23.70%  | 23.50%  | <b>23.70%</b>  | +0.80%                 |

|                                  | Definition                               | Unit of measure  | 2008   | 2009   | 2010   | 2011          | Variation<br>2010/2011 |
|----------------------------------|--|--|--------|--------|--------|---------------|------------------------|
|                                  | by job<br>category                       | in total<br>workforce  |        |        |        |               |                        |
|                                  |  | % of of<br>Sales Reps.<br>employees<br>in total<br>workforce     | 32.70% | 31.30% | 29.90% | <b>26.40%</b> | -11.70%                |
|                                  |  | % of others<br>in total<br>workforce                             | 43.00% | 45.00% | 46.60% | <b>49.80%</b> | +6.80%                 |
| Workforce<br>by gender           | Male and<br>female<br>Group<br>employees | Number of<br>women   | 45,856 | 48,825 | 46,988 | <b>52,033</b> | +10.70%                |
|                                  |  | Number of<br>men   | 52,357 | 56,042 | 54,578 | <b>61,827</b> | +13.30%                |
| Gender<br>equity                 | % of total<br>workforce                  | % of<br>women  | 46.70% | 46.60% | 46.30% | <b>45.70%</b> | -2.00%                 |
|                                  |  | % of men   | 53.30% | 53.40% | 53.70% | <b>54.30%</b> | +1.10%                 |
| Use of<br>temporary<br>employees |  | Number of<br>temporary<br>employees<br>(full-time<br>equivalent) | 5,090  | 6,419  | 5,653  | <b>5,736</b>  | +1.40%                 |
|                                  |  | %<br>compared<br>with PC<br>workforce                            | 5.40%  | 6.60%  | 6.00%  | <b>5.40%</b>  | -1.00%                 |
| Recruitment                      | Hired on<br>permanent<br>contracts       | Number of<br>employees<br>hired on PC                            | 8,120  | 5,622  | 8,924  | <b>4,611</b>  | -48.30%                |
|                                  | Hired on<br>fixed-term<br>contracts      | Number of<br>employees<br>hired on<br>FTC                        | 3,152  | 4,483  | 5,479  | <b>4,048</b>  | -26.10%                |

|                   | Definition                                  | Unit of measure            | 2008                 | 2009                  | 2010                  | 2011                                    | Variation<br>2010/2011 |
|-------------------|---|----------------------------|----------------------|-----------------------|-----------------------|---|------------------------|
| Departures        | Group departures PC                         | Number of PC terminations  | 9,235                | 8,594                 | 11,357                | <b>11,354</b>                           | 0.00%                  |
|                   | Group departures FTC                        | Number of FTC terminations | 2,410                | 3,073                 | 5,087                 | <b>3,181</b>                            | -37.50%                |
| Dismissal         | Dismissals for personal or economic reasons | Total number of dismissals | 2,205                | 3,127                 | 6,040                 | <b>3,181</b>                            | -44.24%                |
| Average age       | Average age of PC employees                 | Number of years            | 40 years<br>9 months | 40 years<br>9 months  | 41 years<br>10 months | <b>40 years</b><br><br><b>4 months</b>  | –                      |
| Average seniority | Average seniority of PC employees           | Number of years            | 10 years<br>0 month  | 10 years<br>10 months | 11 years<br>11 months | <b>10 years</b><br><br><b>10 months</b> | –                      |
| Working hours     | Mean theoretical number of hours worked per | Number of hours            | 1,562                | 1,554                 | 1,568                 | <b>1,554</b>                            | –                      |

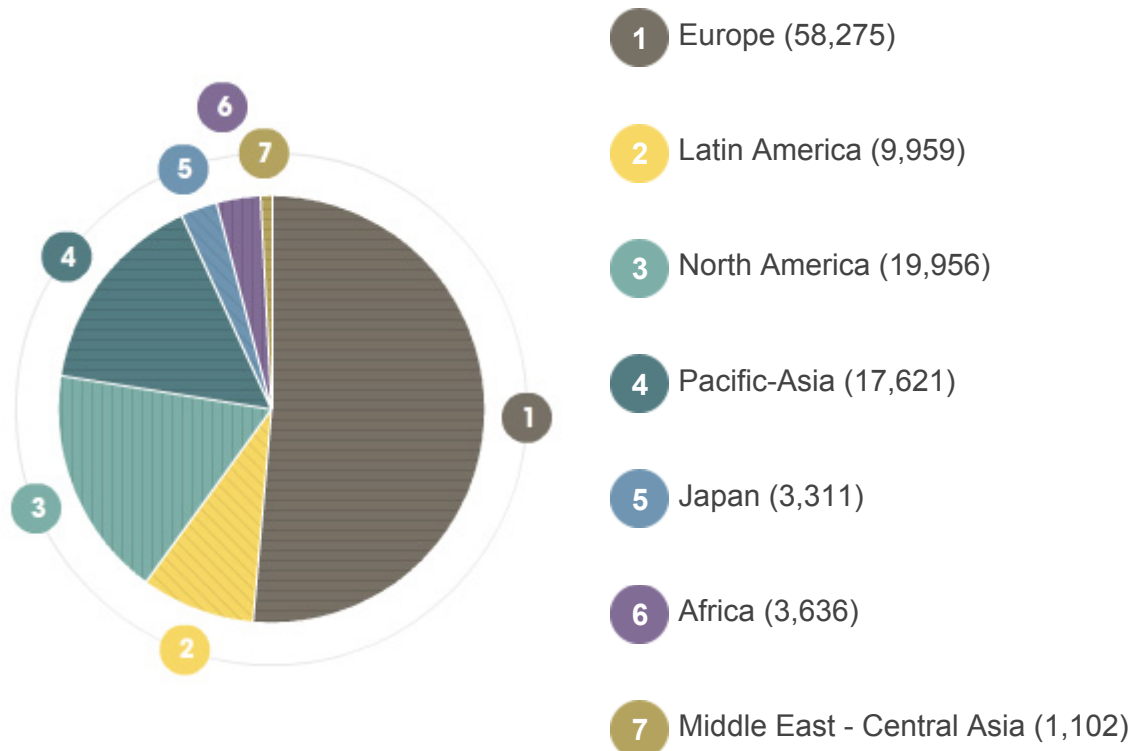


|                          | Definition   | Unit of measure                                    | 2008    | 2009    | 2010    | 2011           | Variation<br>2010/2011 |
|--------------------------|--|--|---------|---------|---------|----------------|------------------------|
|                          | year in<br>France  |  |         |         |         |                |                        |
| Hours of<br>training (1) | Mean time<br>spent in<br>training for<br>employees<br>participating<br>in at least<br>one training<br>course         | Average<br>number of<br>hours spent<br>in training | 27      | 30      | 29      | <b>29.5</b>    | –                      |
| Absenteeism              | Days of<br>absence<br>due to<br>sickness.<br>occupational<br>or<br>commuting<br>accidents,<br>maternity<br>and other | Number of<br>days absent<br>in France              | 288,205 | 316,579 | 314,594 | <b>337,423</b> | +16.80%                |

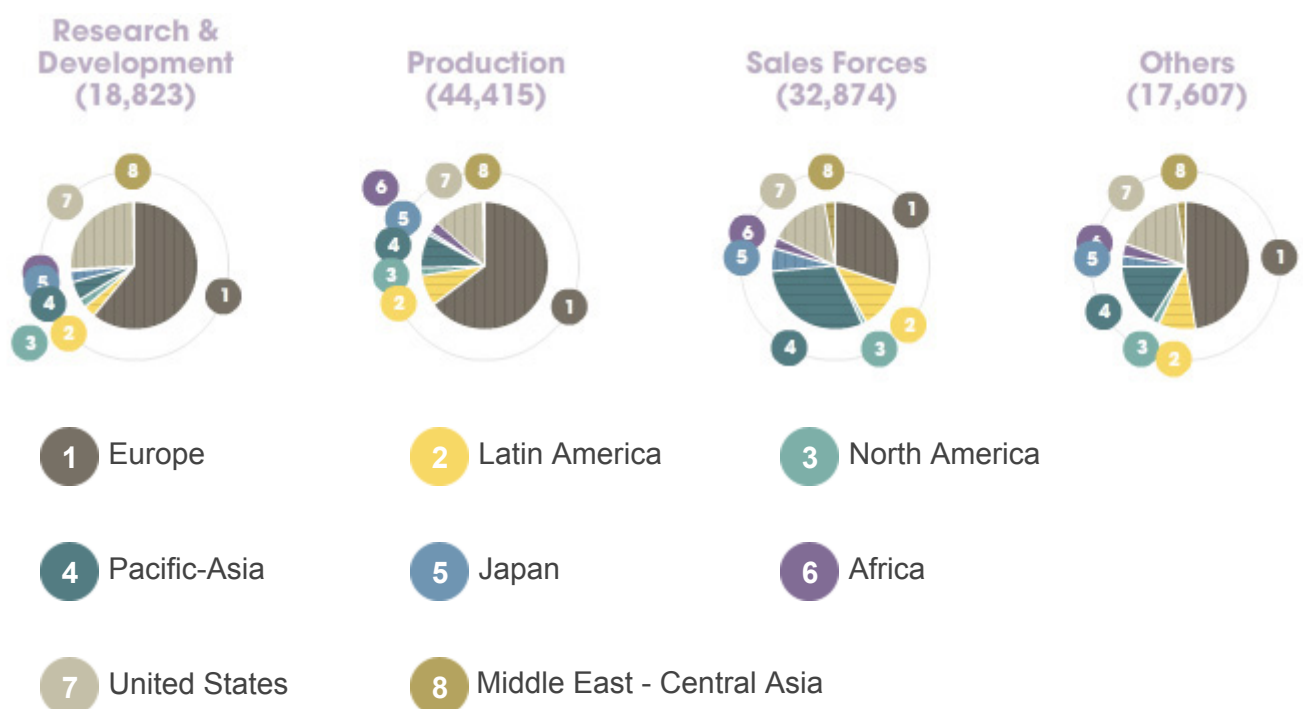
(1) Includes all data for employees receiving training during the year, including those who were no longer with the Group as of December 31, 2011.

## Workforce distribution

Distribution of workforce worldwide as of December 31, 2011

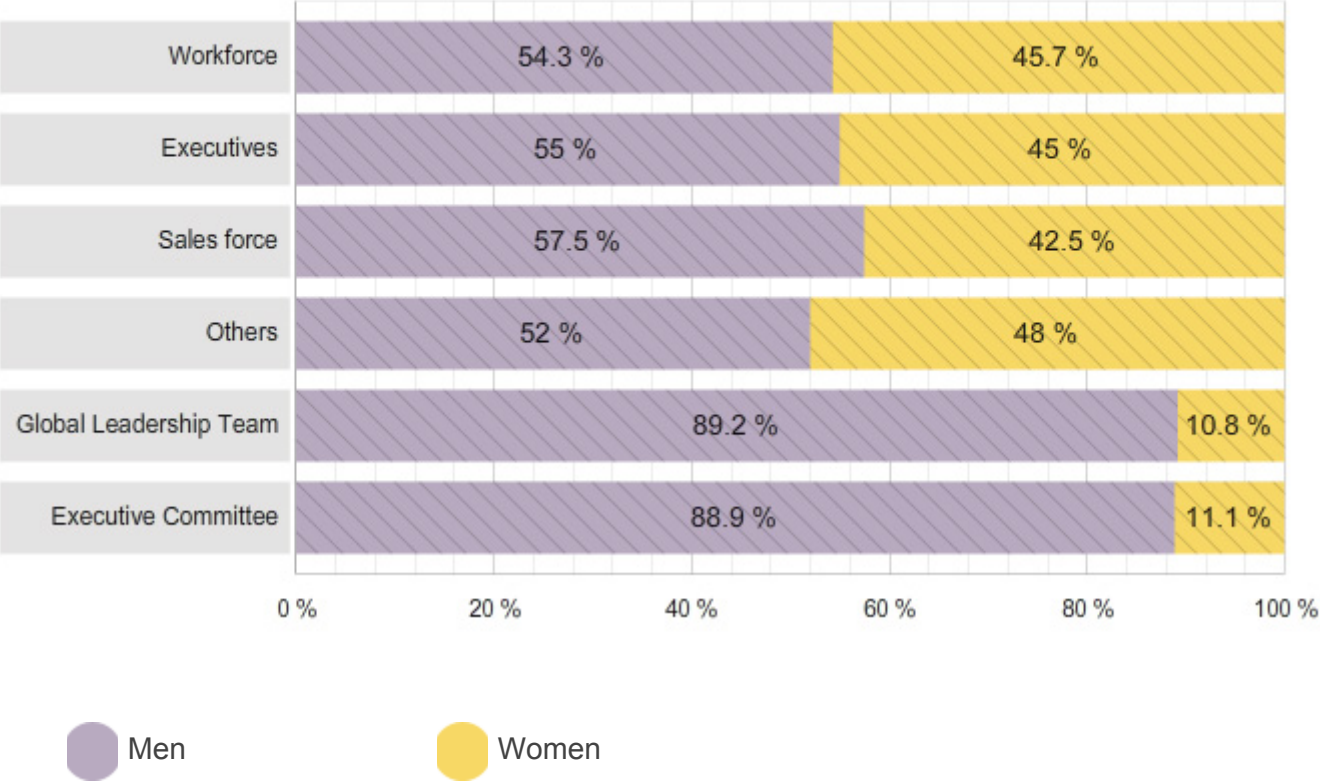


Workforce by function and region (number of employees) as of December 31, 2011



Percentage of women at various levels of the organization

(in %)



## Consolidated frequency rate for accidents by function

### Consolidated lost time injury frequency rate by function (2011)

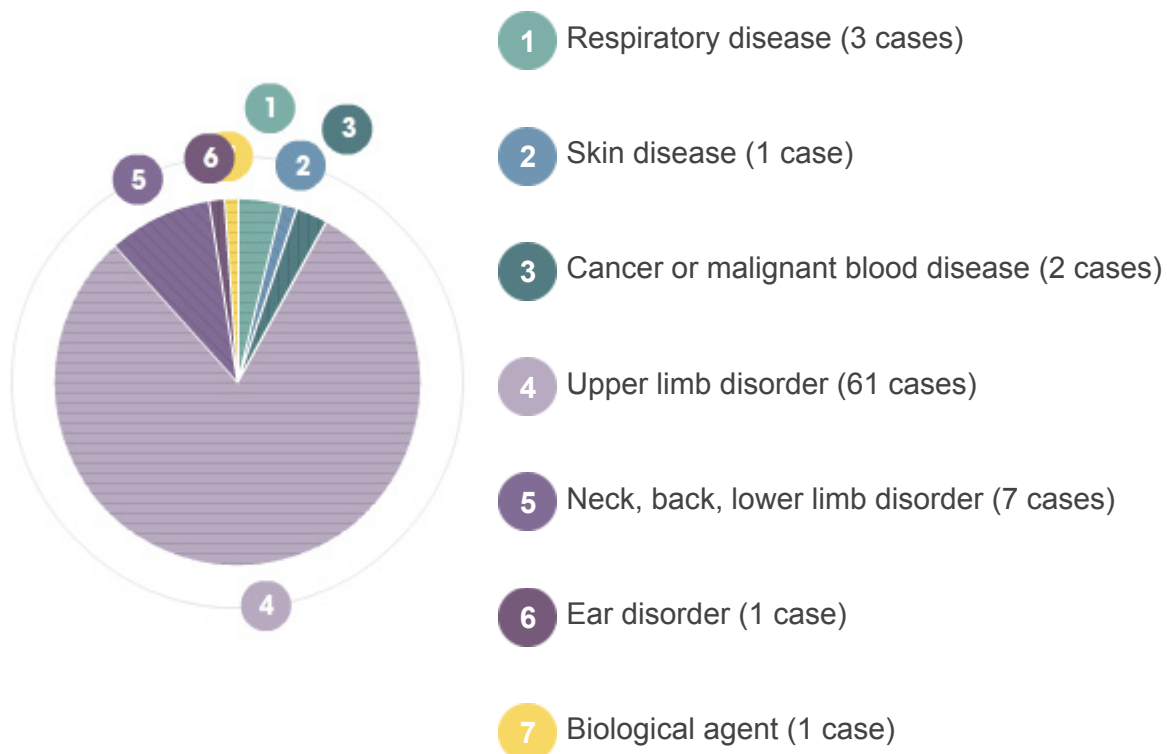
| <b>LOST TIME INJURY FREQUENCY RATE (1)</b>                 |            |            |                   |            |            |             |                        |
|--|------------|------------|-------------------|------------|------------|-------------|------------------------|
|  | 2006       | 2007       | 2008              | 2009       | 2010       | 2011        | Variation<br>2006/2011 |
| Research and Development                                   | 2.0        | 1.9        | 1.7<br>(2)        | 2.0<br>(2) | 1.5<br>(2) | <b>0.9</b>  | -55%                   |
| Industrial Affairs   | 2.5        | 2.3        | 3.0<br>(2)        | 2.0        | 2.1        | <b>1.7</b>  | -32%                   |
| Commercial Pharmaceutical<br>Operations (including Merial) | 3.7        | 3.4        | 2.9               | 2.6        | 2.1        | <b>2.2</b>  | -41%                   |
| Vaccines   | 1.6        | 1.5        | 2.0               | 1.1        | 2.3        | <b>1.2</b>  | -25%                   |
| Support Functions  | 1.2        | 0.9        | 1.5<br>(2)        | 1.4        | 1.9<br>(2) | <b>1.7</b>  | +42%                   |
| Sanofi total   | <b>2.9</b> | <b>2.6</b> | <b>2.6</b><br>(2) | <b>2.2</b> | <b>2.1</b> | <b>1.8*</b> | <b>-38%</b>            |
| Temporary employees  | 2.0        | 2.1<br>(2) | 2.3<br>(2)        | 1.0<br>(2) | 2.3<br>(2) | <b>2.2</b>  | +10%                   |

(1) Number of occupational related lost time injuries per one million hours worked. These data are consolidated for all Group companies.

(2) Previous years frequency rates were adjusted in 2011 based on: eliminating injuries dismissed by regulatory authorities, including injuries reported late, changes in reporting scope.

## Occupational diseases reported in 2011

Sanofi employees (worldwide)



### Cause of the disease

- **Chemical agent (6 cases ; 8%):**

1 Respiratory disease (3 cases) - 2 Skin disease (1 case) - 3 Cancer or malignant blood disease (2 cases)

Other illnesses caused by chemical agents (0 case)

- **Physical agent (69 cases ; 91%):**

4 Upper limb disorder (61 cases) - 5 Neck, back, lower limb disorder (7 cases) - 6 Ear disorder (1 case)

Other Diseases caused by a physical agent (0 case)

- **Biological agent (1 case ; 1%):**

7 Disease caused by a biological agent (1 case)

\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)

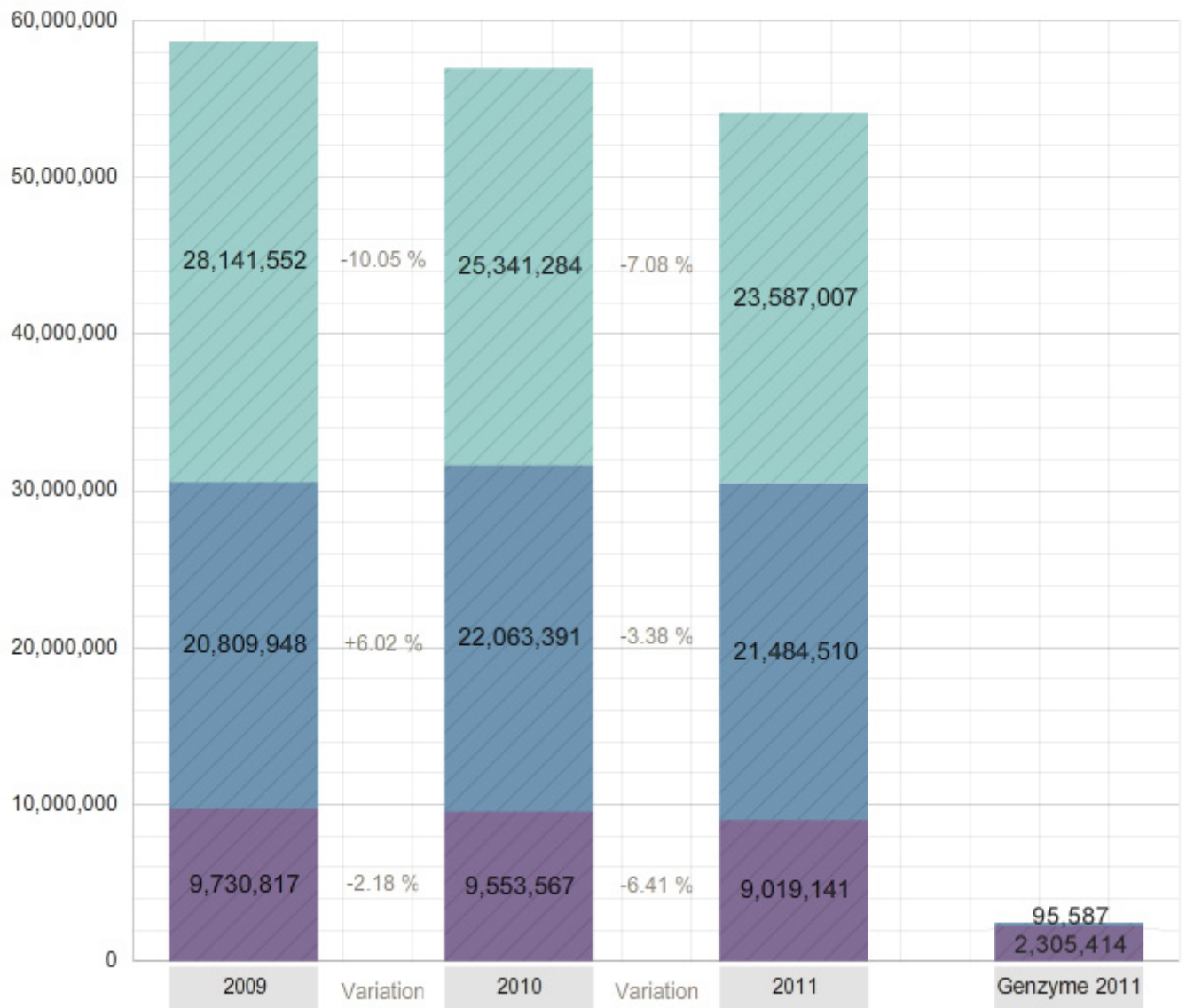
## Environmental indicators

- ▼ Water consumption
- ▼ Wastewater discharge
- ▼ Energy consumption
- ▼ CO<sub>2</sub> emissions
- ▼ Solvent consumption
- ▼ VOC emissions
- ▼ SO<sub>x</sub> emission
- ▼ NO<sub>x</sub> emission
- ▼ Waste
- ▼ Ozone-depleting substances
- ▼ Biodiversity
- ▼ Other environmental indicators

## Water consumption

(In m3)

Total water: 58,682,317 -3.06 % 56,958,242 -6.97 % 54,090,658 \* 2,401,001



Surface water



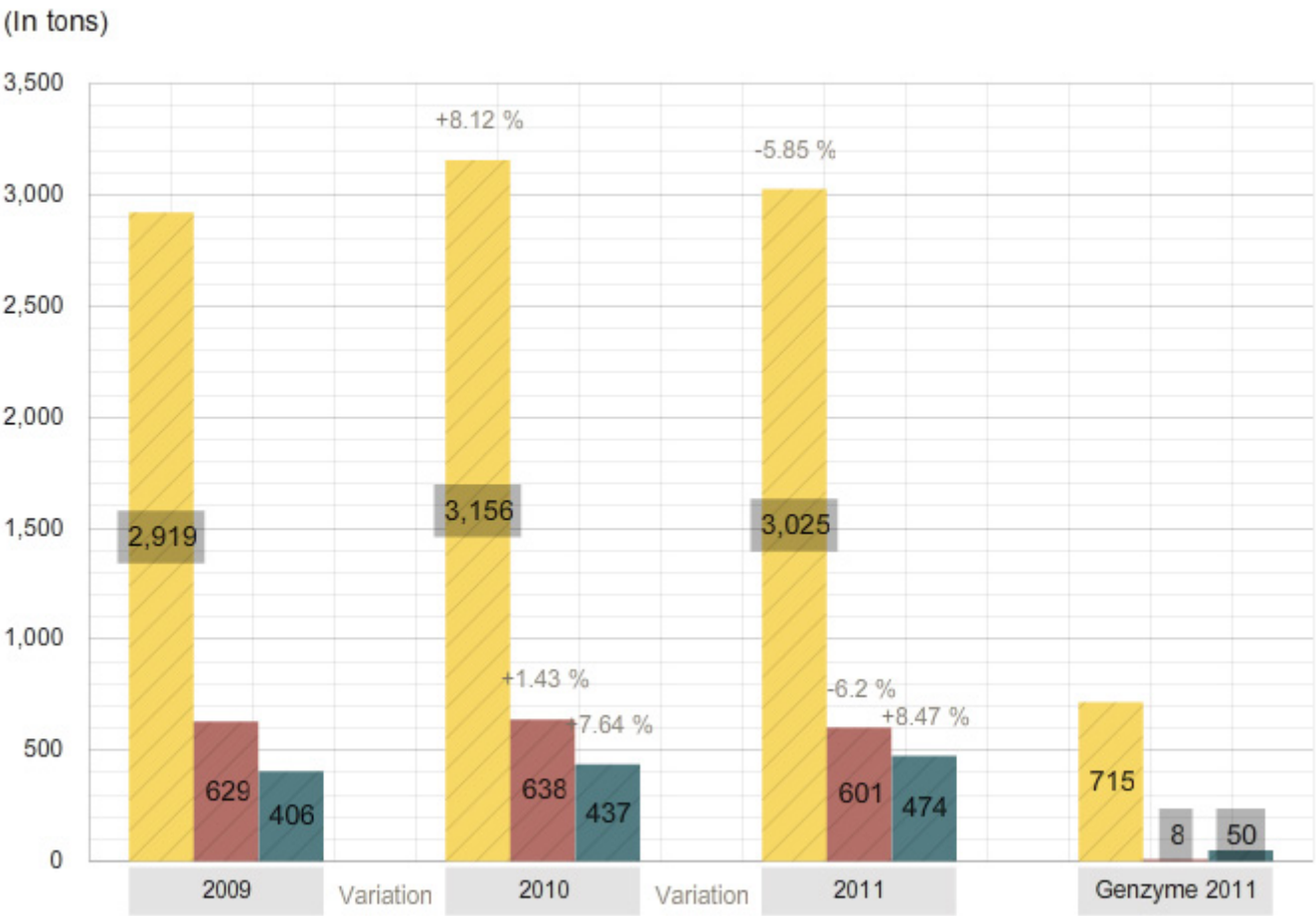
Well water



City water



# Wastewater discharge



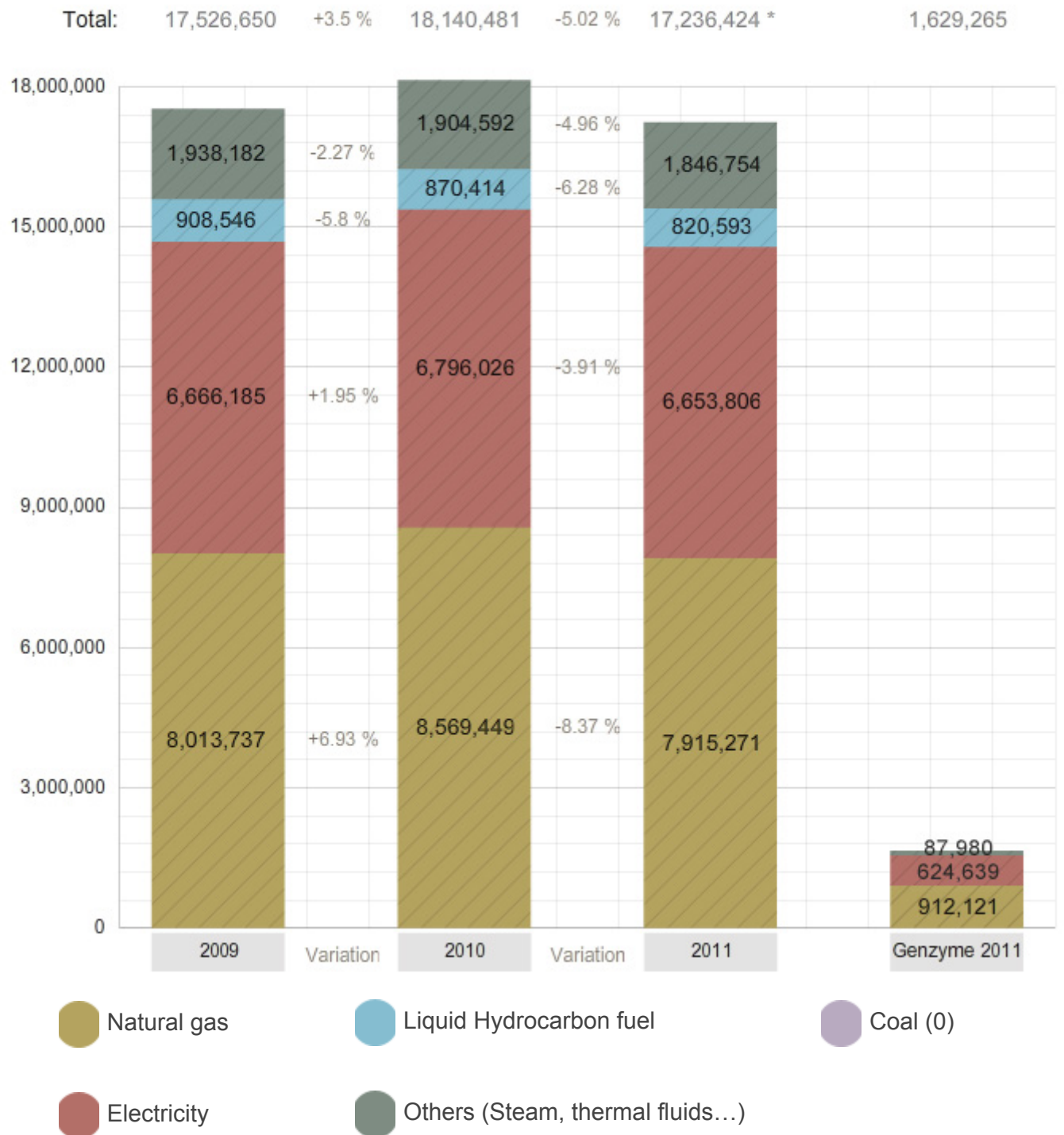
COD (Chemical Oxygen Demand)

TSS (Total Suspended Solids)

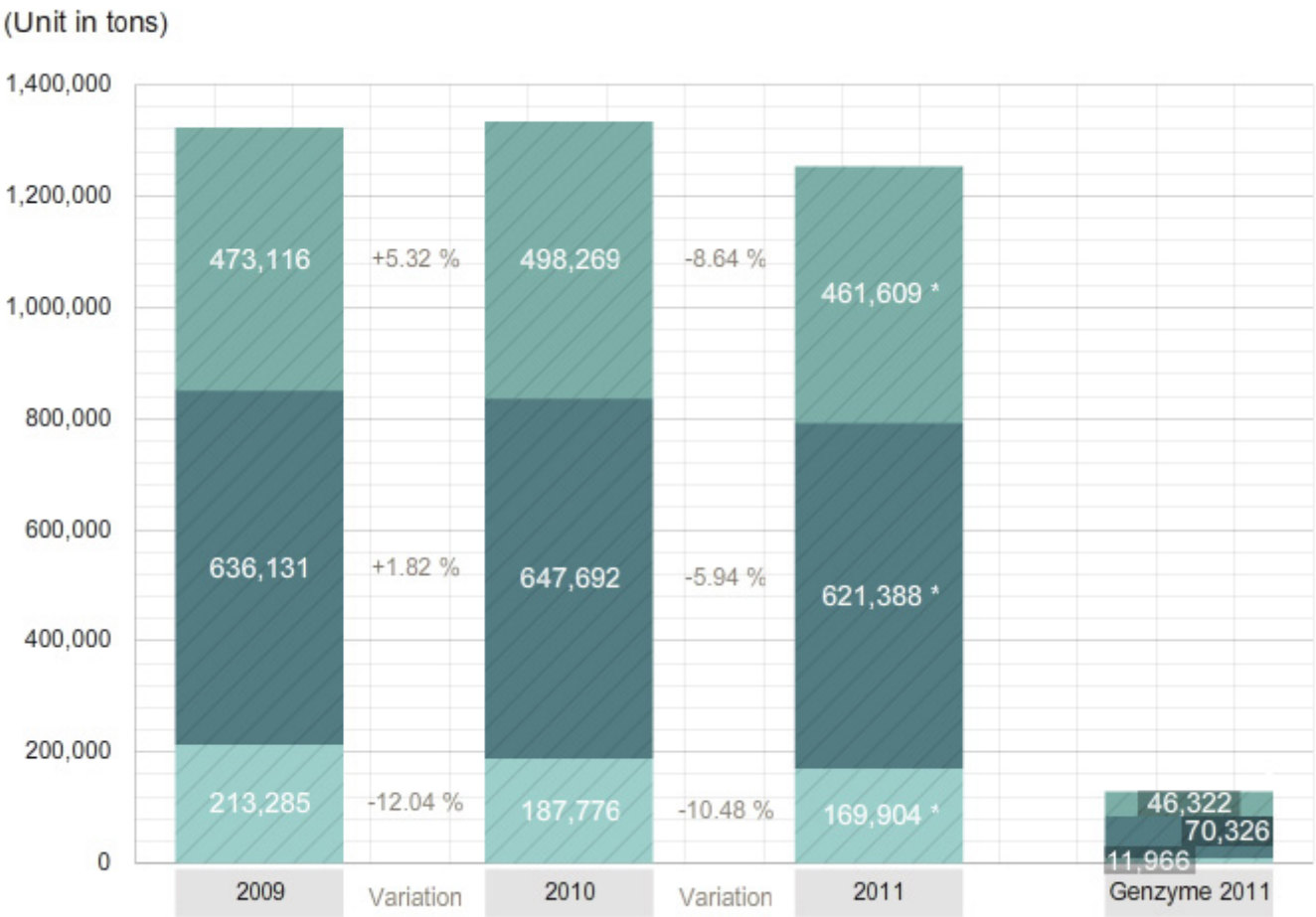
Nitrogen

## Energy consumption

(Unit Gigajoules)



CO<sub>2</sub> emissions

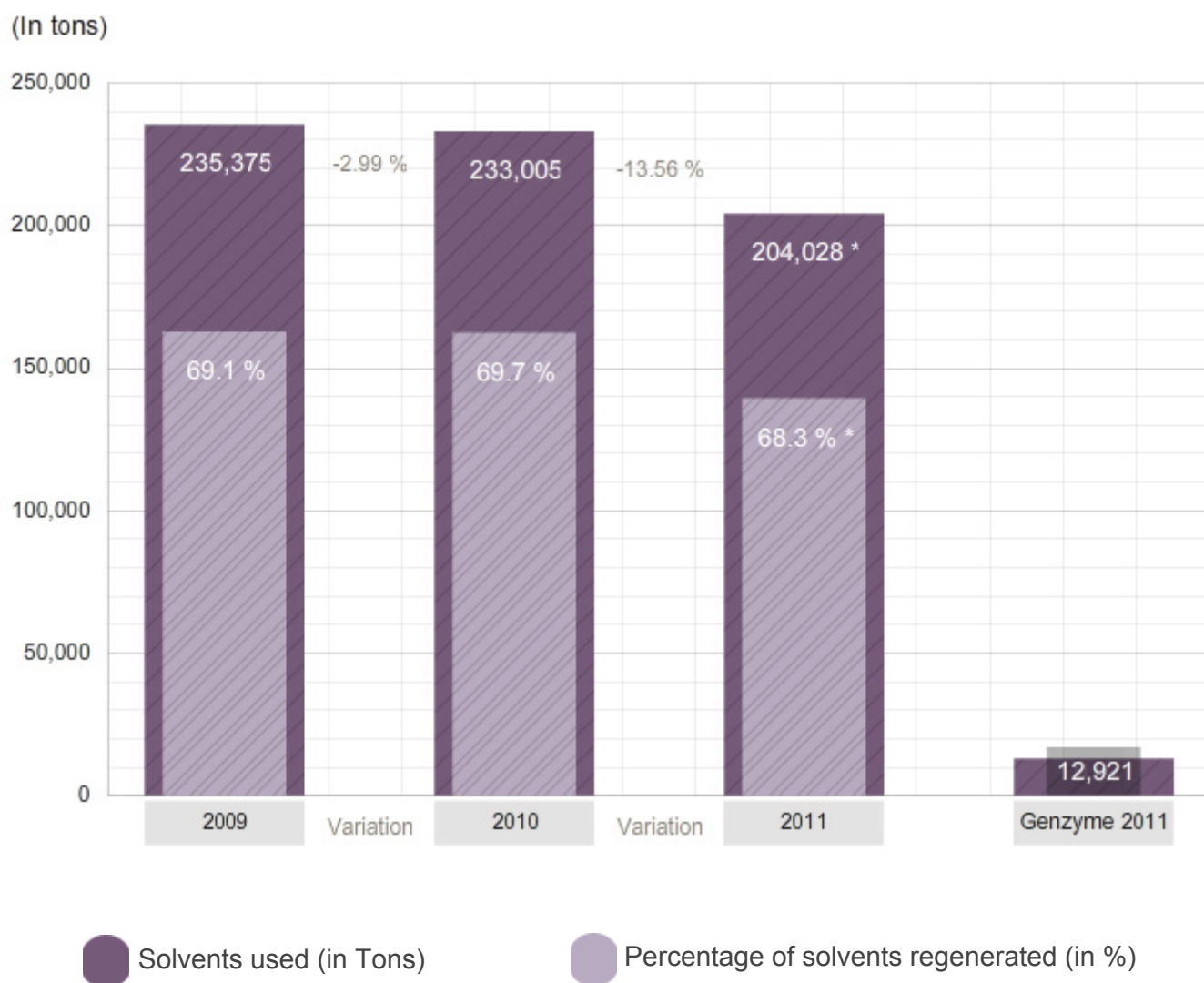


- Fossil fuel (direct CO<sub>2</sub>)
- Production of electricity and steam (indirect CO<sub>2</sub>)
- Medical sales fleet vehicles (estimated)

## Other CO<sub>2</sub> emission indicators

- 2005-2011 Variation in CO<sub>2</sub> emissions per unit produced: **-9.5%** for direct CO<sub>2</sub> emissions and **-15.6%** for indirect CO<sub>2</sub> emissions.
- 2005-2011 Variation in CO<sub>2</sub> emissions per km traveled (emissions generated by medical sales vehicles): **-20%**.
- 2011-2010 Variation in CO<sub>2</sub> emissions (per kg of CO<sub>2</sub>/pallet) generated by product transport between sites in Europe (road transport): **+0.01%**.
- 2011-2010 Variation in CO<sub>2</sub> emissions (per kg/pallet) generated by intercontinental product transport between sites (by air or by sea): **+33%**.

## Solvent consumption

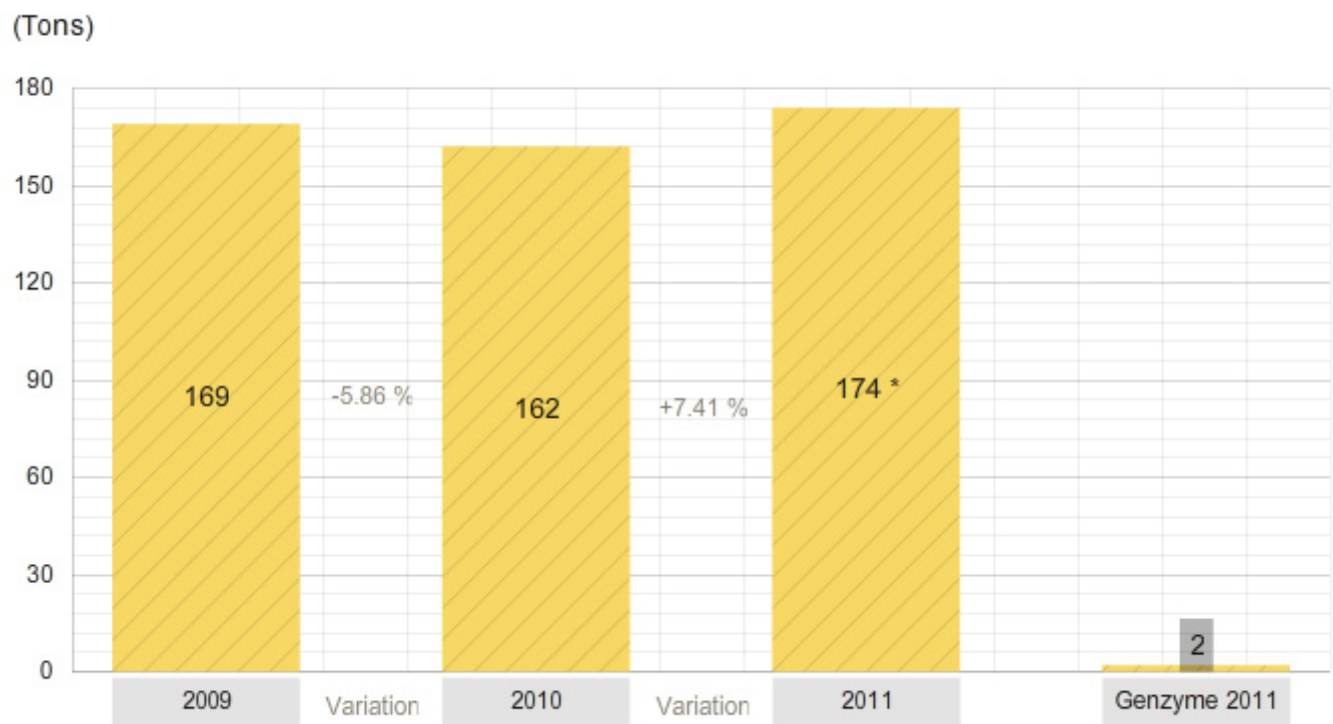


VOC emissions



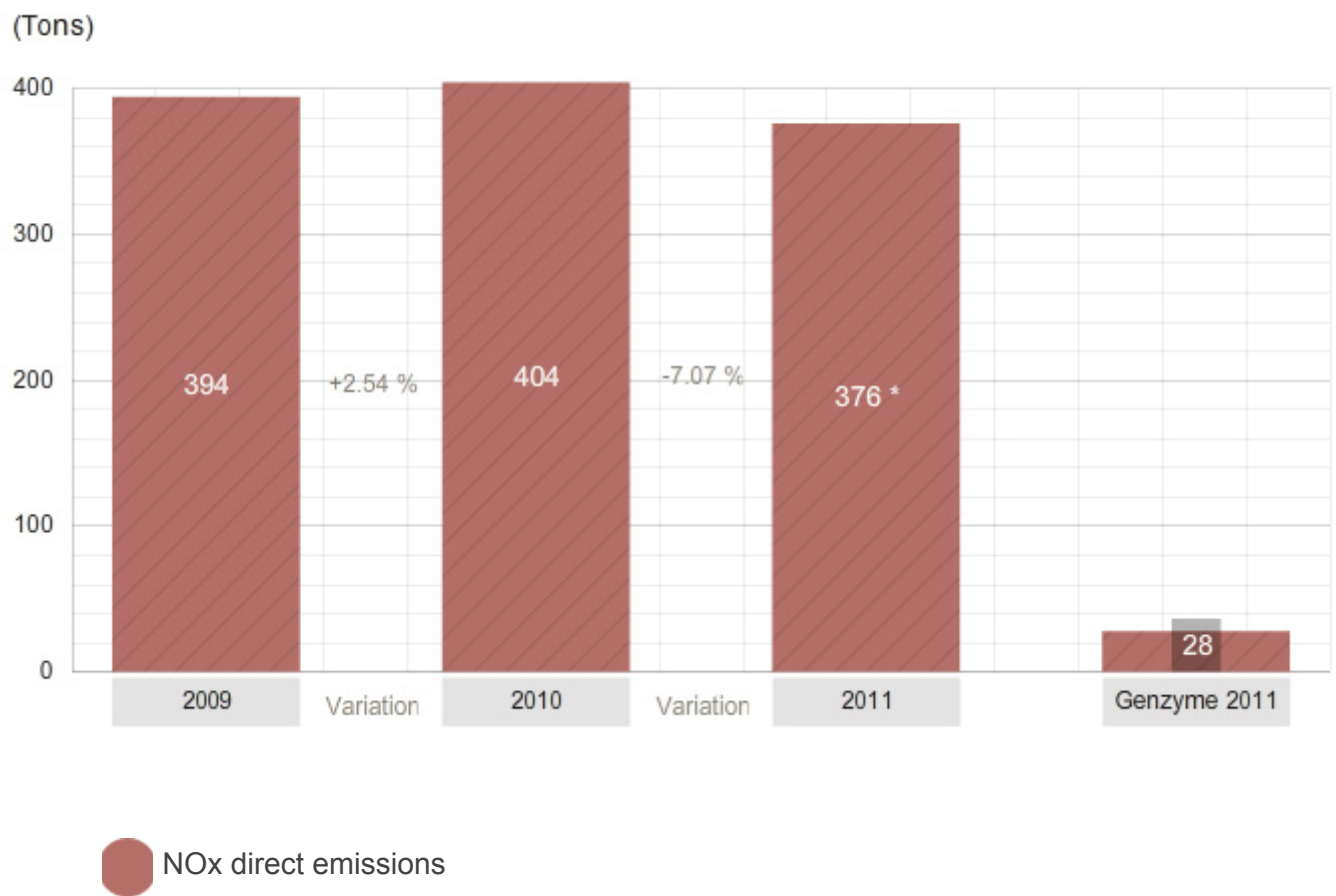
VOC

SOx emission



SOx direct emissions

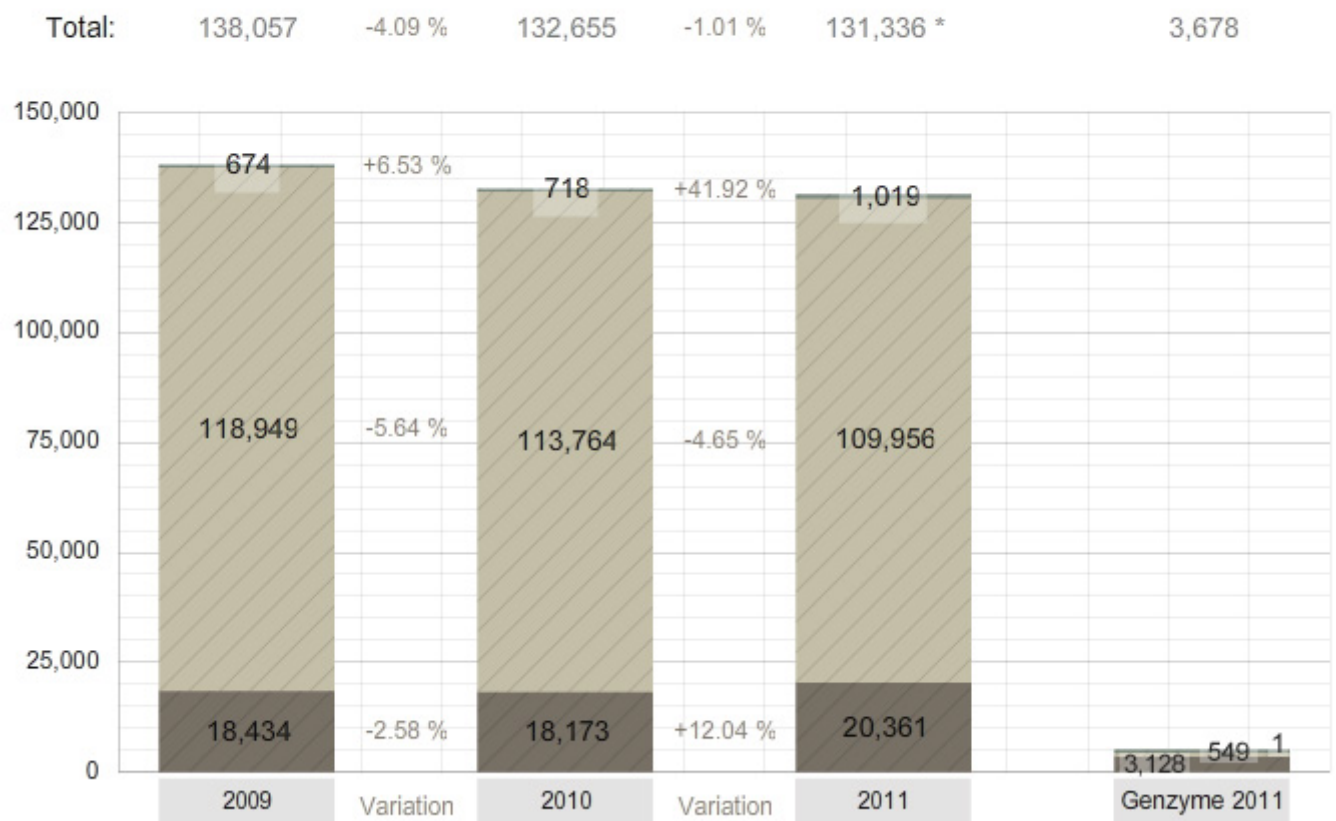
NOx emission



## Waste

### Hazardous waste

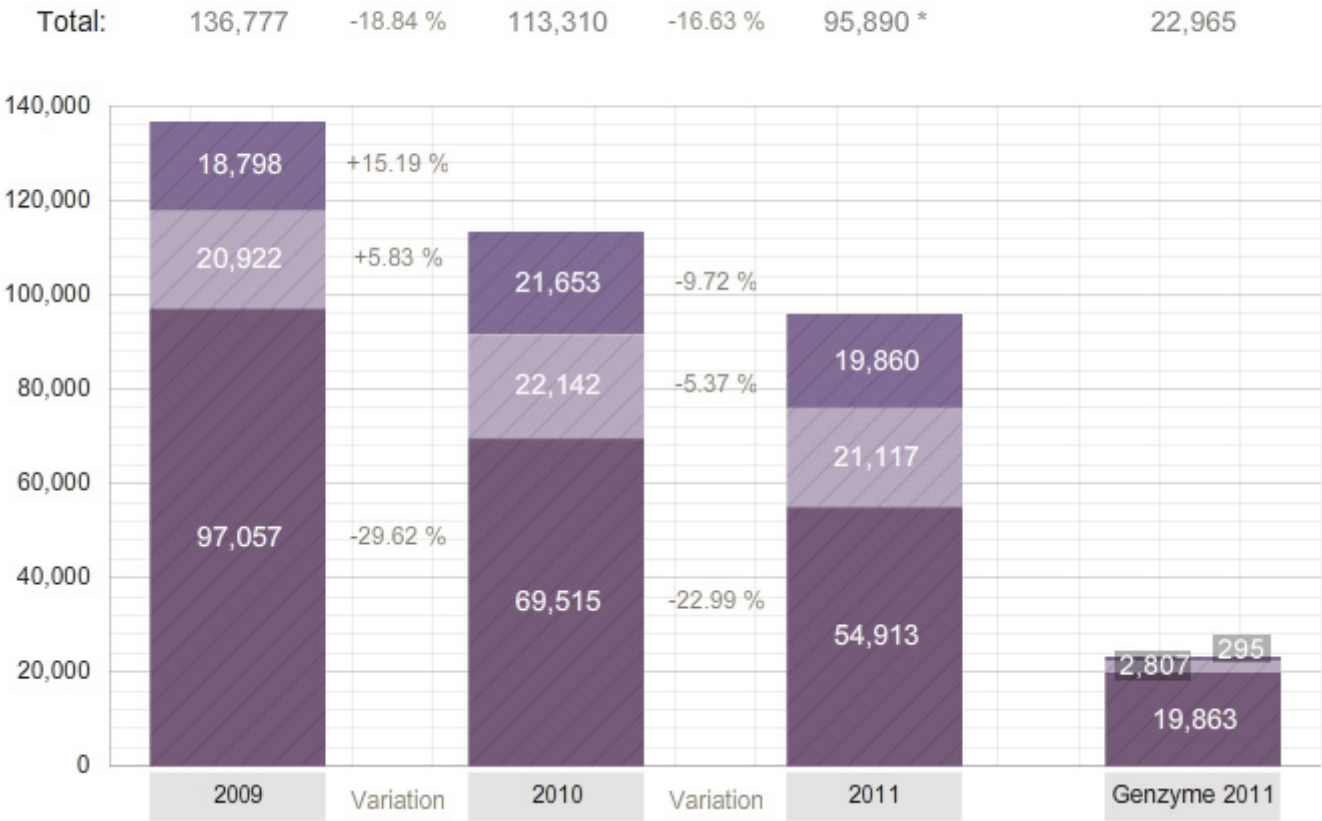
(Tons)





Non-hazardous waste

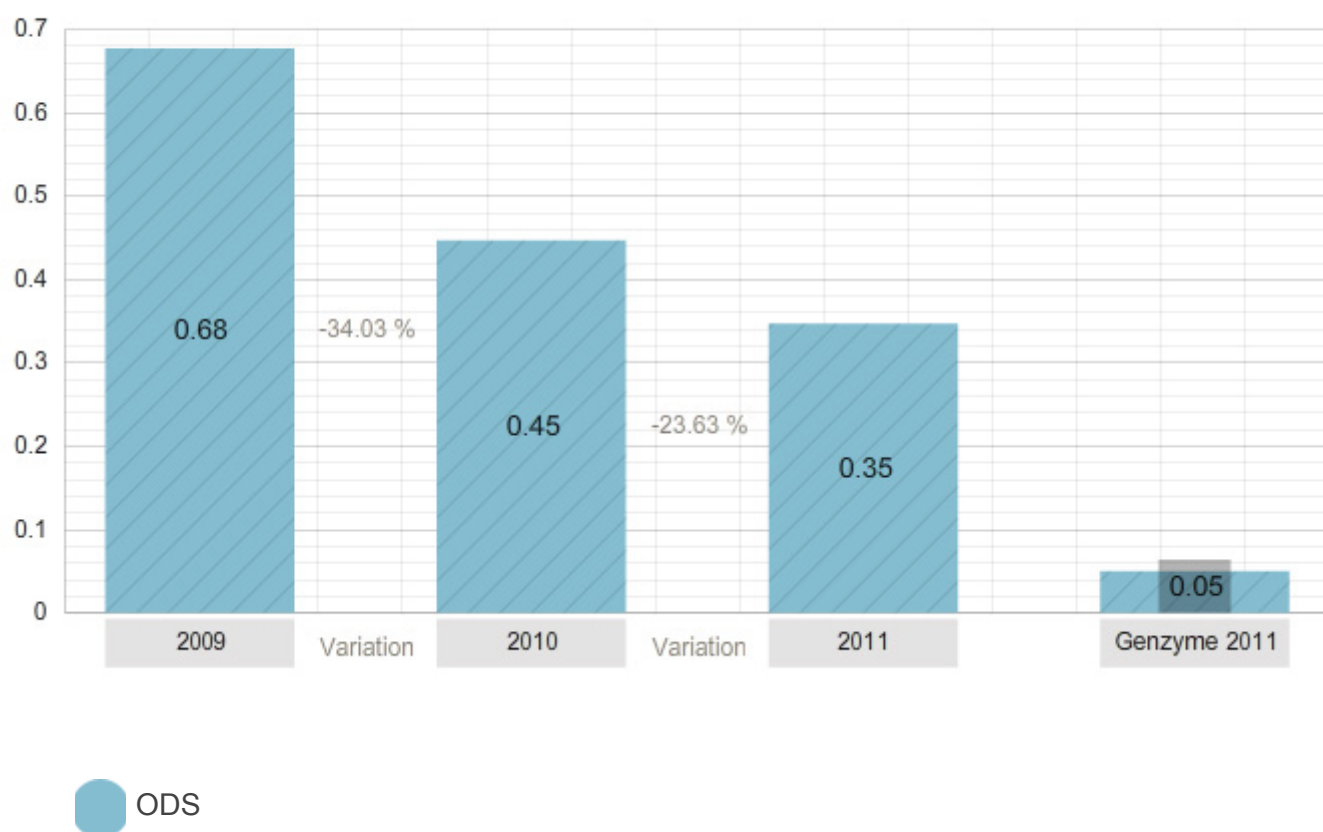
(Tons)



- Non-hazardous waste recycled
- Non-hazardous waste incinerated
- Non-hazardous waste landfilled

## Ozone-depleting substances

(In CFC-11 equivalent Tons)



## Biodiversity

- Number of natural plant substances studied by the Group between 2003 and 2010: **647**.
- Number of plants on which the Group conducted research between 2003 and 2010: **152**.
- Percentage of plants held by the Group appearing on the IUCN (International Union for Conservation of Nature) Red List of Threatened Species™: **1.3%**.

## Other environmental indicators

- In 2011, proportion of hybrid vehicle in the Group's vehicle fleet: **5%**.
- 2010-2011 variation in weight of products transported by sea (intercontinental): **-7.2%**.

\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)

## Other indicators

### Patient's indicators

- [Access to healthcare](#)
- [Supporting patients](#)
- [Product quality and safety](#)
- [The fight against counterfeit drugs](#)

### Ethics indicators

- [Ethics in clinical trials](#)
- [Use of laboratory animals for research](#)
- [Corporate governance](#)
- [Institutional relations](#)
- [Responsible marketing](#)
- [Fighting corruption](#)
- [Responsible procurement](#)

# PATIENT

## Patient Indicators

- Access to healthcare
- Supporting patients
- Innovation for patients
- Product risk management

## Access to healthcare

Ensuring healthcare for all is one of the most pressing challenges facing societies today. For a diversified healthcare partner like Sanofi, enabling individuals to assert their right to health means facilitating access to quality medicines and vaccines to benefit as many patients as possible.

## The Group's commitment



## Background

- ▼ A challenge for society
- ▼ Stakeholders' expectations

### A challenge for society

Making sure that primary healthcare systems are accessible to those who need them most represents a fundamental challenge facing societies today. Such access may be defined as the opportunity or ease with which people are able to use appropriate services in proportion to their needs.

Access to healthcare is a complex issue that the pharmaceutical industry cannot tackle alone. Good health is in fact often a direct correlate of many different factors, including access to essential services such as clean water and access to education.

Other factors include social and economic conditions, as well as the health policies in a given region. Access to healthcare varies across countries and among groups and individuals. According to the World Health Organization (WHO), a well-functioning healthcare system requires a robust financing mechanism; a well-trained and adequately-paid workforce; reliable information on which to base decisions and policies; and well maintained facilities and logistics to deliver quality medicines and technologies.

From our perspective as a global healthcare leader, Sanofi considers that access to healthcare is not only a matter of the patient having access to affordable medicines and vaccines, but of having the opportunity to receive comprehensive therapeutic care – from diagnosis to treatment.

One-third of the global population does not have access to essential medicines and vaccines. Why?

- In most situations, inadequate distribution channels, a lack of healthcare personnel, insufficient diagnostics, and a general lack of public health infrastructure are the primary reasons. The role that the pharmaceutical industry can play in such situations is often limited to long-term development aid programs, campaigns to raise awareness, and training for healthcare professionals.

- When access to healthcare is limited due to the cost of treatment or the lack of appropriate treatments, then pharmaceutical companies can be more directly involved.

### Stakeholders' expectations

The implicit demands made on pharmaceutical companies by civil society are growing today. A number of developing countries have become emerging markets: Life expectancy in these countries has grown longer and lifestyles have changed. Patients in developing countries are increasingly affected by the same diseases found in industrialized countries, yet often healthcare systems and coverage do not meet the same standards as in developed countries.

As a result, the pharmaceutical industry faces several challenges:

- Develop less expensive treatments and modes of administration that are more closely adapted to developing and emerging markets
- Reduce the prices of medicines locally
- Support the commercialization of generics, including by having a company manufacture generic versions of its own products
- Increase access to diagnostics
- Contribute to innovative strategies and programs that improve health outcomes beyond access to medicines, especially when it comes to chronic and non-communicable diseases (cancer, diabetes, mental illness, etc.)
- Integrate the United Nations Millennium Development Goals

While continuing to develop a sustainable business model that includes major R&D investments.

**For more information** about stakeholders' expectations concerning access to healthcare:

**Médecins Sans Frontières (MSF) “Campaign for access to essential medicines” website:**

- [www.accessmed-msf.org](http://www.accessmed-msf.org)

**WHO website:**

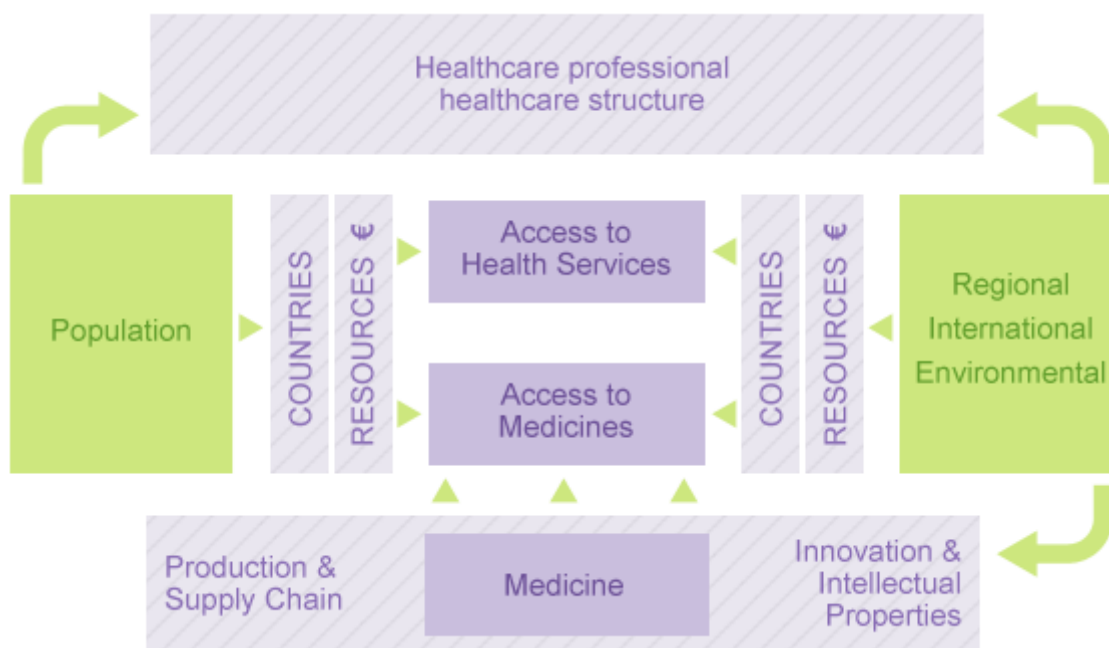
- [www.who.int](http://www.who.int)

**CARE website:**

- [www.care.org](http://www.care.org)

## Challenges

In all countries, ensuring access to healthcare and access to medicines depends on several factors, as is shown in the following diagram.



For the pharmaceutical industry, it involves addressing numerous and complex challenges, ranging from the price of products to the protection of intellectual property.

The table below gives a brief overview of challenges and obstacles relating to specific diseases, as well as possible initiatives and stakeholders' expectations.

| Drugs Challenge  | Primary obstacles to access  | Possible initiatives and stakeholders' expectations   |
|--|--|---|
| Off-patent and inexpensive medicines and vaccines<br><b>Examples of diseases:</b><br>Infectious and parasitic diseases, diarrhea, ENT (ear, nose and throat) disorders, different kinds of pain<br>Non-communicable diseases | <b>Lack of:</b> <ul style="list-style-type: none"> <li>Ability to properly diagnose condition (e.g. insufficient healthcare personnel)</li> <li>Awareness of what's available</li> </ul> | <ul style="list-style-type: none"> <li>Work with stakeholders to ensure access to healthcare</li> <li>Support for training, distribution and treatment infrastructures</li> </ul> |

| Drugs Challenge  | Primary obstacles to access   | Possible initiatives and stakeholders' expectations  |
|--|---|--|
|  | <ul style="list-style-type: none"> <li>● Time and incentives to access information</li> <li>● Skills and peer support to interpret information</li> <li>● Demand</li> <li>● Access to prenatal and infant health services</li> <li>● Access to preventive health information</li> </ul> <p>Note: price plays a secondary role</p> | <ul style="list-style-type: none"> <li>● Optimization of production costs by manufacturing in developing and emerging countries, technology transfer and the production of generics</li> <li>● Define priorities by using epidemiological approach</li> <li>● Foster healthcare structure development via information and patient support programs</li> </ul>  |
| <p>Drugs used to treat diseases that specifically affect developing and emerging countries</p> <p><b>Examples of diseases:</b><br/>Malaria, tuberculosis, leishmaniasis, sleeping sickness, schistosomiasis, etc.</p>                    | <ul style="list-style-type: none"> <li>● Price of medicines</li> <li>● Lack of specific R&amp;D programs</li> <li>● Difficulty contemplating a return on investment for diseases that are rarely or never found in developed countries</li> </ul>   | <ul style="list-style-type: none"> <li>● Fund R&amp;D programs, including innovative public – private partnerships to discover and accelerate treatments</li> <li>● Innovation and IP policy: Waiving specific patents</li> <li>● Innovative delivery channels</li> <li>● Differentiated pricing policies including "at cost" and/or subsidies to make medicines and vaccines affordable consistent with applicable law</li> <li>● Support for training, distribution and treatment</li> </ul> |
| <p>Patented medicines associated with serious diseases affecting developed and developing countries and emerging markets</p> <p><b>Examples of diseases:</b><br/>CV, cancer, diabetes, psychiatric diseases, HIV / AIDS, respiratory</p> | <ul style="list-style-type: none"> <li>● Price of medicines</li> <li>● Patient compliance</li> <li>● Patents that prevent the commercialization of generics and limit differentiated pricing</li> </ul>   | <ul style="list-style-type: none"> <li>● Differentiated pricing policy</li> <li>● Support for training, distribution and treatment</li> <li>● Innovation and intellectual property policy; voluntary licenses</li> </ul>   |

| Drugs Challenge   | Primary obstacles to access   | Possible initiatives and stakeholders' expectations  |
|---|---|--|
| <p>illness (asthma, allergies), etc.</p> <p>Rare diseases</p> | <ul style="list-style-type: none"> <li>● policies for the time established by applicable law</li> <li>● Business interests and drug registration</li> </ul> | <ul style="list-style-type: none"> <li>● Support for broader health and development goals in developing countries</li> <li>● Patient support programs</li> </ul> |

## Policy

### Taking a global approach to access to medicines and healthcare

As a global healthcare company and the number one pharmaceutical company in emerging countries, Sanofi faces a double challenge: a changing economic model in our industry combined with the Group's social responsibility with respect to access to healthcare for the most disadvantaged patients. In striving to help ensure that access to healthcare systems is equitable and available to those who most need it, providing vaccines and medicines is essential, but in addition initiatives and resources must simultaneously be organized. This is facilitated by:

- Enhancing the availability of treatments thanks to a local presence and differentiated pricing policies consistent with applicable law
- Improving prevention and awareness among communities
- Implementing innovative healthcare initiatives for groups at risk (neglected tropical diseases, maternal and infant mortality, etc.)
- Forming partnerships or collaborations to facilitate the development of healthcare infrastructures

Sanofi's policy today is based on a global approach to access to medicines and access to healthcare, implemented in cooperation with a wide range of stakeholders worldwide.

This global approach is exemplified in many ways, in particular by:

- ▼ Empowering the Group's solidarity programs through the Sanofi Espoir Foundation
- ▼ Continuing the Group's diversification, which strengthens access to healthcare
- ▼ Implementing policies to promote sustainable access to medicines and vaccines
- ▼ Participating in collaborative efforts to promote access to healthcare
- ▼ Facilitating access to medicines by deciding not to patent a drug
- ▼ Bringing production sites closer to the final consumer and develop local expertise

### Empowering the Group's solidarity programs through the Sanofi Espoir Foundation

The Sanofi Espoir Foundation is a corporate foundation created in October 2010 to strengthen the Group's commitment to international solidarity. It also improves the visibility of our actions for all stakeholders.

With a budget of €33.7 million over five years, the Foundation strives to reduce healthcare inequalities and impacts of poverty among the most underprivileged communities by fighting diseases that are too often neglected and by acting to help prevent maternal and infant mortality. It also coordinates response to humanitarian emergencies following conflicts and natural disasters.

During its first year of existence, the Foundation set up a multi-layered system of governance with a Board of Directors and a Selection Committee composed of eight external experts. It adopted a charter to guide project selection on the basis of criteria published on the Foundation's website, as well as a rigorous validation procedure for all donations of medicines and vaccines in accordance with WHO recommendations and applicable law.

When designing programs and selecting partners, the Foundation is mindful of local needs and healthcare policies. It pays particular attention to capacity building within local communities, evaluating social and economic impacts, and ensuring that each initiative is developed to its full potential. All Sanofi Espoir projects are considered with a holistic approach taking into account the key issues of prevention, training and access to care.

#### Sanofi Espoir Foundation's programs in 2011 in figures

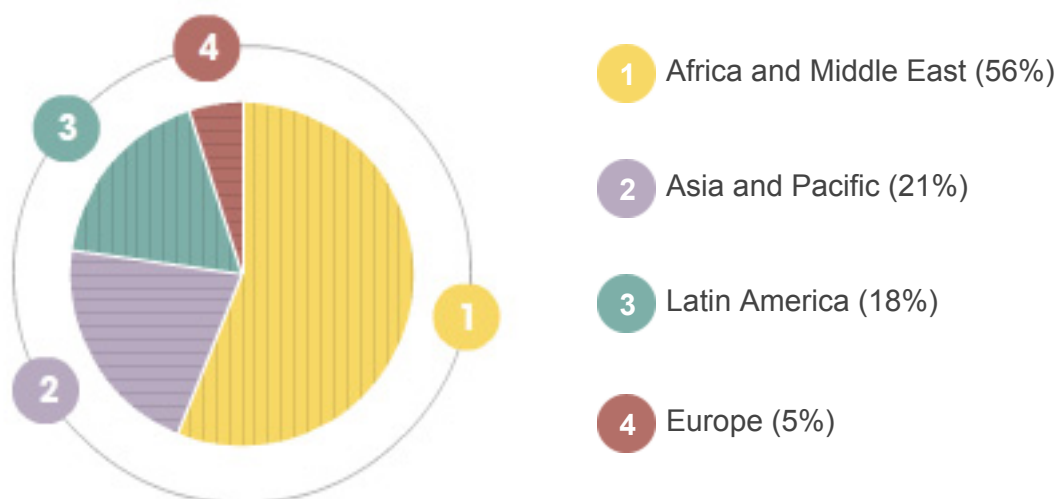
In 2011, the Foundation has supported the launch and / or the development of 39 solidarity programs (divided into 79 field projects) with 53 major partners (NGOs, hospitals, health centers, etc.) in 46 countries.

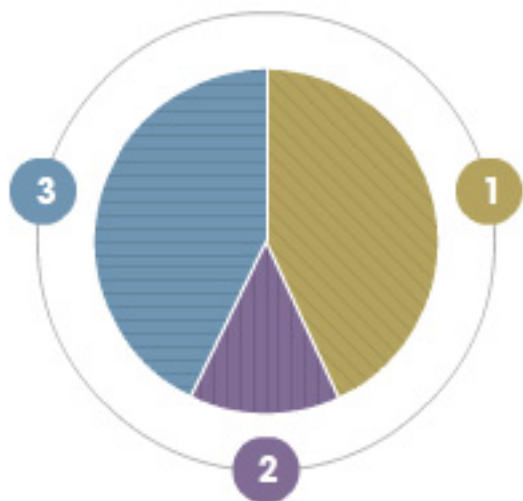
In addition, during the same period the Sanofi Espoir Foundation also responded to humanitarian emergencies to help ensure that injured and displaced persons had continued access to healthcare in 13 countries: Australia, Brazil, New Zealand, Japan, Pakistan, Thailand, Turkey, Côte d'Ivoire, Libya, Ethiopia, Somalia, Djibouti and Kenya.

The Foundation selected three new projects to encourage the employees of Group affiliates to take an active part in solidarity projects – in Argentina, Cambodia and Vietnam.

The Foundation's initiatives are complementary to those carried out directly by Group affiliates.

#### Breakdown for solidarity programs (1)





- 1 Non-infectious diseases (43%)
- 2 Infectious and neglected diseases (14%)
- 3 Improving primary health and fighting against child / maternal mortality (43%)

(1) 2011 figures do not take into account humanitarian emergencies

Facilitating access to healthcare for victims of disasters and displaced populations

As a healthcare leader, Sanofi believes that responding to humanitarian emergencies is one of the Group's missions. The challenge is to ensure access to healthcare for victims of disasters and displaced populations.

For more information:

- [www.fondation-sanofi-espoir.com / Humanitarian emergencies](http://www.fondation-sanofi-espoir.com / Humanitarian emergencies)

Supporting development aid to sustainably reduce healthcare inequalities

In addition to humanitarian emergencies, the Foundation invests in building more long-term relationships to sustainably reduce healthcare inequalities. Initiatives focus primarily on non-communicable diseases (such as cancer, diabetes and epilepsy) and infectious diseases (tuberculosis) as well as neglected diseases (leishmaniasis, Buruli ulcer, sickle cell disease, etc.).

An example of a program launched in 2011 is the "Inhibit TB" project organized in partnership with the Aurum Institute and the South African Ministry of Health, which seeks to fight tuberculosis in South Africa through public awareness raising, the home screening of families, training social workers and strengthening healthcare systems.

In 2011, the Foundation allocated €8.4 million to support programs run by our partners. It supports 39 development aid programs (commitments of three years or more) in 46 countries.



**For more information:**

- [www.fondation-sanofi-espoir.com / Support aid](http://www.fondation-sanofi-espoir.com / Support aid)

Improving primary healthcare: reducing maternal and infant mortality

Improving primary healthcare is one of the United Nations Millennium Development goals. Through the Foundation, Sanofi takes part in a number of programs designed to reduce maternal and infant mortality around the world.

This approach was applied to the project “A Call for Life,” initiated by the NGO Care, to which the Sanofi Espoir Foundation will allocate €893,000 over three years. This new project is designed to help make it possible to reduce maternal and newborn infant mortality in 35 villages in Benin. It applies a participatory approach involving village communities, healthcare partners, local media and health authorities, with the establishment of the “Women for Women’s Initiative” fund. Mobile phones are used to link people in communities and healthcare centers, especially for obstetric and neonatal emergencies.

**For more information:**

- [www.fondation-sanofi-espoir.com / Support aid](http://www.fondation-sanofi-espoir.com / Support aid)

**Video: The Foundation’s initiatives**

Watch the entire video: [www.fondation-sanofi-espoir.com / video](http://www.fondation-sanofi-espoir.com / video)

The Sanofi Espoir Foundation: created in 2010 to coordinate all the Group’s solidarity initiatives with a budget of €33.7 million over 5 years.

- [www.fondation-sanofi-espoir.com](http://www.fondation-sanofi-espoir.com)

Continuing the Group’s diversification, which strengthens access to healthcare

Promoting access to healthcare also means offering patients a broader and more accessible product portfolio. This has been a particular focus of the Group’s diversification strategy over the last three years to help it respond to the needs of the greatest number of patients.

## Expanding our generics activity

Generic drugs are a vital part of establishing a balance in healthcare systems, from a financial standpoint and to promote access to care. In 2011, Sanofi continued to expand this activity worldwide:

- Starting in January 2011, in France, Germany, Italy, Switzerland, Portugal and the United Kingdom, Sanofi decided to create a European platform under the Zentiva name to manage the Group's generics activities in Europe, Russia and Turkey.
- In Japan, Sanofi signed an agreement with Nichi-Iko Pharmaceutical Co. Ltd., a rapidly growing company that leads the Japanese generics market.

Many generic products have been registered and launched in various markets through the Zentiva (central and eastern Europe) and Medley (Brazil) affiliates.

## Diversification at the heart of Sanofi's access to healthcare strategy

Diversification promotes sustainable growth for the Group, placing us in a better position to meet the needs of healthcare systems worldwide and remain a dependable long-term healthcare provider. In 2011, Sanofi completed two acquisitions that will significantly contribute to meeting our commitments: Genzyme and BMP Sunstone Corporation.

### Genzyme, a Boston-based biotech company focused on rare diseases

Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. This biotech company provides products focused on rare genetic diseases, multiple sclerosis, cardiovascular disease and endocrinology. The company's commitment to innovation is lived out through a substantial development program in these fields and other areas of unmet medical needs.

Since Genzyme was founded in 1981, the company has introduced breakthrough treatments in several fields of medicine that have provided new hope for patients. It has a strong presence in developing countries, where it works with physicians and governments to build sustainable healthcare systems and provide free medicines to patients in countries where such systems do not yet exist. Genzyme was acquired by Sanofi in 2011.

For more information:

- [Innovative acquisitions partnerships and other business ventures](#)

In China, BMP Sunstone provides a strong consumer healthcare platform

BMP Sunstone Corporation, acquired by Sanofi in February 2011, is a specialty pharmaceutical company with a growing proprietary portfolio of branded pharmaceutical and healthcare products in China. Through Sunstone, the Company manufactures leading pediatric and women's health products sold in pharmacies throughout the country. BMP Sunstone's main office is located in Beijing, with a U.S. office in Pennsylvania.

### Implementing a policy to promote sustainable access to medicines and vaccines

To promote access to healthcare for the neediest patients, Sanofi has for many years been strongly committed to a specific access to medicines and vaccines approach overseen by a dedicated department created within the Group – Access to Medicines (ATM), which works, for vaccine-preventable diseases, in collaboration with Sanofi Pasteur, the Group's vaccines business. ATM has chosen to be active in selected disease areas where we have extensive expertise based on our portfolio of medicines: malaria, tuberculosis, Neglected Tropical Diseases (sleeping sickness, leishmaniasis, Chagas disease, Buruli ulcer), epilepsy and mental disorders.

The Access to Medicines Department has developed a global approach that encompasses:

- Tiered pricing to help ensure medicines are affordable
- Information and education programs for all links in the health chain
- R&D to meet future needs
- Partnerships and collaborations for success in the field
- A tailored approach for access to vaccines

### Tiered pricing to help ensure medicines are affordable

Sanofi's ATM Department applies a tiered pricing policy consistent with applicable law, to help make medicines more affordable for all patients, even the most disadvantaged ones.

Medicines are sold in industrialized countries and in the private sector in developing countries at market prices. Within the framework of our access to medicines programs, medicines are provided to public sector and non-governmental organizations (NGOs) at tiered pricing consistent with applicable law, which may reach "no profit – no loss" levels.

Unlike donations – which remain essential in the event of humanitarian emergencies – this tiered pricing policy is designed to ensure the long-term economic viability of our programs.

Information and education programs for all links in the health chain

Medicines alone are not enough. For this reason, we have developed information and education programs that include prevention, diagnosis and treatment as part of a global approach to disease management.

Sanofi ATM's Department provides educational tools to help train healthcare professionals, inform communities and educate patients. We make these tools available to governments and others who are active in the field, thanks to partnerships and collaborations with national programs and NGOs.

R&D to meet future needs

Research is a priority for infectious diseases because the development of resistance threatens to make existing medicines ineffective. Within our Research and Development (R&D) Division, Sanofi has created a unit focusing on infectious diseases, including multi-resistant bacterial infections, malaria, tuberculosis and neglected tropical diseases.

Partnerships and collaborations for success in the field

Our approach to partnerships and collaborations is intended to respond to the public health challenges in developing countries. The participation of many different players is necessary to meet these complex challenges. By soliciting expertise to complement our own, we increase our chances of success in the field.

Sanofi ATM's Department has a role in the Group's industrial policy for developing countries: by producing some of our medicines in developing countries, our programs contribute to job retention and knowledge transfer.

In addition, the Group helps promote access to healthcare when it comes to diseases and conditions for which we have longstanding and recognized expertise at the corporate, regional and local levels.

A tailored approach for access to vaccines

Sanofi Pasteur has developed a similar global approach that includes:

- Applying a differentiated pricing policy for vaccines
- Training and information programs that are adapted to all the different stakeholders in the healthcare pyramid

- Seeking to developing adapted vaccines to meet patients' needs by continuously conducting research
- Producing quality medicines and vaccines based on the Group's industrial expertise

For more information:

- [Access to Vaccines](#)



[Brochure - Access to Medicines 2011](#) (PDF, 2739Kb)

## Participating in collaborative efforts to promote access to healthcare

Improving access to healthcare also involves innovative collaborations to help reduce the time required to bring new products to market, so that patients may benefit from these medicines as rapidly as possible.

### Collaborations to develop new treatments for neglected diseases

According to the World Health Organization (WHO), neglected tropical diseases impair the lives of an estimated one billion people today. In 2011, Sanofi signed several agreements focused on developing new treatments for neglected diseases.

### Collaboration agreement with DNDi

In May 2011, Sanofi and the Drugs for Neglected Diseases initiative (DNDi) announced a three-year research collaboration agreement concerning new treatments for nine neglected tropical diseases (NTDs) listed by the WHO. Under this agreement, Sanofi will initially bring molecules from our libraries into the venture, while DNDi and Sanofi collaborate in research activities on innovative molecular scaffolds. The rights to results produced by the partnership will be co-owned by Sanofi and DNDi. Together, they anticipate publishing research findings and seeking to develop drugs that will benefit the public sector.



Sanofi is committed to bringing therapeutic solutions to those most affected and exposed to neglected tropical diseases. In this new research collaboration with DNDi, we have taken a firm step towards greater flexibility in the sharing of knowledge to produce new medicines.

**Dr. Elias Zerhouni,**  
President, Global Research & Development, Sanofi

Drugs for Neglected Diseases initiative (DNDi) is a collaborative, patients' needs-driven, non-profit drug research and development organization that is developing new treatments for Neglected Diseases.

For more information:

- [www.dndi.org](http://www.dndi.org)

Sharing certain intellectual property through the consortium “WIPO Re:Search”

In November 2011, Sanofi joined a new consortium created to share expertise and speed up the development of new drugs. “WIPO Re:Search” is a consortium of public and private sector organizations that share knowledge and valuable intellectual property (IP) information with the global health research community to help enable the development of faster and more effective treatments to help fight neglected tropical diseases, malaria and tuberculosis in the developing world. The consortium was created at the initiative of the World Intellectual Property Organization (WIPO).



We look forward to working with the WIPO Re:Search consortium to deliver treatments for conditions such as tuberculosis and malaria to patients and to share our product and technical know-how. This type of collaborations is invaluable in accelerating the creation of new drugs, vaccines and diagnostics to help combat what are all too often fatal diseases.

**Dr. Robert Sebbag,**  
Vice President, Access to Medicines, Sanofi

Supporting research for a drug to treat Chagas disease

CONICET, Argentina's National Scientific and Technical Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas), signed an agreement with Sanofi in December 2011 for a collaborative effort designed to endeavor to lead to a new drug to treat Chagas disease as

well as the development of innovative diagnostic methods. According to the terms of the agreement, Sanofi will provide the CONICET scientific team more than 300 molecules, which are property of the Group, to be tested in the experimental model they have designed so that clinical development may begin.

#### Taking part in innovative programs to speed up development of TB Drug Combinations

In October 2011 Sanofi joined collaborators including AstraZeneca, Tibotec, TB Alliance and the World Health Organization with the Critical Path to TB Drug Regimens (CPTR) to share information on tuberculosis (TB) drugs in development within their respective pipelines with the aim of quickly identifying and working together to develop the most promising TB drug regimen, regardless of sponsor. By sharing data, partners can identify opportunities to test their compounds in combination, which may speed availability of future TB regimens.

CPTR is a cross-sector initiative that brings together the world's leading pharmaceutical companies with regulatory agencies and civil society (non-profit) organizations to help expedite the testing of promising TB drug regimens. It also will endeavor to identify new regulatory pathways and other tools needed to speed up the delivery of improved treatments to TB patients worldwide.



Through this one of a kind initiative, we have the potential to make a real difference in the lives of patients suffering from TB. This is an exciting example of pharma players collaborating within and outside the industry, to contribute their best assets for the benefit of the wider society.

**Dr. Elias Zerhouni,**  
President, Global Research & Development, Sanofi

#### Facilitating access to medicines by deciding not to patent a drug

Sanofi considers that defending intellectual property rights is not only one of the pillars of the healthcare industry, but essential for the Group's future. Under certain circumstances, such as in the case of ASAQ Winthrop® to treat malaria, the Group may deliberately choose to waive our right to patent a product – even an innovative one – to make it more accessible. In addition, the Group strives to facilitate access to our products for economically disadvantaged populations, in particular medicines for neglected tropical diseases, which primarily affect developing countries. From its prequalification by the WHO in October 2008 to the end of 2011, more than 120 million ASAQ Winthrop® units had been distributed – this volume implies the

accessibility of the product to those who needed it, which in turn may be interpreted as a strong sign that Sanofi's approach was successful under its access to healthcare policy.

ASAQ Winthrop® is a single tablet containing a fixed-dose combination of artesunate and amodiaquine to treat malaria. The Group set up a differentiated pricing policy consistent with applicable law for this antimalarial drug (including selling at a “no profit – no loss” price of less than one dollar for an adult and less than 50 cents for a child) for sales to major international organizations, government purchasing agencies, etc.

**For more information:** The Sanofi Position Paper on Intellectual Property

- [\*Responsible Lobbying\*](#)

Bringing production sites closer to the final consumer and develop local expertise

To promote access to healthcare, Sanofi strives to bring some production sites closer to the final consumer. The Group's Industrial Affairs organization is present on all continents and pays constant attention to market needs to develop, produce, package and distribute high quality medicines at competitive costs for all markets. Industrial Affairs continues to make investments worldwide to increase Sanofi's production capacity, in particular for the production of vaccines in emerging countries and to contribute to technological developments in emerging markets.

**For more information:**

- [\*en.sanofi.com / Our company / Worldwide\*](#)



## Our investments and programs

In 2011, the Group invested more than €54 million for our many different access to healthcare programs, in addition to donating 700,000 boxes of medicines and over 900,000 doses of vaccines to 60 countries.

### The Group's investments in 2011

- Over €6 million in programs carried out by a dedicated team of 30 people in the Access to Medicines Department supported by 7 dedicated people in sub-Saharan Africa
- Over €38 million invested in research and development, specifically to fight malaria, tuberculosis, leishmaniasis and sleeping sickness
- \$5 million per year for the WHO partnership on neglected diseases (\$55 million since 2001)
- €33.7 million over 5 years allocated to responding to humanitarian emergencies and to developing more long-term access to healthcare programs

#### In addition:

- 700,000 boxes of drugs and more than 900,000 doses of vaccine, with an estimated value of €28 million were given in 2011. These donations have allowed the medical care of 6.1 million people in 60 countries including 55 emerging or developing.
- 51.4 million units of ASAQ (artesunate-amodiaquine) were sold at differentiated prices (for a value of €22 million).
- In 2011, primarily in the United States, but also in various emerging countries, nearly 200,000 patients benefited from the Group's products through Patient Assistance Programs (PAP), which provide medicines at reduced prices – and even free of charge – for those low-income individuals and their families who are eligible under the terms of the applicable PAP.

In 2011, Sanofi donated **700,000** boxes of medicines and over **900,000** doses of vaccines in **60** countries.

## Malaria

Total Sanofi  
monetary  
investment in  
2011: €2.6  
million (this does  
not include R&D)

| Type of action                                     | Program details                                | Location                          | Collaborators  | Date | Results / Impact                                |
|--|--|-----------------------------------|--|------|---|
| National Malaria Control Program (NMCP) – training | Training the trainers                          | Burundi<br>Chad                   | Ministry of Health   | 2011 | 37 students providing malaria information tools |
| NMCP - PNLP – training                             | Teaching malariology<br>Intellectual property  | Madagascar<br>+ 9 other countries | Ministry of Health<br>Réseau International des Instituts Pasteur (RIIP)<br>Agence Universitaire de la Francophonie | 2011 | 10 participants                                 |
| Training   | Inter-university diploma, inventory management | Burkina Faso                      | University of Auvergne (France)<br>University of   | 2011 | 40 students from 14 countries                   |

| Type of action               | Program details  | Location   | Collaborators         | Date  | Results / Impact  |
|------------------------------|--|--|-----------------------|---|---|
|                              |  |  | Lyon<br>(France)      |   |   |
| NMCP -<br>PNLP –<br>training | Combating malaria<br>training in<br>companies  | Benin &<br>Democratic<br>Republic of<br>Congo<br>(DRC)                                     | Ministry of<br>Health | 2011  | Benin<br>11 firms<br>250,000<br>employees<br>DRC<br>32 firms<br>100,000<br>employees<br>500,000<br>beneficiaries; |
|                              | Training for<br>community health<br>agents   | Malawi   |                       | 2011  |   |
| Tiered<br>pricing            | Commercialization<br>of a fixed-dose<br>combination of<br>artesunate and<br>amodiaquine<br>(ASAQ<br>Winthrop®) | In 24<br>countries of<br>sub-Saharan<br>Africa   | DNDi<br>Foundation    | Started in<br>2009<br>Ongoing<br>in 2011    | 120 million<br>units sold by<br>end 2011, of<br>which 95%<br>sold at "no<br>profit – no<br>loss" prices           |
| Population<br>program        | Schoolchildren<br>against malaria  | No action in<br>2011<br>More than 3<br>projects<br>started to be<br>implemented<br>in 2012 |                       | Started in<br>2008<br>continuing<br>in 2012 | Approximately<br>200,000<br>children<br>educated  |
| Risk<br>Management<br>Plan   | ASAQ Winthrop®<br>Pharmacovigilance<br>program   | In 14<br>countries   | WHO                   | Started in<br>2009<br>Ongoing<br>in 2011    | First RMP<br>submitted to<br>the WHO<br>involving over<br>20,000<br>patients                                      |

## Epilepsy

Total Sanofi monetary investment in 2011: €225,000

Total Sanofi monetary investment since starting date of the Epilepsy programs: €1,200,000

| Type of action                                    | Program details  | Location | Collaborators   | Date                        | Results / Impact  |
|---|--|----------|---|-----------------------------|---|
| Partnership with National League against epilepsy | <ul style="list-style-type: none"> <li>● Training healthcare professionals</li> <li>● Epidemiology study in one region</li> <li>● Raising awareness</li> </ul>   | Cambodia | Institute of Epidemiology and Tropical Neurology (IENT) | 2007-2011                   | <ul style="list-style-type: none"> <li>● Slide kit in Khmer for training</li> <li>● 130 healthcare professionals trained</li> <li>● Estimation of prevalence of epilepsy in the Prey Veng province (0.58%) published in Epilepsia</li> <li>● 96 people with epilepsy included in follow up program</li> </ul> |
| Partnership with Ministry of Health               | <ul style="list-style-type: none"> <li>● Training for healthcare professionals</li> <li>● Education for general public</li> <li>● Epidemiological surveillance</li> <li>● Supply of more affordable drugs</li> </ul> | Cameroon | Ministry of Health, Cameroon                            | Started in 2009 for 3 years | <ul style="list-style-type: none"> <li>● Slide kit for training</li> <li>● Awareness / education materials</li> <li>● 12 doctors trained to date</li> <li>● 100 healthcare primary</li> </ul>   |

| Type of action                      | Program details  | Location | Collaborators             | Date                            | Results / Impact   |
|-------------------------------------|--|----------|---------------------------|---------------------------------|--|
|                                     |  |          |                           |                                 | <ul style="list-style-type: none"> <li>workers trained to date</li> <li>Sanofi anti-epileptic drugs (AED) at tiered pricing</li> </ul>   |
| Partnership with Ministry of Health | <ul style="list-style-type: none"> <li>Training for healthcare professionals</li> <li>Supply of drugs at tiered pricing</li> </ul>                                     | Benin    | Ministry of Health, Benin | Started end of 2010 for 3 years | <ul style="list-style-type: none"> <li>Started in December 2010, 2011 was mostly dedicated to the preparation of the project and adaptation of the training kits</li> <li>40 GPs trained</li> <li>Sanofi anti-epileptic drugs (AED) at tiered pricing</li> </ul> |
| Partnership with a NGO: the KAWE    | <ul style="list-style-type: none"> <li>Supply of affordable drugs</li> <li>Raising awareness</li> <li>Epilepsy clinics</li> <li>Medicines at tiered pricing</li> </ul> | Kenya    | Santé Sud                 | 2006-2011                       | <ul style="list-style-type: none"> <li>6,066 patients had been seen and treated, including 493 new patients</li> <li>Slide kit for training</li> </ul>   |

| Type of action                    | Program details   | Location                        | Collaborators            | Date                        | Results / Impact   |
|-----------------------------------|---|---------------------------------|--------------------------|-----------------------------|--|
|                                   | <ul style="list-style-type: none"> <li>Epidemiology study</li> </ul>  |                                 |                          |                             | <ul style="list-style-type: none"> <li>12,517 patients registered in 3 clinics</li> <li>139 weekly sessions conducted in the 3 clinics</li> <li>Sanofi anti-epileptic drugs (AED) at preferential prices</li> </ul>  |
| Partnership with a NGO: Santé Sud | <ul style="list-style-type: none"> <li>Training for doctors</li> <li>Diagnostic clinics</li> <li>Medicines at more affordable prices</li> </ul> | Mali<br>Madagascar<br>Argentina | Santé Sud                | 2006<br>2011                | <ul style="list-style-type: none"> <li>40 GPs trained in Mali &amp; 9 in Madagascar</li> <li>Sanofi anti-epileptic drugs (AED) at tiered pricing</li> <li>Over 2,500 patients in program in Mali &amp; 265 in Madagascar</li> <li>Slide kit for training<br/>Specific materials for awareness</li> </ul> |
| Partnership with a Province       | <ul style="list-style-type: none"> <li>Evaluation of resources</li> </ul>   | Argentina                       | Province of Buenos Aires | Started in 2010 for 3 years | 25,000 patients in the program network of 58   |

| Type of action                              | Program details   | Location                                    | Collaborators                  | Date                               | Results / Impact  |
|---|---|---|--------------------------------|------------------------------------|---|
| Ministry of Health                          | <ul style="list-style-type: none"> <li>management implementing an information platform with online notification system</li> </ul>                               |   | Ministry of Health             |                                    | General Provincial Hospitals, 150 Local Hospitals, 95 adult neurologists, 98 psychiatrists, and 40 pediatric neurologists   |
| Support for project in developing countries | <ul style="list-style-type: none"> <li>Annual grant for 1 innovative project about access to care for patients with epilepsy in developing countries</li> </ul> | Support for project in developing countries | French League Against Epilepsy | Started in 2006<br>Ongoing in 2011 | 2011 Laureate: Rindra Andriambololona for project entitled "Access to healthcare evaluation and aid for patients with epilepsy in a district of the Diana Region of Madagascar" |

## Mental illness

Total Sanofi monetary investment in 2011: €450,000

Total Sanofi monetary investment since starting date of the Mental illness programs: €1,220,00

| Initiative                                    | Program details   | Location | Collaborators       | Starting date               | Results / Impact  |
|---|---|----------|---------------------|-----------------------------|---|
| Millennium Villages Project for mental health | <ul style="list-style-type: none"> <li>Pilot Psychosis Pathway Project: feasibility testing and validation of training tools</li> </ul> | Nigeria  | New York University | Started in 2011 for 2 years | <ul style="list-style-type: none"> <li>Awareness / education materials</li> </ul> |

| Initiative  | Program details  | Location   | Collaborators   | Starting date  | Results / Impact   |
|---|--|------------|---|--|--|
| Study of access to healthcare services for mental health patients in communities                              | <ul style="list-style-type: none"> <li>● Estimation of prevalence of psychosis and other mental health disorders</li> <li>● Description of healthcare services utilization and access to medicines for psychosis/ mental disorders</li> <li>● Suggestions to improve access to healthcare services and medicines for patients with mental disorders</li> </ul> | Vietnam    | Health Strategy & Policy Institute  | Started in 2008 for 3 years                                      | <ul style="list-style-type: none"> <li>● Study completed</li> <li>● Results to be published</li> <li>● Recommendations made concerning future projects</li> </ul>  |
| Regional & national program for developing access to healthcare for people with mental disorders and epilepsy | <p>Creation of a network of healthcare professionals for psychiatric care in each province for:</p> <ul style="list-style-type: none"> <li>● Training</li> <li>● Affordable medicines</li> <li>● Cooperation with patient organizations</li> </ul>   | Mauritania | Ministry of Health, Mauritania<br>World Association for Social Psychiatry | Pilot started in 2008 for 3 years<br>Renewal in 2011 for 5 years | <p>Pilot project in Nouadhibou completed:</p> <ul style="list-style-type: none"> <li>● Information for public</li> <li>● Training for GPs</li> <li>● Training personnel at Regional Hospital</li> <li>● Treatment gap decreased by 37% in 30 months</li> </ul> |



| Initiative | Program details   | Location | Collaborators   | Starting date               | Results / Impact  |
|------------|---|----------|---|-----------------------------|---|
|            | <ul style="list-style-type: none"> <li>● to combat stigma</li> <li>● Information campaigns</li> </ul> <p>Pilot project in Nouadhibou implementation in 12 provinces over 5 years</p>  |          |   |                             | <ul style="list-style-type: none"> <li>● Project to be expanded by Ministry of Health to include more mental health diseases and epilepsy</li> <li>● Medicines at tiered pricing</li> <li>● Slide kit for training</li> <li>● Materials for awareness/ education</li> </ul>   |
| SFOSAM     | <ul style="list-style-type: none"> <li>● Training for GPs from public sector in Benslimane District</li> <li>● Building awareness among GPs and nurses in private sector</li> <li>● Affordable antipsychotic drugs for patients in need</li> <li>● Information and communication programs for general public</li> </ul> | Morocco  | Ministry of Health, Morocco, League for Mental Health | Started in 2008 for 3 years | <ul style="list-style-type: none"> <li>● 63 Health professionals trained</li> <li>● Awareness meetings targeting different groups</li> <li>● Family association created in Benslimane</li> <li>● Antipsychotic drugs sold at tiered pricing</li> <li>● Slide kit for training</li> <li>● Materials for awareness and education</li> </ul> |

| Initiative   | Program details   | Location  | Collaborators   | Starting date               | Results / Impact   |
|--|---|-----------|---|-----------------------------|--|
| Improving care for people with mental disorders and epilepsy | <ul style="list-style-type: none"> <li>● Develop primary care for mental health patients via training of primary healthcare personnel starting with 1 pilot region</li> <li>● Medicines at tiered pricing</li> <li>● Information and communication campaign for the public</li> <li>● Aiding local NGOs in their work in mental healthcare and epilepsy care</li> </ul> | Guatemala | Ministry of Health, Guatemala & World Association of Social Psychiatry (WASP) | Started in 2011 for 5 years | <ul style="list-style-type: none"> <li>● Slide kits for training</li> <li>● Materials for awareness/ education</li> <li>● Psychotherapeutic medicines sold at preferential prices</li> <li>● Antipsychotic drugs sold at tiered pricing</li> </ul> |
| Pilot program against schizophrenia                          | <ul style="list-style-type: none"> <li>● Drugs sold at tiered pricing</li> <li>● Adapted tools for training and communication</li> <li>● Training for doctors and staff</li> </ul>  | Benin     | Ministry of Health, Benin   | Started in 2010 for 3 years | <ul style="list-style-type: none"> <li>● Roll-out in 6 pilot zones</li> <li>● Slide kits for training</li> <li>● Materials for awareness/ education</li> <li>● Antipsychotic drugs sold at tiered pricing</li> </ul>                               |

## Neglected Tropical Diseases (NTDs)

Total Sanofi monetary investment in 2011: \$5 million

Total Sanofi monetary investment since started 2009 (ongoing programs): \$60 million

| Neglected Tropical Diseases | Program details   | Location    | Collaborators | Date  | Results / Impact  |
|-----------------------------|---|-------------|---------------|---|---|
| Sleeping sickness           | <ul style="list-style-type: none"> <li>To eliminate sleeping sickness</li> <li><u><a href="#">Business case: sleeping sickness</a></u></li> <li>Focus on distribution of drugs, screening and treatment programs</li> </ul> | Worldwide   | WHO           | 2001<br><br>In 2011 partnership renewed for 5 more years                                    | <ul style="list-style-type: none"> <li>Over 1.5 million ampoules distributed since 2001</li> <li>2 million people screened and 10,500 new cases detected and treated</li> </ul> |
| Sleeping sickness (R&D)     | <ul style="list-style-type: none"> <li>To develop fexinidazole as the first potential oral treatment for sleeping sickness</li> </ul>   |             | DNDi          | Started in 2009   | Collaboration with DNDi   |
| Buruli ulcer                | <ul style="list-style-type: none"> <li>Support WHO initiatives</li> <li>To facilitate earlier treatment of the disease and to attempt to develop antibiotic therapy to be</li> </ul>  | West Africa | WHO           | Started in 2006<br>Renewed in 2011 for 5 more years<br>Support through drug donation to WHO | <ul style="list-style-type: none"> <li>Sponsoring antibiotic treatments in 9 countries</li> <li>Training healthcare professionals in 5 African countries</li> </ul>             |

| Neglected Tropical Diseases | Program details  | Location | Collaborators | Date  | Results / Impact  |
|-----------------------------|--|----------|---------------|---|---|
|                             | <ul style="list-style-type: none"> <li>administered orally</li> </ul>  |          |               | Buruli Ulcer Clinical Trial                         | <ul style="list-style-type: none"> <li>Epidemiological surveillance in 11 countries</li> </ul>  |
| Chagas disease              | <ul style="list-style-type: none"> <li>Support WHO initiatives</li> <li>To improve epidemiological surveillance</li> </ul>   |          | WHO           | Started in 2006<br>Renewed in 2011 for 5 more years | Development of systems for information and epidemiological surveillance in non endemic countries  |
| Leishmaniasis               | <ul style="list-style-type: none"> <li>Support WHO initiatives</li> <li>To improve epidemiological surveillance and treatment centers for this disease, especially in the Middle-East</li> </ul> |          | WHO           | Started in 2006<br>Renewed in 2011 for 5 more years | <ul style="list-style-type: none"> <li>Over 2.9 million ampoules of Glucantime® distributed at a single, tiered pricing</li> <li>Publication on leishmaniasis therapy, available in 6 languages (English, French, Spanish, Portuguese, Arabic and Farsi)</li> </ul> |

Access to vaccines

Total Sanofi monetary investment in 2011

Total Sanofi monetary investment since starting date (ongoing program)

| Vaccines     | Program details   | Location                           | Collaborators  | Date  | Results / Impact   |
|--------------|---|------------------------------------|--|---|--|
| Polio        | Global Polio Eradication Initiative (GPEI), commitment to supply 400 million doses of oral polio vaccine in 2011-2012 for use in developing countries |                                    | Global Polio Eradication Initiative (GPEI), WHO, UNICEF, Rotary International  | GPEI started in 1988                              | <ul style="list-style-type: none"> <li>● Delivery of 400 million doses in line with our commitment</li> <li>● Development of adapted formulations</li> <li>● Sanofi Pasteur's donation to the WHO of the vaccine strain used in the production of OPV against type 3 poliovirus.*</li> </ul> |
| Yellow fever | To promote access to vaccines for children living in the poorest countries  | Africa                             | GAVI (Global Alliance for Vaccines and Immunization)   | Started in 2003 continued in 2011                 | 6 million doses of vaccines stockpile supplied annually to combat African epidemics  |
| Yellow fever | EPIVAC Program, to train doctors involved in the implementation of vaccination programs   | Central and West African countries | Preventive Medicine Agency (AMP), the local governments, the Universities of Cocody-Abidjan (Côte d'Ivoire) & Paris-Dauphine (France), in collaboration with the | Capacity building or Yellow Fever Started in 2002 | <ul style="list-style-type: none"> <li>● Funding of programs</li> <li>● 400 district medical officers and 50 national supervisors trained from 11 countries from West and Central Africa</li> <li>● 1,500 supervision reports generated 400 operational</li> </ul>                           |

|           |   |           |   |                 |   |
|-----------|---|-----------|---|-----------------|---|
|           |   |           | WHO, UNICEF and the GAVI Alliance, as well as other collaborators working in Africa |                 | ● research theses   |
| Influenza | Working with the WHO within the scope of the influenza pandemic | Worldwide | WHO Local authorities   | Started in 2010 | Commitment to donate up to 100 million doses of pandemic influenza vaccine to be distributed by the WHO to eligible countries in need |

\* *Donation of viral strain to make oral polio vaccine*

In 2011, Sanofi Pasteur donated to the World Health Organization the vaccine strain used in the production of oral polio vaccines against type 3 poliovirus. From now on, the WHO is in full control of the vaccine strain and will distribute it to vaccine manufacturers.

Within the scope of the **Global Polio Eradication Initiative (GPEI)**, Sanofi Pasteur has committed to supply **400 million doses of polio vaccine** in 2011-2012 for use in developing countries.



Sanofi Pasteur is a leading contributor to the fight against polio and a committed supporter of the Global Polio Eradication Initiative. We have provided polio type 3 viral seeds free of charge to polio vaccine manufacturers worldwide for the last 30 years. This donation is a demonstration of our continued commitment to public health.

**Olivier Charmeil,**  
President and CEO, Sanofi Pasteur

## Sanofi Espoir Foundation

The Sanofi Espoir Foundation seeks to build long-term partnerships to sustainably reduce health inequalities. The following table provides examples of 7 programs to illustrate our approach.

### Fighting Non communicable diseases

| Type of action  | Program objectives   | Location                     | Collaborators                                 | Date   | Results / Impact  |
|---|--|------------------------------|---|--|---|
| "My Child Matters" - Fighting childhood cancers in developing countries                                   | Enable local partners, hospitals and NGOs to benefit from financial support and advice from international pediatric oncology and public health experts | Africa, Latin America, Asia  | Union for International Cancer Control (UICC) | Started in 2005 and renewed in 2010 for 3 more years | 6 years after it was launched, the program has supported 40 projects run by 43 hospitals and NGOs in 26 countries   |
| Fighting epilepsy   |  | Ghana, Vietnam               | WHO   | Started in 2011 for 4 years                          | Pilot project aims to improve early diagnosis and the treatment of epilepsy   |
| Improving early diagnosis and integration of children with mental disabilities in Mediterranean countries | <ul style="list-style-type: none"> <li>Algeria: raising awareness among early childhood workers and parents about the early detection of</li> </ul>    | Algeria, Lebanon and Tunisia | Santé Sud and institutional local partners    | Started in 2008                                      | <ul style="list-style-type: none"> <li>40,000 babies examined in Algeria in 2011</li> <li>1,400 families receiving support in the treatment and integration of their child</li> </ul> |

| Type of action | Program objectives   | Location | Collaborators | Date | Results / Impact |
|----------------|--|----------|---------------|------|------------------|
|                | <ul style="list-style-type: none"> <li>● disorders right from birth</li> <li>● Lebanon: develop early diagnosis and referral for the appropriate care of children suffering from intellectual disabilities.</li> <li>● Tunisia: focus on socio-economic integration of people with intellectual disabilities.</li> </ul> |          |               |      |                  |

### Fighting neglected diseases

| Type of action | Program objectives  | Location                        | Collaborators                                  | Date                       | Results / Impact   |
|----------------|---|---------------------------------|--|----------------------------|--|
| Buruli ulcer   | Fight against BU thanks to prevention/ awareness among the populations, training of health professionals, | Benin,<br>Togo,<br><br>Cameroon | Handicap International<br><br>Institut Pasteur | 2007-2011<br><br>2011-2012 | 24,500 beneficiaries of awareness meetings, 170 health care professionals trained, 52 disabled people helped in 2011 |



| Type of action | Program objectives  | Location | Collaborators           | Date       | Results / Impact  |
|----------------|---|----------|-------------------------|------------|---|
|                | <p>detection and early treatment, and rehabilitating those with disabilities</p> <p>Improve prevention and treatment, verify the hypothesis of the domestic transmission (presence of M Ulcerans on insects captured around houses)</p> |          |                         |            |   |
| Leishmaniasis  | <p>Train healthcare professionals, educate the populations of Pernambuc region, follow the patients during and after treatment, study the evolution of the virus in the region</p>  | Brazil   | Oswaldo Cruz Foundation | Since 2002 | Model program for the government to set up in other regions |

## Improving primary health and fighting against and child / maternal mortality

| Type of action  | Program objectives  | Location | Collaborators              | Date                      | Results / Impact  |
|-----------------|---|----------|----------------------------|---------------------------|---|
| A Call for Life | Improve primary healthcare/ fighting maternal and infant mortality in 35 villages | Benin    | CARE<br>Ministry of Health | Mid-2011, to last 3 years | It is estimated that over 25,000 women will benefit from this project |



Women play a key role in development and reducing poverty. We felt that it was essential to take an innovative, participatory approach involving all the links in the healthcare chain, especially village communities, alongside our partner CARE, to support Benin in this integrated program to reduce maternal and infant mortality. Another strength of the CAR E project: it is part of an inter-country Mothers Matter initiative, which focuses on sharing best practices.

**Caty Forget,**  
Managing Director, Sanofi Espoir Foundation

**For more information:** A map of Sanofi Espoir's major partnerships around the world to help reduce healthcare inequalities

- [www.fondation-sanofi-espoir.com / Map partners](http://www.fondation-sanofi-espoir.com / Map partners)

**For more information:** Sanofi Espoir's projects to combat maternal and infant mortality

- [www.fondation-sanofi-espoir.com / Thematic file](http://www.fondation-sanofi-espoir.com / Thematic file)

## Infectious diseases

An infectious disease is any disease that can be spread from one person to another, directly or through a vehicle-borne transmission. As a global healthcare leader, Sanofi makes a long-term investment in the fight against infectious diseases worldwide.

## Malaria

### MALARIA, A GLOBAL PUBLIC HEALTH CHALLENGE



#### MALARIA: COUNTRIES AND REGIONS WITH RISK OF INFECTION

Source: World Health Organization (WHO), 2011<sup>10</sup>



Countries and regions  
where infection occurs



Countries and regions with  
limited risk of infection

For more information about malaria:

- [www.who.int / Malaria](http://www.who.int / Malaria)
- [www.bcccc.net / Center for corporate citizenship / Films Festival](http://www.bcccc.net / Center for corporate citizenship / Films Festival)
- [www.impact-malaria.com](http://www.impact-malaria.com)



[Brochure - Access to Medicines 2011](#) (PDF, 2739Kb)

Background: A global public health challenge

Malaria is a parasitic disease transmitted to humans through the bite of the Anopheles mosquito. The Plasmodium parasite colonizes and destroys red blood cells, causing malaria

attacks with the sudden appearance of fever, fatigue, headache, shivering, vomiting, etc. Attacks may be very serious, leading to severe anemia, convulsions, coma, permanent damage and even death.

However, the international community has mobilized considerable resources to combat this terrible disease and effective solutions exist to prevent and treat malaria. For these efforts to succeed, a number of collaborators must coordinate their work, and actions must be adapted to each country over many years.

## Policy

### **The Impact Malaria Program, Sanofi's commitment to the fight against malaria**

Active since the 1930s in research and the production and distribution of anti-malaria drugs, Sanofi created the Impact Malaria program within our Access to Medicines Department in 2001, strengthening the Group's role as a major player in the fight against malaria.

The management of malaria is a complex task and requires many different kinds of know-how. By mobilizing the Group's resources as well as those of our collaborators (health authorities, ministries, NGOs, experts and universities), Impact Malaria has developed a working method based on a four-fold approach:

- Producing medicines designed to meet patients' needs, based on our industrial know-how
- Making medicines more affordable by applying a tiered pricing policy
- Designing information and education initiatives that are adapted to all actors in the health chain
- Establishing a Research and Development (R&D) program dedicated to therapeutic innovation to strive to meet the challenges of the future, in particular the development of resistance to existing medicines

## Actions

- ▼ Information and education initiatives adapted to each actor in the health chain
- ▼ Training the trainers
- ▼ Working to help ensure that drugs reach people who need them
- ▼ Schoolchildren against Malaria: Teaching 200,000 children about malaria
- ▼ Over 120 million treatments of ASAQ Winthrop® : an innovative antimalarial medicine
- ▼ Tiered pricing to help make medicines more affordable
- ▼ R&D alliances to meet future needs

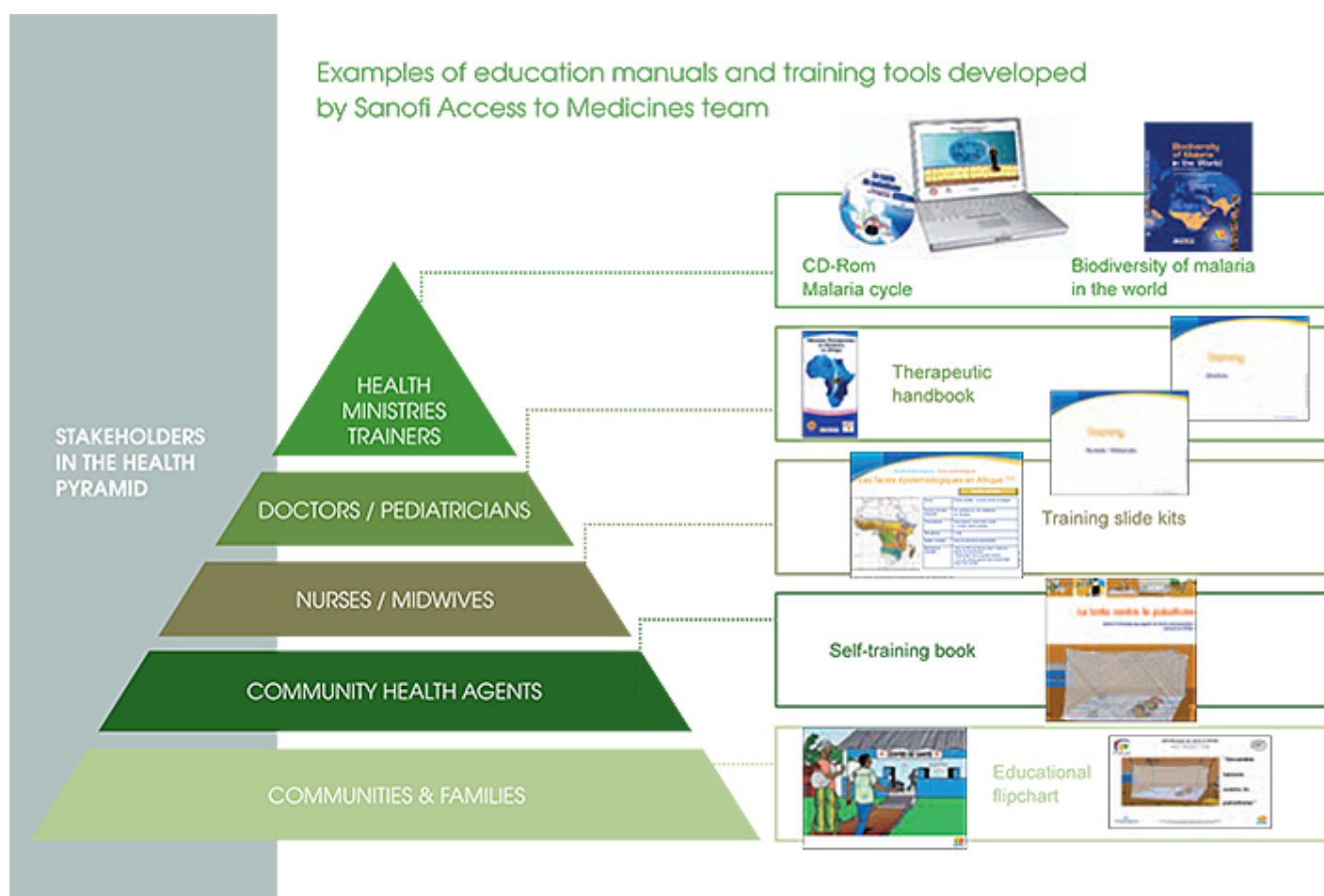
### Information and education initiatives adapted to each actor in the health chain

Many different stakeholders must be involved in a comprehensive approach designed to achieve success of that initiatives in the field will be successful: experts, instructors in National Malaria Control Programs (NMCPs), doctors, field nurses, community health workers and schoolteachers.

Success in the field also requires the development of educational tools designed to meet a range of different needs, and adapted to different audiences. Along with scientific experts and National Malaria Control Program (NMCP) directors, we develop training and medical information tools to provide the most complete information possible about the prevention, diagnosis and treatment of malaria.

Education manuals and training tools developed by Sanofi Access to Medicines team are provided to public health authorities and NGOs so they can be adapted to fit the specific characteristics of each country.

This comprehensive approach is essential: drugs alone are not enough to combat malaria.



## Training the trainers

To raise awareness among health stakeholders, we have developed an innovative program for “Training the trainers” designed for **NMCPs** and NGOs working in the field. Training sessions, which take place over several days, focus on techniques for managing malaria. One session is devoted to communication techniques, enabling participants in the training program to learn how to pass down their knowledge so that they, in turn, can become trainers.

In 2011, 72 trainers were trained thanks to this program, 21 doctors in Tchad, 17 doctors in Burundi, and 34 clinical officers in Malawi. All these initial trainers were afterwards able to train numerous community health workers in who learned about ways to combat malaria.

## Working to help ensure that drugs reach people who need them

Ensuring that drugs actually reach people who need them is a clear priority. To this end, in 2011, in collaboration with Sanofi and the Impact Malaria program, Ouagadougou University

(Burkina Faso) introduced a new inter-university degree in sub-Saharan Africa, devoted to pharmaceutical supply chain management. The first course was held from February 7 to March 5, 2011, at Ouagadougou University, in collaboration with two French academic institutions – the University of Auvergne and University of Lyon. Some 40 students from 14 different countries attended the course. Sanofi took part by addressing issues such as intellectual property, access to medicines and the fight against counterfeit drugs.

#### Schoolchildren against Malaria: Teaching 200,000 children about malaria

Children are the primary victims of malaria, and they are also the adults of tomorrow. Educating them is an essential part of the fight against malaria.

The Schoolchildren against Malaria program, designed specifically for children, was developed through collaboration between Sanofi and the NMCP in Côte d'Ivoire. Several sub-Saharan African countries subsequently adopted the program.

Schools organize classes about malaria, how it is transmitted and techniques to prevent it. The teachers then ask the children to write a theatrical play to act out what they need to do to combat malaria. The best play receives an award during an interschool theater contest.

Between 2008 and 2011, this program contributed to raising awareness among 200,000 children in Côte d'Ivoire, Ghana and Burkina Faso. The Schoolchildren against Malaria initiative is intended to be expanded to include other countries in the future.

#### Over 120 million treatments of ASAQ Winthrop® : an innovative antimalarial medicine

ASAQ Winthrop® is an antimalarial medicine developed by Sanofi and the Drugs for Neglected Diseases initiative (DNDi) Foundation within the scope of their innovative public / private partnership. ASAQ Winthrop® is particularly adapted to the needs of African patients, especially children, who are most vulnerable to malaria. Dosing is simple: one or two tablets once a day, depending on weight and age. This ease of use contributes to better patient compliance and helps reduce the phenomenon of drug resistance.

Since the prequalification by the WHO of ASAQ in October 2008 through the end of 2011, more than 120 million treatment units have been distributed in sub-Saharan Africa. This drug is manufactured and packaged at Sanofi's Maphar facility in Morocco.

#### Tiered pricing to help make medicines more affordable

Our antimalarial medication is sold according to a tiered-pricing policy consistent with applicable law that includes "no profit – no loss" prices to public organizations (such governments and



NGOs, the WHO, etc.). This price, which is less than one dollar to treat an adult and 50 cents for child, has become the standard reference price for new antimalarial drugs.

R&D alliances to meet future needs

### **Combating drug resistance: agreement with MMV**

Research aimed at developing to develop new treatments remains a priority due to the risk of emerging drug resistance.

Sanofi's malaria research program therefore includes several projects focused on uncomplicated as well as severe malaria, developed in collaboration with research institutions and university research programs.

In 2011, Sanofi entered into an agreement with Medicines for Malaria Venture (MMV) to conduct research on malaria treatments. Both parties will work to identify, characterize and optimize new candidate compounds to treat malaria and carry out early development programs where appropriate. The three-year research project agreement, "Orthology Malaria," aims to develop drug candidates from a set of Sanofi compounds that have been selected for their potential activity against malaria parasites. Each stage of the project will be evaluated by the Sanofi / MMV joint steering committee and assessed according to MMV's criteria for compound progression.

### **Developing drug monitoring capacity in malaria-endemic countries**

In close collaboration with the national malaria control programs in participating countries, Sanofi and DNDi have set up a field monitoring program to gather quality information about the safety and efficacy of our antimalarial agent. This initiative receives support from MMV. The program contributes to develop local expertise, particularly on pharmacovigilance, in line with the needs and resources of these countries.



treatments.

By joining forces with MMV in the search for innovative anti-malarial drugs, Sanofi strives to stay one step ahead in the fight against the malaria parasites that are beginning to show resistance to existing

**Dr. Elias Zerhouni**

President, Global Research & Development, Sanofi



◀ The development of new malaria medicines requires the existence of a generous cache of promising compounds of which only a handful will emerge as groundbreaking treatments, after a series of rigorous trials. Given the emerging threat of resistance to artemisinin in southeast Asia, we need to ensure we have alternatives in the medicine chest to fight this terrible disease. ▶▶

**David Reddy**  
CEO, Medicines for Malaria Venture

## Neglected tropical diseases

One billion people are at risk of or affected by tropical diseases that the international community considers to be “neglected diseases”. Very often, these diseases affect communities in remote rural areas, urban slums and conflict zones with poor living conditions and hygiene.

According to the WHO, neglected tropical diseases impair the lives of an estimated **1** billion people today.

▼ Background

▼ Policy

### Background

Neglected tropical diseases are very low on the list of international public health priorities and health agendas. These diseases are referred to as “neglected” because they are not mentioned in the United Nations Millennium Development Goals. Funding for research and development to find new treatments typically is limited given that the potential return on investment is either very small or nonexistent. Consequently, most of the medicines available today were developed years ago and are not always adapted to the needs of patients and caregivers. There is also a real risk that resistance to these treatments will develop, making them ineffective.

The support of endemic countries and increased awareness within the international community are fundamental factors to support the elimination and control of these diseases.

There are **149** countries and territories where neglected tropical diseases are endemic. At least **100** of them are endemic for **2** or more of these diseases.

For more information:

- [www.who.int / Neglected diseases](http://www.who.int/Neglected_diseases)

## Policy

Sanofi's commitment to neglected tropical diseases corresponds to the Group's corporate social responsibility as well as our expertise, developed since 1946 in the research and production of treatments for sleeping sickness and leishmaniasis.

Sanofi and the WHO have joined forces in the fight against neglected tropical diseases since 2001 and their collaboration continues to grow.

Since 2001, Sanofi has been working in collaboration with the WHO in a joint effort to combat sleeping sickness, leishmaniasis, Chagas disease and Buruli ulcer.

- **2001-2005:** An initial collaboration is formed to combat sleeping sickness.
- **2006-2010:** The collaboration is expanded to include other neglected tropical diseases: leishmaniasis, Buruli ulcer and Chagas disease.
- **2011-2016:** The collaboration is renewed for an additional five years with the goal of eliminating sleeping sickness and controlling leishmaniasis, Buruli ulcer and Chagas disease.

Since 2001, the Group contributed \$50 million in financial backing and donations of medicines.

Since 2001, Sanofi's contribution amounted to a total of USD \$50 million (financial backing as well as donations of three of the five medicines necessary for the treatment of sleeping sickness). One of the key features of our collaboration with the WHO is the donation of drugs used. This is because patients with sleeping sickness are among the most disadvantaged and treatments for the disease are expensive and complex to administer.

Sanofi's contribution has made it possible to provide treatment for 170,000 patients with sleeping sickness, which is fatal if left untreated. It has also contributed to improving the control of leishmaniasis, Chagas disease and Buruli ulcer.

In 2012, Sanofi entered into a new collaboration to join the WHO's existing program to eliminate lymphatic filariasis (commonly known as elephantiasis) by 2020. Sanofi engaged, together with the Bill & Melinda Gates Foundation and the Japanese pharmaceutical company Eisai, Sanofi committed to donate to make a donation of 120 millions tablets of diethylcarbamazine citrate (DEC) to the WHO, one half in 2012 and the other half in 2013.

### Developing new treatments and sharing intellectual property

Developing new treatments for neglected tropical diseases remains a key priority. In May 2011, Sanofi and the Drugs for Neglected Diseases initiative (DNDi) announced they entered into an innovative research collaboration agreement seeking to find new treatments for nine neglected tropical diseases (NTDs) listed by the WHO. New and effective therapies are urgently needed to treat patients in endemic countries. This agreement marked a new step in a history of successful collaboration between Sanofi and DNDi.

For more information:



[Sanofi and DNDi - Drugs for Neglected Diseases initiative - Sign an Innovative Agreement to Generate New Drugs](#) (PDF, 27Kb)

Also in 2011, Sanofi joined a new research consortium created to share expertise and speed up the development of new drugs. "WIPO Re:Search" is a consortium of public and private sector organizations that share certain knowledge and valuable intellectual property (IP) information with the global health research community with the goal of supporting the development of faster and more effective treatments to help fight neglected tropical diseases, malaria and tuberculosis in the developing world. The consortium was created at the initiative of the World Intellectual Property Organization (WIPO).

For more information:



[Leading Pharmaceutical Companies & Research Institutions Offer IP and Expertise for use in Treating Neglected Tropical Diseases as Part of WIPO Re:Search](#) (PDF, 633Kb)



« The intellectual property held by companies such as Sanofi obviously includes patents, but also technical know-how – the art behind the science. This includes drug discovery tools, expertise in areas such as toxicology or medicinal chemistry, not to mention countless other knowledge bases. This type of information is invaluable in accelerating the creation of new drugs, vaccines and diagnostics to help combat what are all too often fatal diseases. »

**Dr. Robert Sebbag,**  
Vice President, Access to Medicines, Sanofi

At the same time, because drugs alone are not enough, Sanofi has always emphasized the need for a comprehensive response to diseases. Screening and organization of information, education and communication programs are essential – in addition to treatments -- for bacterial and protozoan diseases like sleeping sickness, leishmaniasis, Chagas disease and Buruli ulcer, it is essential to provide screening and organize information, education and communication programs – in addition to treatments.

For more information: [The 2011 ATM Brochure](#)



[Brochure - Access to Medicines 2011](#) (PDF, 2739Kb)



« Through our collaboration with the WHO and our global approach to disease, we are at the forefront of the fight against neglected tropical diseases. Our ambition is to be involved in building long-term partnerships that will make it possible to achieve a lasting reduction in healthcare inequalities, in particular in the field of neglected tropical diseases. »

**Dr. Robert Sebbag,**  
Vice President, Access to Medicines, Sanofi

## Sleeping sickness

Sleeping sickness (Human African trypanosomiasis, or HAT) is a parasitic disease transmitted by the bite of an infected tse-tse fly. It affects mostly poor populations living in remote rural areas of sub-Saharan Africa. Left untreated, sleeping sickness is generally fatal.



Over the last ten years, the success of the partnership between the WHO and Sanofi for the treatment of sleeping sickness, which has made it possible to treat over 170,000 patients, is a marvelous illustration of what can be accomplished when the complementary skills of two key healthcare actors are combined.

**Dr. Jean Janin,**  
Coordinator, Intensified Disease Management, Department of Neglected Tropical Diseases

Sanofi receives CSR award for the Group's contribution to the fight against sleeping sickness

For the second year in a row, Sanofi received an excellence award for our campaign to combat sleeping sickness in collaboration with the WHO. Entitled "Human African Trypanosomiasis – Not Neglected by Sanofi," this campaign was praised by the jury for its ambition and clear impact. The number of patients treated for sleeping sickness has dropped by over 60% since the campaign was launched in 2001.

For the first time, the stage has been set for the potential elimination of sleeping sickness, a prospect that was unthinkable just ten years ago. This corporate responsibility award was presented at the *Pharmaceutical Marketing Excellence Awards Ceremony* in London in November 2011.

Committed to providing treatments for sleeping sickness – as long as needed

Five medicines are available to treat sleeping sickness. Sanofi manufactures three of them (pentamidine, eflornithine and melarsoprol) and provides them to the WHO at no cost, within the scope of their collaboration.

The Group is committed to providing drugs for the treatment of sleeping sickness for as long as necessary. In addition, Sanofi is collaborating with the Drugs for Neglected Diseases Initiative (DNDi) in an effort to develop a promising new oral treatment to replace complex and often poorly tolerated treatments with a simpler drug. If this new drug is safe and effective, it will make patients' lives much easier.

#### Continued downward trend in the number of new cases

Reported new cases fell from 30,000 in 2001 to less than 7,200 in 2010  
Source WHO

Since 2001, more than 170,000 patients have received treatment for sleeping sickness. Thanks to improved detection and disease management, the annual number of patients being treated fell below the symbolic number of 10,000 in 2009 for the first time in 50 years. Moreover, this decrease has continued, with 7,139 new cases reported in 2010.

#### Support for mobile medical teams

Through our collaboration, the WHO organizes training for personnel from national sleeping sickness programs in several countries. Training focuses on the administration and optimum utilization of Human African trypanosomiasis (HAT) treatments.

Mobile medical teams that provide diagnosis and treatment have greatly contributed to decreasing the number of new cases of sleeping sickness. Because this disease affects patients living in remote areas, these mobile teams are specially trained and equipped to detect the disease and to manage treatment. Their goal is to help provide screening and diagnosis at the earliest stage possible. If sleeping sickness is not treated, it is always fatal, whereas if treatment is administered during the first stage of illness, the patient's life can be saved.

Patients who are diagnosed with stage 1 sleeping sickness can be treated in the village by the local healthcare professional. Those who are diagnosed with stage 2 of the disease are taken for treatment to the nearest hospital, which may be several hours away by car or boat.



## BUSINESS CASE



### Putting sleeping sickness on the road to elimination

To meet the challenge of combating sleeping sickness, Sanofi has been very active in a continuously renewed collaboration with the WHO for the last 11 years. Their collaborative efforts have made a clear impact and are being applied to other neglected tropical diseases (NTDs). In addition to the benefits for patients, this collaboration gives Group employees a sense of pride and distinguishes Sanofi as a full-fledged ally in the fight against NTDs.

- Business case: Sleeping Sickness



Sanofi is committed to bringing therapeutic solutions to those most affected and exposed to neglected tropical diseases. In this new research collaboration with DNDi, we have taken a firm step towards greater flexibility in the sharing of knowledge to produce new medicines.

**Dr. Elias Zerhouni,**  
President, Global Research & Development, Sanofi

## Leishmaniasis

Leishmaniasis is caused by protozoan parasites and transmitted by the bite of infected sand flies. It exists in two forms, a visceral form, affecting notably the liver and spleen, and a cutaneous form, affecting the skin. It is estimated that 1.6 million new cases occur annually.

**1.6** million  
new cases each  
year  
Source WHO

### The challenge of a complex disease

Sanofi's commitment to combating leishmaniasis takes several forms:

- A collaboration with the WHO since 2006 to improve epidemiological surveillance and treatment centers for this disease, especially in the Middle-East region
- Providing meglumine antimoniate for developing countries at a single, discounted price consistent with local law: 4 million vials were sold at discounted prices in developing countries in 2011
- Forming research collaborations seeking to find new treatments that are better adapted to patients' needs
- Funding the full publication of a work by Dr. Pierre Buffet about leishmaniasis therapy, which is available in 6 languages (English, French, Spanish, Portuguese, Arabic and Farsi)
- A partnership with the Oswaldo Cruz Foundation to improve the diagnosis and the effectiveness of treatment in the Bernambuc region of Brazil

## Buruli ulcer

Buruli ulcer is a chronic necrotizing skin disease caused by infection with a mycobacterium, which may lead to extensive destruction of the skin and soft tissues, usually on the arms or legs.

### Moving towards earlier, simplified treatment

This disease has been reported in over 33 countries, primarily located in sub-Saharan Africa. Although a vast majority of the 5,000 patients reported to have the disease each year live in West Africa, there are also small outbreaks in Australia. Most African patients are children under the age of 14.

Early diagnosis and treatment with antibiotics can prevent the appearance of large ulcers, which take long periods to heal and may require hospitalization.

### **Sanofi has implemented a tiered pricing policy for Rifampicin, an antibiotic, consistent with applicable law**

Through our collaboration with the WHO, we are working to facilitate earlier treatment of the disease and develop antibiotic therapy that is only administered orally.

The Sanofi Espoir Foundation partners the NGO handicap International in Togo and Benin to fight Buruli Ulcer. The actions on the ground and supports of the countries Ministry of Health and local stakeholders involve community awareness-raising, training health professionals, the detection and early management of patients, and rehabilitating those with disabilities.

## Chagas disease

Chagas disease, which is also called American Trypanosomiasis, is a parasitic chronic infection transmitted by the fecal matter of a bug, the triatome. This disease affects 10 million people worldwide, especially in Latin America, but due to mass migration, patients are found today outside of traditional endemic areas. In the chronic phase of the disease, 30% of patients will develop cardiac disorders.

Chagas disease -  
10 million  
patients  
worldwide

Through our collaboration with the WHO, Sanofi contributes to developing epidemiological surveillance of Chagas disease in Europe.

New treatments are necessary, and Sanofi is forming research collaborations for this purpose. In December 2011, Sanofi entered into an agreement with CONICET, Argentina's National Scientific and Technical Research Council, to join a collaborative effort with the goal of developing that may lead to a new drug to treat Chagas disease, in addition to the development of innovative diagnostic methods. According to the terms of the agreement, Sanofi will provide the CONICET scientific team more than 300 molecules, which are property of the Group, to be tested in the experimental model they have designed so that potential clinical development may begin.

## Business case

### The challenge

Contribute to the effort to eliminate sleeping sickness, a parasitic disease that is fatal if left untreated.

### Our response

Human African trypanosomiasis, or sleeping sickness, affects mostly poor populations living in remote rural areas of sub-Saharan Africa. In 2001, when the availability of drugs to treat this disease was seriously endangered, Sanofi and the World Health Organization (WHO) entered into a unique collaboration. Since the beginning of their collaboration, which was renewed in 2006, Sanofi has provided over 1.5 million vials of medicines and more than 170,000 patients have received treatment.

Sanofi manufactures three of the five drugs that may be prescribed to treat this disease. Two of them, eflornithine and melarsoprol, are produced solely for the treatment of sleeping sickness, and Sanofi is the only company that makes them.

In 2006, the WHO/Sanofi collaboration was expanded to include other neglected tropical diseases. Sanofi contributes the Group's expertise in manufacturing and research, as well as financial support, with the aim of eliminating neglected tropical diseases such as sleeping sickness.

### Benefits for stakeholders

For patients: Since 2001, more than 30 million people have been screened for sleeping sickness, and over 170,000 patients have received life-saving treatment free of charge.

Thanks to initiatives such as this one, the annual incidence of sleeping sickness has decreased by over 60% in less than ten years. In 2009, the total number of reported cases was below 10,000 for the first time in more than 25 years. This downward trend continues.

For local health authorities: Because national health programs to curb sleeping sickness have had logistical supplies, diagnostic tools, and drugs to help them carry out their mission successfully, the burden of sleeping sickness has been greatly reduced. Today only two countries report more than 1,000 cases per year.

For the WHO:

With the ongoing success of the program to combat sleeping sickness, the WHO has demonstrated its leadership and ability to coordinate the work of many essential allies: health authorities, NGOs, international aid programs, academia and pharmaceutical companies.

#### Opportunities for the Group

For Sanofi employees, knowing that their company is playing a leading role in the effort to eliminate longstanding and potentially fatal neglected tropical diseases is a source of great pride. In addition, Sanofi is today recognized as a full-fledged collaborator in the fight against neglected tropical diseases.

#### The future

In March 2011, Sanofi renewed the collaboration with the WHO for a third five-year term. The Group continues to be committed to providing drugs for the treatment of sleeping sickness. In addition, Sanofi is collaborating with the Drugs for Neglected Diseases initiative (DNDi) to work towards developing a promising new oral treatment that potentially could replace complex and often poorly tolerated treatments with a simpler drug. If this new drug is safe and effective, it will make treatment much easier for patients.

Also in 2011, Sanofi announced a three-year research collaboration agreement with DNDi for research on new treatments for nine neglected tropical diseases listed by the WHO, including sleeping sickness.

## Tuberculosis

### Background

Along with HIV / AIDS and malaria, tuberculosis is one of the most widespread infectious diseases in the world. This contagious disease, caused by the bacterium *Mycobacterium tuberculosis*, is spread through respiratory droplets.

- 9.4 million new cases in 2009, including 1.1 million among people living with HIV / AIDS
- 1.7 million victims in 2009, the vast majority of them in developing countries

### **The challenge: simplify treatment and fight resistant strains**

Standard treatment for tuberculosis consists of a combination of antibiotics taken daily, usually for six months: two months of treatment with four antibiotics, followed by four months with two antibiotics.

When administered properly, the treatment for tuberculosis generally is highly effective. However, for many patients it is difficult to comply with six months of treatment. Poor compliance not only puts the patient at risk of treatment failure, it also creates conditions that encourage the development of antibiotic-resistant bacteria.

Since the early 1990s, the WHO has recommended a strategy known as DOTS (Directly Observed Therapy, Short-course treatment). This strategy relies on having healthcare personnel who can support and monitor patients, to ensure that they take their entire course of treatment. This approach is costly, however, and efforts are needed to simplify tuberculosis treatment.

Strains of *Mycobacterium tuberculosis* that are resistant to conventional treatments have begun to appear. In 2008, they caused 440,000 new cases of tuberculosis and 150,000 deaths. It is crucial to stop the progression of resistance and to develop new treatments.

**For more information:** (Source: WHO)

- [www.who.int / topics / tuberculosis](http://www.who.int/topics/tuberculosis)

## Prevalence of tuberculosis



Estimated TB incidence rates, by country, 2009  
Estimated new TB cases (all forms) per 100,000 population

0 - 24    25 - 29    50 - 99    100 - 299     $\geq 300$

Source: World Health Organisation (WHO)



## Policy

Sanofi was the very first company to manufacture rifampicin and remains one of the key producers of this basic component in all tuberculosis treatments. Several of the Group's manufacturing facilities have developed and currently produce a range of antibiotics to treat tuberculosis, which are distributed in many countries.

Rifampicin, a key antibiotic for the treatment of tuberculosis, was isolated in 1959 by scientists at Lepetit Research Laboratories in Milan (Italy), now part of the Sanofi Group.

Building on the strength of the Group's experience, Sanofi introduced a program of industrial optimization and development designed to expand our product range and offer products that are better adapted, at lower cost, which is expected to improve access to treatment for as many patients as possible. This program is based essentially on existing production capacities in South Africa.

In 2011, rifapentine, a member of the rifamycin family, was shown by teams of scientists led by the U.S. Centers for Disease Control and Prevention to have the ability of considerably simplifying the treatment of latent tuberculosis.<sup>1</sup> The proposed development of rifapentine may create the prospect of simpler and shorter tuberculosis treatments, with the aim of improving patient compliance.

<sup>1</sup>Ref: Sterling TR, Villarino ME, Borisov AS, et al. Three months of once-weekly rifapentine and isoniazid for M. tuberculosis infection. N Engl J Med 2011;365:2155–66.

## Actions

- ▼ Tuberculosis treatment solutions
- ▼ In R&D, sharing information to speed up the development of TB drug combinations
- ▼ Fighting tuberculosis in the slums of Mumbai, India

### Tuberculosis treatment solutions

#### **Rifampicin, discovered in 1959**

Rifampicin, a key antibiotic for the treatment of tuberculosis, was isolated in 1959 by scientists at Lepetit Research Laboratories in Milan (Italy), now part of the Sanofi Group. Sanofi is one of the world's primary producers of rifampicin as well as of fixed-dose combinations of antibiotics used to treat tuberculosis.

#### **Simplifying tuberculosis treatment**

Fixed dose combinations of drugs can greatly simplify TB treatments. In addition to developing such combinations, our current efforts are focused on endeavoring to simplify and shorten the course of treatment for non-resistant tuberculosis.

#### **Sanofi has implemented a tiered pricing policy for Rifampicin, an antibiotic, consistent with applicable law**

Through our collaboration with the WHO, we are working to facilitate earlier treatment of the disease and develop antibiotic therapy that is only administered orally.

#### **Finding solutions with our collaborators**

The development of the potential new antibiotic belonging to the rifamycin family is carried out in close collaboration with the Centers for Disease Control and Prevention in Atlanta (United States), which coordinates an international group of researchers and clinicians.

Sanofi's Access to Medicines Department also collaborates with the TB Alliance in efforts to discover new medicines and conduct research for the development of potential treatment combinations.

Taking a more long-term perspective, one of the Group's R&D units is working to identify potential new medicines that may be effective against all forms of tuberculosis, including multi-resistant forms.

In South Africa, we are working with the Ministry of Health and the Nelson Mandela Foundation through the “TB Free” initiative to organize DOTS (Directly Observed Treatment Short Course) centers and train DOTS supporters.

In R&D, sharing information to speed up the development of TB drug combinations

In 2011, Sanofi joined other pharmaceutical companies to share information about TB drugs in development within their respective pipelines, with the aim of more quickly identifying the most promising TB drug regimens. This cooperative endeavour will also may identify new regulatory pathways and other tools needed to speed up the delivery of dramatically improved treatments to TB patients worldwide.

Many collaborators are involved in the “Critical Path to TB Drug Regimens” (CPTR) initiative, which brings together the world’s leading pharmaceutical companies with regulatory agencies and civil society organizations (i.e. non-governmental organizations, academia and private sector organizations) to expedite the testing of promising TB drug regimens. By sharing data, drug companies will be able to identify opportunities to test compounds in combination, accelerating the availability of future TB regimens.



Through this one of a kind initiative, we have the potential to make a real difference in the lives of patients suffering from TB. This is an exciting example of pharma players collaborating within and outside the industry, to contribute their best assets for the benefit of the wider society.

**Dr. Elias Zerhouni, President,**  
Global Research & Development, Sanofi

Fighting tuberculosis in the slums of Mumbai, India

The Sanofi Espoir Foundation supports a program organized by Inter Aide, an NGO, to help health authorities and local stakeholders reduce the economic impact and risk of tuberculosis infection in the slums of Mumbai. In these poor, densely populated neighborhoods, TB is one of the primary causes of mortality as well as disability and unemployment. The program provides capacity for public health centers to improve care and patient monitoring, reduce regimen non-compliance, and improve the cure rate. The teams visit private doctors in slums to encourage them to send their patients to public or association-based centers where treatment may be given free of charge. They set up centers to deliver DOTS (Directly Observed Treatment Short Course) inside the slums. In addition, awareness campaigns alert people about the risks of this disease.

For more information:

- [www.fondation-sanofi-espoir.com / Inter-aide](http://www.fondation-sanofi-espoir.com / Inter-aide)

## Access to vaccines

### Background and policy

According to the World Health Organization, vaccination provides protection against more than 26 infectious diseases today. With our vaccines affiliate, Sanofi Pasteur, the Group has the broadest available range of vaccines, protecting against 20 infectious diseases.

Vaccines save more than three million lives each year, but more than three million people still die due to a lack of access to existing vaccines. This may be due to reasons including weak health systems, conflict, or the cost of vaccine administration.

In response to this major public health challenge, Sanofi Pasteur's commitment to promote and facilitate access to vaccination is lived out each day. The Group strives to make vaccines that are accessible to as many people as possible, everywhere in the world.

## Actions

- ▼ Forging collaborations to prevent disease
- ▼ Applying a tiered pricing policy
- ▼ Investing in production capacity
- ▼ Helping develop healthcare infrastructure and improving awareness about immunization

### Forging collaborations to prevent disease

Due to reasons such as the cost of vaccine administration, weak health systems and, in some cases, conflict, many people living in the world's poorest countries do not have access to vaccines. To supply vaccines where there is widespread need, Sanofi Pasteur has formed ongoing collaborations with a number of international organizations including the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the World Bank, the Bill and Melinda Gates Foundation, the Red Cross and Rotary International. To respond to patients' needs, the Group has developed flexible solutions and implemented differentiated pricing policies, consistent with applicable law.

Each year, Sanofi Pasteur supplies nearly 300 million doses of vaccines to UNICEF and other international organizations.

### The Global Alliance for Vaccines and Immunization (GAVI)

The GAVI Alliance was founded in 2000 by the Bill & Melinda Gates Foundation, the World Bank, the WHO, UNICEF and vaccine manufacturers, including Sanofi Pasteur. Committed to saving children's lives and protecting people's health through the widespread use of vaccines, GAVI's driving objective is to make a critical contribution to global immunization goals by supporting immunization programs and health systems, and accelerating the introduction of new vaccines.

Sanofi Pasteur shares GAVI's objectives to improve the infrastructures required for effective vaccine administration and to encourage research and development programs focused on diseases that predominantly affect developing countries.

Between 2000 and 2011, programs within the GAVI Alliance made it possible to immunize 326 million children, which represent 5.5 million lives saved. (Source: Gavi Alliance website)

Sanofi Pasteur and the GAVI Alliance members have organized a major initiative designed to contain the risk of yellow fever epidemics. Since 2003, the Group has provided more than six

million doses per year of yellow fever vaccine funded by GAVI to go towards emergency stockpiles of vaccines, in order to help prevent epidemics in Africa.

For more information:

- [Yellow fever](#)

The Global Polio Eradication Initiative (GPEI)

The Global Polio Eradication Initiative, which is spearheaded by certain national governments, the WHO, Rotary International, the United States' Centers for Disease Control and Prevention (CDC) and UNICEF, is the largest public health initiative the world has ever known. Since 1988, some two billion children around the world have been immunized against polio thanks to unprecedented cooperation by more than 200 countries and 20 million volunteers, backed by an international investment of USD \$3 billion.

- In 2011, Sanofi Pasteur **supported Polio Eradication at First International Stock Exchange Event**. Shoulder to shoulder with Rotary International we participated in the first international bell-ringing event by a company listed on NYSE Euronext. The events acknowledged past successes and future challenges in the battle to eradicate polio at the stock exchanges in New York, Paris, Brussels, Amsterdam and Lisbon.
- In September 2011 Sanofi Pasteur donated the vaccine strain used for polio eradication to the WHO. The biological material given to the World Health Organization is the original viral seed used to produce large quantities of oral polio vaccines (OPV) against type 3 poliovirus, provided free of charge by Sanofi Pasteur to polio vaccine manufacturers worldwide for the last 30 years. With this donation, WHO will be in full control of the storage of the vaccine strain and its distribution to vaccine producers worldwide.

Sanofi Pasteur is the principal corporate donor to the GPEI. Thanks to this initiative, an estimated five million people have avoided contracting polio-related paralysis.

For more information:

- [Polio](#)

Sanofi Pasteur and Handicap International celebrate 20 years of solidarity

## 20 years of Solidarity in Figures

In December 2011, Sanofi Pasteur France and the NGO Handicap International celebrated a unique alliance formed 20 years ago to coordinate the humanitarian efforts of Sanofi Pasteur's various sites in France. This solidarity partnership, which has grown stronger over the years, includes a sponsorship program through which employees' contributions are matched by Sanofi Pasteur.

- Nearly 5 million doses of vaccines distributed
- Over 300 Sanofi Pasteur employees make monthly donations to Handicap International
- Programs in 29 countries: Kenya, Haiti, Madagascar, the Philippines, Rwanda, etc.
- Sponsorship of 18 health coordinators working primarily on HIV/AIDS projects in Kenya
- Nearly €4 million to develop Handicap International programs thanks to employees' donations, matched by Sanofi Pasteur, as well as the contributions of Sanofi and the corporate foundation Sanofi Espoir

Handicap International is an independent international aid organization working in situations of poverty and exclusion, conflict and disaster to meet the essential needs and improve the living conditions of disabled and vulnerable persons. Since 1982, the organization has set up programs in over 60 countries and works in emergency situations. Handicap International takes action and speaks out wherever "standing on your own two feet" is easier said than done.

For more information about this organization:

- [www.handicap-international.fr / Discover Handicap International](http://www.handicap-international.fr / Discover Handicap International)



The longevity of this partnership is unique in France, perhaps even in Europe. Based on a solid, intelligent alliance, today it continues

to provide the right answers and demonstrates a willingness to keep taking a 'non-business' approach when it comes to helping those most in need.

**Dr. Jean-Baptiste Richardier,**  
Executive Director, Handicap International

### Applying a tiered pricing policy

Sanofi Pasteur has historically applied a tiered pricing policy, consistent with applicable law, to facilitate access to vaccines for countries that are eligible for programs organized by GAVI. We practice a tiered pricing policy that meets countries' needs according to different levels of development. The goal is to help make vaccines more affordable and accessible to people in all countries, regardless of their level of economic development.

In June 2011, following GAVI's first pledging conference in London, Sanofi Pasteur announced our commitment to maintain GAVI prices to the 16 countries that are expected to exit GAVI, including Bolivia, Honduras, Angola, Congo, Bhutan, Indonesia, and Sri Lanka. Our goal is to help these countries remain able to maintain immunization programs. This pricing policy will apply to all Sanofi Pasteur and Shantha vaccines currently included in GAVI immunization programs: yellow fever vaccine, Shan5® pediatric combination, and Shantha's potential rotavirus vaccine currently under development.

In 2011, WHO prequalification for three Sanofi Pasteur vaccines

Each year, Sanofi Pasteur provides nearly 300 million doses of vaccines to UNICEF and other international organizations

WHO prequalification is a key step that allows for the procurement of vaccines by UNICEF and other United Nations agencies like the Pan American Health Organization (PAHO) Revolving Fund. It is also a prerequisite for GAVI Alliance New and Underused Vaccines Support for vaccine distribution, ensuring and improving developing countries' access to vaccines that meet standards of quality, safety and efficacy.

In 2011, three of our vaccines were added to the list of WHO prequalified vaccines:

- Typhim Vi® polysaccharide typhoid vaccine, the first WHO prequalified typhoid fever vaccine. This serious disease affects the lives of millions of individuals each year, particularly



- in the most impoverished countries. The WHO prequalification will facilitate global access to vaccine for the prevention of typhoid fever among the most vulnerable populations around the world.
- Shanchol, our cholera vaccine produced by Shantha, indicated for age one year and older. Shanchol is a ready-to-use oral vaccine, which facilitates its implementation in large immunization programs for developing countries.
- Vaxigrip®, our seasonal influenza vaccine. The WHO designation is an acknowledgement of our efforts to provide developing countries with sustainable access to high-quality standard influenza vaccines. With more than 60 years of experience and over 1one billion doses supplied since launch, Vaxigrip® and Fluzone® vaccines have established a longstanding safety and seroprotection track record. Today, Vaxigrip® is the most widely used seasonal flu vaccine in the world with over 100 million doses distributed annually in more than 150 countries.

In 2011, 3 Sanofi Pasteur vaccines were added to the WHO list of prequalified vaccines:

- Typhim Vi® polysaccharide typhoid vaccine
- Shanchol cholera vaccine
- Vaxigrip® seasonal flu vaccine

Investing in production capacity

#### **Sanofi Pasteur invests to meet local public health needs:**

- Several hundred million Euros have been invested to increase the Group's production capacity, particularly in Mexico, France, the United States and China.
  - Influenza
- The acquisition of Shantha Biotechnics in India, which was finalized in July 2009, illustrates the Group's goals: Shantha Biotechnics develops, manufactures and sells several different

- pediatric vaccines, making it possible to produce vaccines that are adapted to meeting emerging countries' needs.

Helping develop healthcare infrastructure and improving awareness about immunization

In addition to producing vaccines, Sanofi Pasteur strives to promote vaccination in Africa through cooperation and education. Specifically, the Group aims to meet the needs of the most disadvantaged groups. Supported by Sanofi Pasteur, the EPIVAC and PREVAC Plus programs work towards this goal.

#### EPIVAC: Building healthcare infrastructure

The EPIVAC program is a Sanofi Pasteur contribution to the GAVI Alliance. Implemented by the Preventive Medicine Agency (AMP), the program was developed in conjunction with the national governments of eligible countries and participating universities (Cocody-Abidjan in Côte d'Ivoire and Paris-Dauphine in France), in collaboration with the WHO, UNICEF, GAVI and others working in Africa.

The EPIVAC program has been introduced in 11 Central and Western African countries.

The objective of the EPIVAC program is to train doctors involved in the implementation of immunization programs in 11 Central and West African countries. The training teaches them about vaccine organization and management in some of the poorest regions of the globe, and includes basic programs on epidemiology, applied computing, vaccinology, and management of health programs. Participating doctors receive a diploma at the end of their training.

Since 2002, nearly 400 doctors have been trained and certified through the EPIVAC program.

Since 2002, nearly 400 physicians have attended the program and earned a diploma.

#### PREVAC Plus: Practical training in vaccinology

PREVAC Plus is a pilot program launched in 2009 in Cameroon to provide practical training in vaccinology. Sponsored by Sanofi, the program was implemented by the University of Buea with the support of the Ministry of Health. Originally designed for nurses, in 2010 it was expanded to include pediatricians and general practitioners. Training is currently provided by a group of experts who attended the first classes and are able to teach their peers, based on a pyramid system of training the trainers.

In 2011, nine training sessions in vaccinology “PREVAC Plus” were held in five countries of West Africa and Central Africa, during which a total of 256 healthcare professionals were trained. Below is the number of people trained per country and by profession.

| Countries    | Côte d'Ivoire | Gabon     | Burkina Faso | Senegal   | Togo      | TOTAL      |
|--------------|---------------|-----------|--------------|-----------|-----------|------------|
| Doctors      | 74            | 30        | 23           | 27        | 25        | 179        |
| Nurses       | 42            | 0         | 35           | 0         | 0         | 77         |
| <b>TOTAL</b> | <b>116</b>    | <b>30</b> | <b>58</b>    | <b>27</b> | <b>25</b> | <b>256</b> |

For more information:

- GAVI Alliance website: [www.gavialliance.org](http://www.gavialliance.org)
- The Global Polio Eradication Initiative website: [www.polioeradication.org](http://www.polioeradication.org)
- The EPIVAC website: [www.epivac.org](http://www.epivac.org) (in French)

## Polio

### ▼ Background

### ▼ Policy

## Background

Poliomyelitis, more commonly known as polio, is a contagious disease caused by three different serotypes of poliovirus (types 1, 2 and 3). Transmission is human-to-human (primarily fecal-oral), which means that polio eradication is possible. Most people who are infected present no symptoms and there is no specific treatment. However, in some cases, polio may cause incapacitating paralysis and death.

As no treatment is available, vaccination is essential. Two vaccines are used to prevent polio:

- The injectable polio vaccine, made from inactivated virus (IPV, discovered by Jonas Salk)
- The oral polio vaccine, made from live attenuated virus (OPV, discovered by Albert Sabin)

After smallpox, polio is the second infection projected for worldwide eradication. The Global Polio Eradication Initiative – spearheaded by the WHO and based on collaboration between the WHO, UNICEF, the CDC and Rotary International – has been underway since 1988. Sanofi Pasteur has been a partner in the Global Polio Eradication Initiative since its inception.

Since the Global Polio Eradication Initiative (GPEI) was first launched by the WHO in 1988, the number of cases of polio has plummeted (down 99 percent).

Sanofi Pasteur is a longstanding partner in the Global Polio Eradication Initiative launched by the WHO in 1988

Polio is endemic in three countries today (Nigeria, Afghanistan and Pakistan) and the infection has reappeared in several countries. The disease is no longer endemic in India, which used to be the epicenter of polio. As of January 13, 2012, India completed one full year without any reported cases of polio, a clear indication of the impact of polio eradication efforts.

**For more information:** The Global Polio Eradication Initiative

- [\*The Global Polio Eradication Initiative website\*](#)

## Policy

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, both oral (OPV) and enhanced injectable (eIPV) form. For the worldwide polio eradication initiative led by the World Health Organization (WHO) and UNICEF, Sanofi Pasteur provides both OPV and eIPV vaccines.

A critical next step will be the policy recommendation for IPV use after and even possibly before eradication. This turning point in the eradication policy is only conceivable due to Sanofi Pasteur's investments to ensure an adequate worldwide supply of IPV.

**For more information** on our efforts to eradicate polio, see the attached videos titled "Sanofi Pasteur's Contribution to Polio Vaccines and Polio Eradication":

- [\*www.vaccimedia.fr / Video\*](http://www.vaccimedia.fr / Video) (in English)

## Actions

An active collaborate in efforts to eradicate polio

Sanofi Pasteur has been deeply committed to GPEI right from the start. Today the challenge for Sanofi Pasteur is to continue to play a decisive role in eradicating the disease. The Group shares its expertise with health authorities to develop specific vaccine formulations that are adapted for certain regions of the globe. While the standard OPV (oral polio vaccine) contains three strains of the virus, Sanofi Pasteur continues to contribute to the eradication of the disease by manufacturing mono and bivalent oral vaccines to combat virus types 1 and 3 at the request of the WHO for specific situations.

In response to a request from UNICEF, Sanofi Pasteur recently committed to supply 400 million doses of polio vaccine in 2011 and 2012 for developing countries.

Sanofi has committed to supplying more than **400 million doses** of vaccines for use in developing countries in 2011 and 2012.

We are convinced that IPV has a vital role to play both before and after eradication. Achieving flexibility and boosting our production capacities is at the center of our strategy. We have invested €100 million over a five-year period to expand our production capacities to meet this need and support countries prepared to adopt the IPV. A more widespread use of the vaccine will be aided by local partnerships with the goal of giving every child access to the inactivated vaccine. IPV is available alone to prevent one disease (polio), or in combination with other pediatric formulations to confer protection against several diseases.

IPV is available alone to prevent one disease (polio), or in combination with other pediatric formulations to confer protection against several diseases.

As one of the world's leading developers and manufacturers of polio vaccines – both oral and injectable – Sanofi Pasteur is a key industrial stakeholder due to our production capacity and the quality of our vaccines.

In 2011, Sanofi continued to ensure the largest access to polio immunization and contributed to polio eradication efforts:

- by continuing to provide the most efficient OPV vaccines responding to the eradication needs
- through our readiness to respond to polio vaccination needs in a post eradication world

**On August 2, 2011, our bivalent oral vaccine (bOPV) received WHO prequalification**

At the request of the WHO, Sanofi Pasteur has developed a bivalent oral vaccine to combat poliomyelitis types 1 and 3 – the type 2 wild virus is no longer in circulation. WHO prequalification was granted this vaccine is an important addition to the type 1 trivalent and monovalent oral vaccines already prequalified by the WHO.

See video:

- [www.vaccimedia.fr / Video OMS Polio](http://www.vaccimedia.fr / Video OMS Polio)

In **2011**, Sanofi Pasteur donated the vaccine strain used for polio eradication to WHO.

**In September 2011 Sanofi Pasteur donated the vaccine strain used for polio eradication to the World Health Organization.** The biological material given to the World Health Organization is the original viral seed used to produce large quantities of oral polio vaccines (OPV) against type 3 poliovirus, provided free of charge by Sanofi Pasteur to polio vaccine manufacturers worldwide for the last 30 years. With this donation, the WHO will be in full control of the storage of the vaccine strain and its

distribution to vaccine producers worldwide.

In **2011**, Sanofi Pasteur donated to the WHO the vaccine strain used in the production of oral polio vaccines against type **3** poliovirus. The WHO is in full control of the vaccine strain and will distribute it to vaccine manufacturers.

**In Brazil**, Sanofi joined forces with Fiocruz to **include Imovax® Polio** the inactivated polio vaccine (IPV) to Brazil's national immunization program. Formulation, filling and packaging will all take place in Brazil. The introduction of IPV in the largest South American country is a critical marker, South America entering the Post Eradication Era.

**In Japan**, in response to medical needs, the Group will develop a standalone inactivated polio vaccine (IPV). To date, live attenuated oral polio vaccine (OPV) has been successfully used to immunize against polio in this country. Sanofi Pasteur is developing a combination vaccine for potential use in Japan containing diphtheria, pertussis and tetanus vaccines and IPV. The Kitasato Institute and Sanofi Pasteur have also joined forces to produce a quadrivalent pediatric vaccine (tetanus, diphtheria, pertussis, polio).

**In India**, the Group won the tender when the country's public polio vaccine market was opened to foreign companies (traditionally it was open only to local producers and UNICEF) in order to meet the needs of the population rapidly and on a large scale.

Since 1988, we have distributed 10 billion doses of OPV through UNICEF



## Yellow fever

### Background

#### Disease and symptoms

Yellow fever is a viral hemorrhagic fever transmitted by infected mosquitoes.

Following an incubation period of about one week, infection begins with fever, shivering, muscle pain and headache. The symptoms of yellow fever can be confused with influenza, dengue fever and malaria. In severe or toxic forms of yellow fever, after three days the patient experiences an initial remission followed by hemorrhagic syndrome with vomiting. Blood appears in vomit, jaundice occurs (giving the disease its name), and kidney functions deteriorate. People who have a curable form of the disease remain immune for life.

There is no specific treatment for yellow fever.

#### A resurgent disease: Epidemiology and vaccination

The WHO estimates that there are 200,000 cases of yellow fever each year, causing 30,000 deaths. The disease also represents a significant risk for the more than three million travelers who visit yellow fever endemic areas each year.

Although yellow fever immunization campaigns have proven their effectiveness over the last 60 years, this disease remains a major concern in tropical regions of both Africa and South America. In countries at risk for yellow fever, the vaccine is recommended to prevent and contain epidemics. In order to prevent an epidemic, at least 60% to 80% of the population must be immunized against yellow fever.

The vaccine is also recommended for travelers who visit regions at risk for the disease.

### Policy

For 60 years, Sanofi Pasteur, the vaccines division of Sanofi, has been active in combating yellow fever with more than 200 million doses of yellow fever vaccine supplied over the last 20 years. Sanofi Pasteur, which has significantly increased its production capacity, is the primary supplier of yellow fever vaccines in Africa.

## Actions

### Containing epidemics

The Global Alliance for Vaccines and Immunization (GAVI) is a public / private partnership created to facilitate access to vaccines for children in the world's poorest countries.

Since 2003, Sanofi Pasteur has provided most of the annual six million doses of yellow fever vaccines to build emergency stockpiles of vaccines funded by GAVI to control epidemics in Africa.

In addition, redesigned packaging of the yellow fever vaccine has facilitated the implementation of mass immunization campaigns.

### Participating in the development of health infrastructure and teaching about immunization

To promote vaccination in Africa through cooperation and education, Sanofi Pasteur supports the EPIVAC and PREVAC Plus programs.

EPIVAC trains doctors who help organize immunization programs – including for yellow fever – in 11 Central and West African countries. The training teaches them about the organization and management of vaccination initiatives to improve access to vaccines in the poorest regions of the world. Such training provides valuable support and facilitates the success of wide-scale immunization campaigns. Participants receive a diploma at the end of their training.

For more information:

▼ [Epivac and Prevac in Access to Vaccines](#)

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## Influenza

### Background and Policy

Influenza is a highly contagious, acute viral respiratory infection. The influenza virus is characterized by a high degree of variability. Depending on the degree of genetic mutation a virus undergoes compared to previous years, the population may be more or less protected, and the intensity of epidemics consequently varies from one year to the next. The flu virus represents a genuine public health challenge because it spreads so easily and mutates so quickly. The rapid speed at which influenza is transmitted worldwide has considerable economic repercussions: hospitalizations, healthcare costs, loss of productivity.

The influenza vaccine remains the best way to prevent the disease today. Given our expertise in helping to control the spread of influenza, Sanofi Pasteur is an essential player in efforts to manage an influenza pandemic, and combating influenza is one of our top priorities.

Sanofi Pasteur is the world's largest producer of seasonal influenza vaccine, with more than 200 million doses produced in 2011.

As the world's largest producer of seasonal influenza vaccine, with more than 200 million doses produced in 2011, Sanofi Pasteur steadily increases production capacity to help control influenza and innovates to offer new flu vaccines that are adapted to people's needs.

## Actions

- ▼ [Stepping up production capability](#)
- ▼ [Continually innovating to develop new vaccines that meet today's needs](#)

### Stepping up production capability

Since 2003, Sanofi Pasteur's production capacity has grown by more than 40%. We inaugurated two new influenza vaccine production sites in 2010 in China and Mexico to respond to growing demand for seasonal influenza vaccines.

With the Shenzhen site, Sanofi Pasteur now has 11 sites worldwide. This high-tech facility for the production of pandemic influenza vaccines represents an investment of USD \$94 million and confirms the Group's commitment to contribute to the prevention of seasonal as well as pandemic influenza in China. Following regulatory approvals, this new site will produce seasonal influenza vaccines for Chinese patients. It has an initial production capacity of 25 million doses and can easily be expanded to keep pace with demand.

The new Ocoyoacac site is part of the same approach. The new facilities are dedicated to the production of vaccine antigens used to make seasonal and pandemic influenza vaccine in Mexico. The start of commercial production is expected in 2012, following validation of production and approval of the facility by Mexican authorities. The Mexican vaccine manufacturer Birmex will be responsible for the other stages of manufacturing as well as the distribution of the influenza vaccines in Mexico. The facilities will be able to switch from production of seasonal influenza vaccines to pandemic vaccine manufacturing in the event of a new influenza pandemic.

### Continually innovating to develop new vaccines that meet today's needs

In response to the specific needs of patients and healthcare professionals, Sanofi Pasteur provides innovative seasonal influenza vaccines – the fruit of the Group's innovation policy. In 2010 and 2011 new formulations and new means of administration were made available.

**For more information:** [Our 2011 innovation](#)

#### ● [Innovative products](#)

Fluzone® High-Dose, Intanza® / IDflu® and Fluzone® Intradermal **3** innovative vaccines introduced in 2010 and 2011 to protect against seasonal flu

## Non-communicable diseases

The World Economic Forum has identified NCDs as one of the top threats to worldwide development, as they are driving up healthcare costs, disabling workers, and exacting debilitating financial tolls on households.

Some **80%** of all NCD deaths occur in low- and middle-income countries.

The four principal types of NCDs:

- heart attack, stroke and other cardiovascular diseases
- cancer
- chronic respiratory diseases
- diabetes

NCDs are the leading cause of death in the world, representing **50%** of all annual deaths.

NCDs kill more than **36** million people each year.

**For more information:** NCDs and mental health

- [www.who.int / Noncommunicable diseases and mental health](http://www.who.int/Noncommunicable_diseases_and_mental_health)

## Oncology

### Background

In the oncology field, Sanofi's ambition is to fight cancer on all fronts by conducting research into many of the action mechanisms by which cancer cells develop, grow and proliferate.

Sanofi is currently a global leader in oncology with three leading drugs, Taxotere®, Eloxatine® and Jetvana®, as well as five compounds currently in Phase III clinical trials.

## Actions

Access to healthcare for cancer patients is a priority focus for Sanofi.

Since 2005, Sanofi has devoted €5.2 million to “My Child Matters”

- ▼ Program for breast cancer patients in Russia
- ▼ Improving cancer care for children in developing countries: “My Child Matters”
- ▼ New cancer drugs in development and registration
- ▼ Supporting patients with cancer

Our CEO, Christopher A. Viehbacher, stating our commitments in providing solutions for cancer:

The Group is exploring several paths simultaneously with the goal that as many people as possible will be able to receive treatment adapted to their needs. Some examples of our actions:

## Program for breast cancer patients in Russia

Of all cancers affecting women in Russia, breast cancer has the highest mortality rate. The survival rate of women with breast cancer in this country is far below the rate observed in other developed countries. Only a limited number of patients receive appropriate treatment due to a lack of financing, among other reasons.

Sanofi Russia launched an awareness campaign and support program for breast cancer patients in cooperation with leading Russian cancer institutes and clinics. The program makes use of traditional communication channels as well as social media, conveying high-impact messages such as “Each day in Russia, 47 children lose their mothers to breast cancer.”

One outcome of this program: in 2011 more than 2000 breast cancer patients in more than 50 Russian cities were able to access to quality treatment in line with international standards. The awareness campaign has reached an estimated 49 million people. The project’s goal for 2012 is to increase the number of newly-treated patients to 3000.

## Improving cancer care for children in developing countries: “My Child Matters”

Sanofi is one of the rare healthcare companies involved in programs to improve the management of childhood cancer in low- and middle-income countries. The Group



accomplishes this through “**My Child Matters**”, a unique initiative developed with the Union for International Cancer Control.

“**My Child Matters**” aims to reduce this disparity between industrialized countries and countries with limited resources by supporting projects in hospitals or run by NGOs in countries where pediatric oncology is still in its infancy. It combines funding to support projects with a network of international specialists to improve local expertise through a commitment to progress and solidarity.

Since the program was introduced in 2005, it has already provided support for 40 grass-roots projects in 26 countries. Over 20,000 children have benefited from the program worldwide to date and nearly 3,500 healthcare professionals have received training. Currently, 23 projects are ongoing in 18 countries in Latin America, Africa and Asia.

**For more information** about Sanofi’s initiatives to fight childhood cancers in developing countries:

- [www.fondation-sanofi-espoir.com / Child Matters](http://www.fondation-sanofi-espoir.com / Child Matters)

#### New cancer drugs in development and registration

The Sanofi oncology portfolio is made up of a broad range of novel agents with a variety of mechanisms of action for treating cancer and / or cancer side effects, including cytotoxic, antimitotic, anti-angiogenic agents, antivascular agents, monoclonal antibodies and cancer vaccines as well as palliative care therapies.

Addressing unmet patient needs motivates us to discover solutions, bringing innovative science to endeavour to target cancer on all fronts and from every possible angle. Three novel investigational compounds – aflibercept (VEGF-Trap), iniparib and ombrabulin – are now in late-stage Phase III clinical studies that are part of the objective of developing safe and effective treatments for many types of cancer, where there is a high unmet need.

Jevtana®, the Sanofi drug to treat prostate cancer, which received priority review and approval by the U.S. Food and Drug Administration in 2010, is now registered in almost all the western European countries.

Jevtana®, a Sanofi drug for the treatment of prostate cancer, has been approved by the European Commission

## Supporting patients with cancer

Because information, education and prevention are essential in the fight against cancer, Sanofi is involved in a number of programs worldwide to help patients and their families.

**For more information:** The Group's initiatives to support cancer patients

- Supporting patients and their families

| Country                     | In partnership / cooperation with     | Objectives   | Achievements / website  |
|-----------------------------|---------------------------------------|--|---|
| OncoNursing United States   | Sanofi U.S.                           | To provide a general educational website for healthcare providers: patient support brochures, survivorship resources and tools, etc. | For more information: <a href="http://www.onconursing.com">www.onconursing.com</a><br>Watch 2-minute oncology nursing tutorials   |
| Pakistan                    | Leading hospitals                     | To promote a multidisciplinary approach in breast cancer by increasing referrals to oncologists from surgeons                        | Forum bringing together oncologists, surgeons, and pathologists bi-weekly every month   |
| Iraq                        | Iraqi health authorities              | To establish an action plan taking into account local healthcare needs especially in oncology  | - Action plan includes Mobile Mammography Unit and training of the healthcare professionals for the early breast cancer detection<br>- Personal experience document program software to keep medical records of cancer patients |
| Giving life a chance Russia | Leading cancer institutes and clinics | Improve awareness of breast cancer   | Campaign has reached 49 million people through over 250 stories and over 2 million people via social media.<br>For more information: <a href="#">watch the</a>  |

| Country  | In partnership / cooperation with  | Objectives  | Achievements / website  |
|----------|--|---|---|
|          |  |   | <a href="#"><i>video above "Breast cancer is a socially significant disease"</i></a>  |
| Cameroon | Public-private partnership with the Ministry of Health and a global partnership with African Synergies, a non-governmental Pan-African organization of the first Ladies of 27 African Countries mobilized for the fight against health and social scourges | To support early diagnosis and thus increase patients' chance of survival; to improve information, education and communication to healthcare professionals. | This program addresses measures to enhance prevention and provide access to treatments at tiered prices.  |
| Spain    | Spanish authorities, medical professionals and organizations such as SOGUG, AEU and GEPAC  | For patients with prostate cancer: to establish updated information about prostate cancer in Spain and identify and work on critical issues                 | Survey of 2,000 men between 40-65 years; results published in September 2011.<br>For more information: <a href="http://www.noticiadesalud.blogspot.fr/94-de-los-espanoles-entre-40-65-anos">www.noticiadesalud.blogspot.fr / 94 de los espanoles entre 40-65 anos</a> |

## Diabetes

### Background and policy

#### A growing global public health challenge

Diabetes is a major public health challenge today in terms of both the number of people affected and the costs it generates. Diabetes has probably been growing faster than any other noncommunicable disease, with a major impact on people in both industrialized and developing countries. Some even speak of a global pandemic. There has been an exponential rise in the number of people with diabetes. 366 million people have diabetes worldwide in 2011 and this figure is expected to reach 552 million by 2030, with more than 80% of these cases in developing countries (Source: International Diabetes Federation (IDF) 2011). In addition, the life expectancy of people with diabetes is close to average life expectancy, so the cost of care for people living with this condition for decades will be substantial.

Through various programs around the world, including the examples described below, Sanofi is committed to informing and educating patients and healthcare professionals in an effort to help better control the spread of the disease and its potentially fatal major complications – such as foot ulcers and limb amputation, retinopathy and blindness, kidney failure, neuropathy, heart disease and stroke.

#### Nearly one century of experience in diabetes

Combating diabetes is one of Sanofi's therapeutic priorities. With nearly a century of experience in this area, the Group is moving beyond our traditional role as a producer and distributor of insulin to become a comprehensive resource for patients, with a complete range of integrated solutions. These are not only designed to make patients' lives easier, but also to empower people to take control and manage their disease.

Sanofi considers raising awareness and educating patients to be essential in controlling diabetes.

## Actions

To respond more effectively to the exponential rise in the number of diabetic patients and facilitate access to healthcare, Sanofi develops many different global and regional initiatives. These initiatives focus on the patient and the comprehensive management of diabetes, from prevention to treatment. The Group also works on developing new technology solutions to facilitate access to healthcare.

- ▼ The International Diabetes Federation
- ▼ Programs to simplify the lives of people with type 1 diabetes, especially teenagers
- ▼ E-Diabetes in Africa
- ▼ Programs Supported by the Sanofi Espoir Foundation
- ▼ Collaboration with Diabeo in France for innovative telemedicine tools
- ▼ Supporting patients with diabetes

### The International Diabetes Federation

In late March 2011, Sanofi entered into a landmark agreement with the International Diabetes Federation (IDF), an umbrella organization of over 200 national diabetes associations in more than 160 countries. The new global collaboration will allow the Group to act as an advocate for the IDF, helping to champion its mission of promoting diabetes care, prevention and a cure worldwide.

Through this collaboration, Sanofi will support a variety of activities organized by the IDF throughout the year by contributing to workshops, education programs, task forces and expert meetings; participating in policy support and research; supporting outreach programs; and promoting the *Diabetes Atlas*, a unique annual resource on diabetes data and information for a wide range of audiences.

### Programs to simplify the lives of people with type 1 diabetes, especially teenagers

There are 20 million people worldwide with type 1 diabetes, representing 10% of all diabetes patients. This number is constantly increasing and, more alarmingly, the age of diagnosis is getting younger and younger. As a leader in diabetes, Sanofi recognizes that effective action is key to helping people living with Type I diabetes, and the Group is demonstrating our

commitment in this area with four main projects aiming to optimize type 1 disease management. These projects focus on key drivers for the improvement of care for type 1 diabetes patients around the world, including enhancing research and awareness, strengthening the focus on emerging markets and supporting type 1 diabetes education.

Sanofi formed an important alliance with the Juvenile Diabetes Research Foundation – a world-leader in charitable funding of type 1 diabetes research – to foster research into new treatments for the early stages of the disease. Sanofi is also working on the improvement of disease management through an innovative collaboration with the International Diabetes Federation and the Chinese Diabetes Society, which consists of a situation analysis of type 1 diabetes in selected regions of China. This work may contribute to building the first type 1 diabetes registry in China.

Furthermore, to raise awareness about type 1 diabetes and improve education, Sanofi continues to work with the Team Type 1 cycling team to spread the message worldwide that type 1 diabetes does not necessarily prevent leading an active life.

Another initiative for improving care is Sanofi Diabetes' new web platform T1DStars. This platform is designed to allow teenagers with type 1 diabetes to share their experience, stories and ways they find to fit diabetes into their lives. Teenagers are a particularly vulnerable group within the type 1 community and the website is intended to be a source of motivation and positive reinforcement to help empower them, for better treatment outcomes. T1DStars provides clear and practical information through friendly advice, videos, games and downloadable documents that teenagers can access anonymously to help minimize impacts of type 1 diabetes on their lifestyles.

For more information:

- [www.T1DStars.com](http://www.T1DStars.com)

## E-Diabetes in Africa

E-Diabetes is an innovative public-private partnership designed for African healthcare professionals to improve diabetes diagnosis and treatment. The partnership brings together Sanofi, the World French-speaking Digital University (UNFM), the network for Telemedicine in French speaking Africa (RAFT), and the Senghor University of Alexandria (Egypt).

Its purpose is to improve diabetes care in Africa through an educational program for healthcare professionals via low-speed internet-based technology, with the participation of local and international diabetes experts. It features a flexible training methodology with a focus on exchange and interaction using different models adapted to local healthcare systems. The

program is developed on a monthly basis with webcasts of lectures every second Thursday of the month. Lectures are in French and English with possible extension in the future (new geographies, new covered therapeutic areas).

Participation in the teleconferences is increasingly being expanded to include diabetologists, internists, nurses, cardiologists, surgeons, chronic diseases management, to help enable healthcare professionals to adopt a common approach when treating people with diabetes.

Over 1,000 healthcare professionals across 20 countries are connecting to the telephone conference each month to update their knowledge of the disease and receive training to provide care for diabetic patients.

The e-Diabetes program: more than 1,000 African healthcare professionals across 20 countries are trained every month

- [www.e-diabete.org](http://www.e-diabete.org)

With a relatively low technology approach adapted to emerging countries, a relatively low cost adapted to healthcare providers from the public sector, the program takes a targeted approach to endeavor to be an effective way to share best practices. E-diabetes has to date met with much success, including an endorsement from the International Diabetes Federation in Africa in 2011, which hailed it as the “golden” training model for emerging countries.

For more information:

- [www.e-diabete.org](http://www.e-diabete.org) (in French)

Programs Supported by the Sanofi Espoir Foundation

The Sanofi Espoir Foundation partners with the NGO Sante Diabete in Mali to fight diabetes through actions on the ground in support of the country's Ministry of Health and local stakeholders involved in community awareness-raising, training health professionals, the detection and early management of patients, and rehabilitating those with disabilities.

For more information: Fighting Diabetes

- [www.fondation-sanofi-espoir.com / Improving the prevention and management of diabetes](http://www.fondation-sanofi-espoir.com / Improving the prevention and management of diabetes)

Working in collaboration with Handicap International, the Sanofi Espoir Foundation set up a program aimed at the prevention of diabetes and its potential complications, by educating people and healthcare professionals, helping people with disabilities resulting from the complications from diabetes, and providing an epidemiological monitoring service. This program consolidates the fight against diabetes in five countries: Burundi, Kenya, Tanzania, the Philippines and Nicaragua.

Sanofi Espoir Foundation and diabetes management and prevention programs in 6 African, Asian and Latin American countries have treated 28,000 people suffering from diabetes and trained 13,000 health professionals

For more information about the program:

- [Consolidating the fight against diabetes in five countries](#)

Collaboration with Diabeo in France for innovative telemedicine tools

Seeking modern solutions to facilitate patients' lives, in September 2011 in France, Sanofi entered into an agreement with Diabeo focusing on innovative telemedicine solutions to manage type 1 diabetes. Diabeo software enables individualized insulin dose adjustments combined with telemedicine support.

For more information about this agreement, see the press release (in French):



[Sanofi signe un accord pour le développement de DIABEO, une solution de télémédecine innovante dans le diabète](#) (PDF, 23Kb)

Supporting patients with diabetes

Because information, education and prevention are fundamental for the control of diabetes, Sanofi is involved in a number of programs worldwide to assist patients.

For more information:

- ▼ [Support for patients with diabetes](#)



| Program / Country                         | In partnership / cooperation with   | Objective  | Achievements / website   |
|---|---|--|--|
| Dribble to Stop Diabetes<br>United States | <ul style="list-style-type: none"> <li>● National Basketball Association (NBA)</li> <li>● Women's National Basketball Association (WNBA)</li> <li>● NBA Development League (D-League)</li> <li>● American Diabetes Association</li> </ul> | <p>To encourage fans to live an active, healthy lifestyle</p> <p>To raise awareness about diabetes prevention and management.</p> <p>Spread the message that one in three adults are at risk of diabetes and don't know it.</p>            | <p>Special events during basketball games. Distribution of educational materials.</p> <p><a href="http://www.Dribbletostopdiabetes.com">www.Dribbletostopdiabetes.com</a></p>  |
| Siempre a la lado Casa<br>Mexico          | 10 CASA in Mexico<br>Endorsed by Authorities  | To provide personalized support to help patients reach the treatment goals defined by their physician through health education, medication reminders and monitoring support.   | <p>Average 39,000 patient visits per month.</p> <p>Patients remain in the program 1 year aprox.</p> <p>&gt; 90% of people rate the service as 'good to excellent'.</p> <p>Similar program are being set up in Argentina and Venezuela.</p> |
| <b>Educating to win</b><br>Colombia       | Colombian Association of Internal Medicine<br>School of Medicine  | To highlight efforts made on patient education in order to empower patients and their family in managing their disease. To identify, evaluate and reward the best educational programs for patients in three categories: institutions, key | <p>Prizes of €12,000 and €4,000 for each category.</p> <p>Prizes are in the form of grants, allowing winners to invest in improving the quality of services offered.</p>   |

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|   |  | prescribers and patient associations   |  |
| e-diabete<br>AFRICA 20 countries<br>Since 2009  | Université Numérique Francophone Mondiale (UNFM), the RAFT Network, Senghor University, Egypt<br>International Diabetes Federation (IDF), Africa   | educational program that supports the training of health professionals in French in English with possible extension in the future  | <a href="http://www.e-diabete.org">www.e-diabete.org</a> (in French)<br>More than 1,000 HEALTHCARE professionals at each monthly session.<br>Presented as a best practice during a workshop organized by the Commonwealth Business Council (CBC) and IFPMA on "non communicable diseases: challenges and solutions." |
| My diabetes stories<br><b>MIDDLE EAST</b><br>Saudi Arabia, Gulf, Lebanon, Near East, Iran | 9 associations: <ul style="list-style-type: none"> <li>● Pan Arab Society for Endocrinology and Diabetes</li> <li>● Emirates Diabetes Society</li> <li>● Saudi Scientific Diabetes Society</li> <li>● Lebanese Diabetes Society</li> <li>● Jordanian Patient Association</li> <li>● Qatar Diabetes Association</li> <li>● Kuwait Diabetes Society</li> <li>● Iranian Diabetic Patients Association (GABRIC)</li> <li>● Iranian Diabetes Society</li> </ul> | an awareness-raising program about diabetes<br>The program provides peer to peer support to patients and their families, enabling them to better manage their disease.<br>Real-life stories show that it is possible to live a healthy and fulfilling life with diabetes | The program was launched in November 2010  |
| <b>TURKEY</b><br>Diabetes in School Program<br>Started in 2010.<br>for 3 year period      | Pediatric Endocrinology and Diabetes Association, Ministry   | diabetes awareness project implemented in schools in order to improve diabetes care of the children  | Raise awareness on childhood diabetes amongst 750,000 teachers in 60,000 schools<br><a href="http://www.okuldadiyabet.org">www.okuldadiyabet.org</a>   |

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|   | of Health,<br>Ministry of Education  | with Type 1 and raise awareness about obesity and healthy diet to prevent Type 2 diabetes   |   |
| <b>AUSTRALIA :</b><br>Insulin Leadership Summit series (ILS)                                      | GPs<br>Endocrinologist   | education program developed for GPs by GPs in consultation with endocrinologist.  | Since August 2008, more than 900 GPs have attended the ILS.   |
| <b>GERMANY</b><br>Healthier below 7   | Patient organization, professional Healthcare societies, health insurance and media program in four German cities  | educational program addressing key factors in diabetes. <ul style="list-style-type: none"> <li>● blood glucose value (A1c)</li> <li>● measurement to avoid severe complications for people with diabetes</li> <li>● diabetes risk for all visitors for prevention</li> <li>● early diagnosis of diabetes</li> </ul> | Campaign continues annually In 2011 the main outcomes were more than 50,000 visitors to the booth, 3000 diabetes risk checks, 500 articles<br><br><a href="http://www.gesuender-unter-7.de">www.gesuender-unter-7.de</a>  |
| <b>UKRAINE</b><br>"Act for Diabetes"<br>– launched in Ukraine in March 2010 and continued in 2011 | Patient Associations (UDF - representative of IDF, UDA - representative of IDA, PA "Health of Nation"), HEALTHCARE PROVIDERSs and HAs (Chief Endocrinologist of Ukraine, Association of Children Endocrinologists, | to unite parties involved in Diabetes: around 3 pillars <ul style="list-style-type: none"> <li>● DISEASE awareness</li> <li>● DISEASE control</li> <li>● TREATMENT/ management</li> </ul>   | Implementation of 17 Self-control schools around the country (1100 patients involved)<br>Education training for self controls schools educators<br>Self-realization actions (Children Drawing Competition with 1500 participants , Photo-exhibition "Every Day is Yours)<br>Around 400 publications in media, raising awareness on diabetes<br>Pharmaco economic training |

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|  | Regional Heads of HC system), National Academy of Science  |  | around cost of diabetes for regional health authorities  |
| <b>FRANCE</b><br>"DIABEO"<br>2011-2014   | <p>French Diabetics Association (AFD)</p> <p>The Center for Study and Research for Intensified Treatment of Diabetes (CERITD)</p> <p>VOLUNTIS – Online Patient Relationship Management</p> | <p>Co-development of a system of remote monitoring for diabetic patients with electronic notebook, smartphone and web, enabling diabetic patients to adjust their insulin dose based on their blood sugar, their glycemic index and physical activity.</p>   | <p>Establishment of a clinical study of 750 patients that will measure the clinical and economic effectiveness of the solution DIABEO versus a paper patient monitoring system</p> <p>for more information:<br/> <a href="http://www.diabeo.com">www.diabeo.com</a> (FRENCH)</p> |
| <b>RUSSIA</b><br>"Every day is Yours!"<br>Launched in 2009<br>it continues in 2012 | <p>Collaboration with the Russian Diabetes Association and leading endocrinologists.</p>   | <p><b>Educational Program for Diabetes</b> that includes educational seminars (diabetes schools) with formats specially developed for each types of patients such as</p> <ul style="list-style-type: none"> <li>● web-site (electronic diabetes school</li> <li>● sports events for T1 children;</li> <li>● educational materials</li> </ul> | <p>"Every day is yours! is accompanied by a large-scale communication campaign for an audience outreach estimated at about 47 million people</p> <p><a href="http://www.shkoladiabeta.ru">www.shkoladiabeta.ru</a></p>   |
| <b>MALAYSIA</b><br><b>Diabetes Camps</b><br>Q2 –Q'4 2011                           | <p>A partnership with the Public Health Division of Ministry of Health , KOIs and nurses</p>   | <p>The objective was to reach out to youngsters on the deadly effects of diabetes and how to eat the right diet, the</p>   | <p>A total of 30 colleges were reached and a total of 5,000 students attended this program.</p>  |

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|   |   | need to exercise to help maintain health  |   |
| <b>CHINA</b><br>"China Initiative for Diabetes Excellence"<br>2011-2016 | initiative led by the Bureau of Disease Prevention and Control of MOH, undertaken by the Chinese Center for Disease Control and Prevention (CDC) and the Chinese Diabetes Society (CDS) of the Chinese Medical Association, and supported by Sanofi | <p>It consists of three tiers</p> <p>1- to develop 500 emerging experts through a two-year longitudinal clinical and research training program</p> <p>2 to train 10,000 community and county doctors,</p> <p>3- to enhance patients' self-management capabilities through education and organized peer support groups.</p>  | <p>for more information see</p> <p><a href="#"><u>China Initiative for Diabetes Excellence</u></a></p>  |
| <b>USA</b><br>Community Connections to Aging Well (CCAW).<br>2010-2011  | Public/private partnership with the Baltimore County Department of Aging (BCDA), the John A. Hartford Foundation, and the National Council on Aging (NCOA)  | <p>Helping Seniors Manage their Diabetes through a wellness and prevention programs by collaborating with and supporting the patient, caregiver, and payer to:</p> <ul style="list-style-type: none"> <li>● Reduce the numbers and costs of hospitalized patients</li> <li>● Improve behavioral and health outcomes</li> <li>● Improve patient satisfaction and well-being</li> </ul> | <p>The program serves 35,000 people living with Diabetes over 60 years of age in Baltimore County. The CCAW program was launched at eight senior centers during October 2010.</p> <p>for more information see</p> <p><a href="#"><u>www.sanofi.us / Helping Seniors Manage their Diabetes</u></a></p> |

## Epilepsy and mental illness

### Sanofi's pioneering commitment to epilepsy and mental health

#### Background

The World Health Organization estimates that about 450 million people worldwide are affected by mental disorders.

Epilepsy is a chronic neurological disease characterized by recurrent epileptic seizures. An epileptic seizure is defined as the transitory occurrence of signs and symptoms related to abnormal brain activity. Around 50 million people worldwide have epilepsy.

Mental illnesses are found in all countries across the globe. They include a variety of disorders, such as depression, anxiety, addictions and schizophrenia.

In developing countries, inadequate medical resources and stigma are one of the factors contributing to the neglect of these patients, even though in many cases effective treatments exist. Approximately 75% of patients with epilepsy do not receive suitable treatment. The figures are similar for patients with schizophrenia.

#### Policy

Sanofi has extensive expertise and a broad product portfolio in the fields of epilepsy and mental health. With respect to chronic diseases in developing countries, Sanofi decided in 2006 to focus our Access to Medicines initiatives in these areas. Our long-term goal is to promote sustainable access to healthcare for millions of disadvantaged patients who are excluded from society today.

Our epilepsy and mental health programs are based on four pillars:

- Partnerships and collaborations enabling stakeholders from different sectors (public, private, NGOs, universities) to join forces

- Efforts to combat stigmatization by educating communities about the medical causes of many of these disorders, emphasizing that they may be treatable, and teaching patients how to manage them
- Training for front-line healthcare professionals in diagnosis and treatment
- A tiered pricing policy consistent with applicable law to help make medicines accessible to the poorest

Within the scope of our Access to Medicines programs, we sell medicines at tiered prices consistent with applicable law that may reach “no profit – no loss” levels. The list of medicines is determined in cooperation with the relevant ministry of health in each country.

- To treat epilepsy, we offer two of the antiepileptic drugs that appear on the WHO's Essential Medicines List.
- For mental disorders, we provide medicines for treating the majority of psychiatric illnesses.
- As part of a tiered pricing policy, these drugs also may be provided at low prices to eligible public institutions and NGOs in developing countries through some programs.

In late 2009 Sanofi and the World Association for Social Psychiatry joined forces to develop the FAST (Fight Against STigma) project. Fighting the social stigma associated with mental illness is a key factor in access to healthcare and rehabilitation. This program is dedicated to promoting access to healthcare for patients with mental disorders in developing countries.

## Actions

- ▼ Improving access to mental healthcare in Mauritania
- ▼ “IMPACT Mental Health” launched in Guatemala
- ▼ In five African countries, education for epilepsy through an illustrated book

### Improving access to mental healthcare in Mauritania

In Mauritania, a 2005 study in the capital city of Nouakchott revealed that 34% of the population had at least one mental disorder. However, in this country of three million inhabitants, very few mental health clinics are available.

In October 2008, Sanofi launched a pilot project focusing on schizophrenia in Nouadhibou, the economic capital of the country. Since then, 37 healthcare professionals have been trained and outpatient facilities have opened in seven centers. Sanofi has also implemented a differentiated pricing policy, consistent with applicable law, in an effort to help make affordable antipsychotics available to patients.

Since the start of this program, over 350 patients with schizophrenia (of a total estimated population of 1,000 patients with schizophrenia in Nouadhibou) have taken part in the program. The treatment gap has gone from 93% in May 2009 to 58% in December 2011 – an improvement of 38% in 2.5 years.

Following these results, in 2011 the program was extended to other provinces of Mauritania and now includes schizophrenia, other major mental disorders and epilepsy.

### “IMPACT Mental Health” launched in Guatemala

In Guatemala, the burden of mental and epileptic disorders is now estimated to be 1.5 times higher than that of parasitic and infectious diseases, yet resources earmarked for mental health care are inadequate. Scarce resources are especially inaccessible to rural populations, and the country’s only psychiatric hospital is located in the capital city.

The objective of the “IMPACT Mental Health” program, launched in July 2011, is to help enable low-income and geographically isolated Guatemalan patients who suffer from mental disorders or epilepsy to have access to adequate health care services. The Guatemala Ministry of Health, the World Association for Social Psychiatry and Sanofi work side by side in this public-private partnership.



The program focuses on providing information, diagnosis and treatment based on:

- Training health professionals to provide adequate diagnosis and treatment.
- Helping NGOs provide psychosocial support to patients and their families.
- Implementing a countrywide awareness campaign to reduce prejudices and encourage families and patients to seek care.
- Setting up a differentiated pricing policy consistent with applicable law to help improve availability of medicines in the country's health centers.

Diagnosing and integrating children with mental disabilities in Mediterranean countries

The Sanofi Espoir Foundation supported the following projects in 3 countries in partnership with Santé Sud:

- In Algeria, by raising awareness among early childhood workers and parents about the early detection of disorders right from birth, especially in the BEO District.
- In Lebanon, by developing the early diagnosis and referral for the appropriate care of children suffering from intellectual disabilities.
- And in Tunisia, by focusing on the socio-economic integration of people with intellectual disabilities.

The program involved supporting medical-social actions in the field, through the development of vocational training, giving guidance to families, and sharing experiences and practices among associations.

In five African countries, education for epilepsy through an illustrated book

To raise awareness about epilepsy in Africa and fight the misconceptions often associated with it, Sanofi's Access to Medicines Department supported the creation of an educational illustrated book.

More than half of cases of epilepsy start during childhood, and in developing countries, many children with epilepsy may be confronted with poor acceptance by teachers and other children, relational problems due to lack of comprehension and even rejection by others, and absenteeism.

The book tells the story of Lamine and Keifa, who receive treatment so they can keep playing football and going to school. Using this fictional story to reach out to families, the book provides

important information about epilepsy. It conveys the key message that epilepsy is a disease like any other disease, and it can be treated.

Sanofi hopes the story of Lamine and Keifa will help combat stigma associated with epilepsy. In addition, the Group aims to improve access to proper care for all those who need treatment. In 2012, 50,000 copies of the book will be distributed to schools in five African countries: Benin, Cameroon, Madagascar, Senegal and Kenya.

For more information:

▼ Epilepsy

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▼ Mental illness

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## Our affiliates' achievements

### Background and policy

Chronic diseases are a growing global public health concern.

In the coming decades, governments may have little choice but to address the causes and management of NCDs, which are expected to weigh more and more heavily on the developing world, including in some of the world's most powerful emerging markets.

The efforts that may be necessary to improve healthcare systems and services depend on the cooperation of a large number of stakeholders: communities, the private sector, civil society, and many others.

Sanofi is willing and may be able to help contribute effectively to these efforts and provide our expertise to help improve access to the care for chronic diseases.

At the local level, our affiliates undertake local initiatives based on their understanding of the true burden of a disease. Through these programs, they raise awareness and help improve access to healthcare.

## Actions

- ▼ The African Pain Club introduces e-Learning
- ▼ Cardiopulmonary Resuscitation (CPR) training for Canadian high school students
- ▼ In India, programs focusing on diabetes, hypertension and empowering rural doctors
- ▼ Other initiatives worldwide

### The African Pain Club introduces e-Learning

Pain is one of the most underdiagnosed, neglected and undertreated medical problems in Africa. In light of the Group's broad portfolio of analgesics, Sanofi created the African Pain Club, a multidisciplinary scientific committee composed of experts from seven countries in Africa, which meets twice a year under the leadership of Professor Alain Serrie (Lariboisière Hospital, Paris), Chairman of the African Pain Club and President of Douleurs Sans Frontières (Pain without Borders).

The objective of the African Pain Club is to help improve pain management through the development of specific training on topics tailored to the African environment. Initially nine modules were developed, followed by case studies and modules on patient education. Each member of the Pain Club is responsible for training "trainers" who will in turn train healthcare professionals in their own country at meetings organized by Sanofi.

To date, more than 10,000 healthcare professionals (doctors, pharmacists, dentists, nurses in health clinics, etc.) have thus been trained. Given this success, Sanofi, in partnership with an African health e-magazine, decided to create the African Pain e-Club [www.clubdouleurafrique.com](http://www.clubdouleurafrique.com). The site was launched on October 17, 2011, during the World Day Against Pain.

This original tool provides healthcare professionals an opportunity to train at home 24/7, which may be particularly useful to professionals who are far from major African towns. Several events were held in the African affiliates to promote this new Sanofi service.

### Cardiopulmonary Resuscitation (CPR) training for Canadian high school students

In Canada, Sanofi is a key national health ally to the Advanced Coronary Treatment (ACT) Foundation.

ACT is a national charitable organization dedicated to establishing free CPR as a mandatory program in every Canadian high school. In addition to core funding, the collaborators provide ACT with a pool of resources and expertise to draw from. The Foundation wants to see all high school students acquire CPR skills and knowledge that potentially could enable them to help save lives by the time they graduate. The program also has a strong health promotion component, encouraging young people to adopt a healthy lifestyle from a young age.

More than 4,000 high school teachers are trained as CPR and defibrillator instructors for their students. ACT has donated more than 40,000 durable mannequins to high schools, ensuring 1:1 mannequin / student ratio. To date, more than 1.8 million youth have been trained by their high school teachers, with an additional 250,000 being trained each year.

**For more information** about the high school CPR program:

- [www.actfoundation.ca](http://www.actfoundation.ca)

In India, programs focusing on diabetes, hypertension and empowering rural doctors

Sanofi's affiliate in India provides an excellent demonstration of what can be accomplished by working at the grass-roots level and focusing on making progress in many different areas simultaneously.

Sanofi India participates in a wide range of programs designed to improve the well-being of the community and continuously strives to change the lives of the less fortunate. In particular in cooperation with stakeholders (such as doctors, hospitals, institutes and policy makers), Sanofi India is organizing actions to understand the real burden of disease, raise awareness about diabetes and help increase access to health care in rural areas.

The following accounts are taken from "India: The Private Sectors Takes Action on NCDs," published in Global Health Magazine (issue 12, Fall 2011). The authors are Dr. Muruga Vadivale, Medical and Regulatory Affairs, Sanofi India, and Aparna Thomas, Communications and Public Affairs, Sanofi India.

**For the full article**, see:

- [www.globalhealthmagazine.com](http://www.globalhealthmagazine.com)
  - ▼ Diabetes and hypertension: Screening India's Twin Epidemic
  - ▼ Prayas: Empowering doctors in rural India
  - ▼ "Champions" advocate positive attitude to manage diabetes

## Diabetes and hypertension: screening India's twin epidemic

India's twin epidemic of diabetes and hypertension is a growing concern in the healthcare sector, especially since a large number of patients with these diseases are believed to remain undiagnosed. In January 2009 Sanofi launched SITE (Screening India's Twin Epidemic), a cross-sectional study to estimate the prevalence of diagnosed and undiagnosed cases of diabetes and hypertension in outpatient settings in major cities across India. Patients are surveyed at the first point of contact — at the general practitioner or consultant physician's level, and important parameters of disease management such as food habits and smoking and alcohol history are evaluated.

As of July 2011, SITE has enrolled 15,662 patients from 802 centers across eight states in India (Maharashtra, Delhi, West Bengal, Tamil Nadu, Andhra Pradesh, Karnataka, Gujarat, and Madhya Pradesh) and has collaborated with 800 general practitioners and consulting physicians to conduct the screenings, record and report the results consistent with applicable law. The study was conducted in waves over two years, one state at a time, with 2,000 patients screened from each state over two days per wave. The results obtained in the different cities are progressively communicated at congresses.

The study indicates that patients should be treated holistically, giving attention to assessing risk factors and underlying diseases. Salient features of the study are also to:

- Assess the prevalence of obesity, truncal obesity, cardiovascular disease (IHD/MI/Stroke), dyslipidaemia and microalbuminuria and other variables in the context of diabetes and hypertension
- Evaluate other parameters in disease management, such as food habits, lifestyle (smoking and alcohol history), family history, demographics, etc.

Through collaborations with doctors, hospitals and other organizations in these eight states, SITE has already started to raise disease awareness of the risk factors, symptoms and treatment of diabetes, hypertension and other related conditions, such as cardiovascular diseases.

## Prayas: Empowering doctors in rural India

Prayas, which means endeavor in Sanskrit, focuses on empowering doctors in rural India with the latest developments and updates in medicine and disease management practices.

Introduced in 2009, Prayas aims to bridge the diagnosis-treatment gap through a structured continuing education program for rural doctors across India. Specialists from semi-urban areas can share the latest medical knowledge, clinical experience and practical insights through

structured workshops targeting general practitioners from smaller towns and villages in the interiors of India based on a 'mentor-mentee' model.

## BACKGROUND

Top end specialist  
clinicians in urban  
India

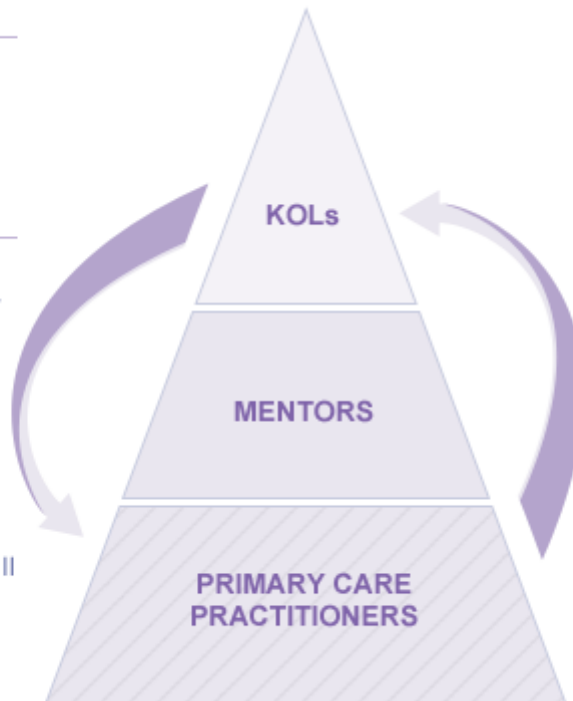
**48 ACROSS  
14 STATES**

Post graduates in  
internal medicine or  
other subjects  
practicing at semi  
urban areas

**574 ACROSS  
14 STATES**

Primary care  
practitioners in Tier II  
towns in India

**11,500 ACROSS  
14 STATES**



## ROLE

Guide the development of  
a particular therapy area.  
Train mentors on relevant  
topics for improving the  
quality of Prayas.

Train mentee doctors per  
curriculum. Share one's  
own experience through  
case studies and provide  
material to improve the  
knowledge base and  
skills of mentees.

Participate in Prayas  
workshops once every 2  
months. Transfer acquired  
knowledge and skills in  
treating patients in line  
with available evidence.

As of July 2011, 4,700 workshops have been conducted across 14 states for more than 11,500 rural doctors. Forty-eight expert doctors and 574 mentors have so far lent their support to Prayas. The workshops cover major acute-care therapy areas like respiratory diseases, infections, allergies, gastrointestinal disorders, etc. Each course is validated and certified by reputable international medical associations such as the American College of Physicians and the American Gastroenterology Association, among others.

Progressively disease awareness workshops were organized to improve awareness and treatment seeking behavior of patients in these regions. These workshops focus on topics like child health, anemia and malnutrition, and diarrhea, which are in line with the needs of the patients.

As part of Prayas, Sanofi also makes available a new range of quality medicines at affordable prices in these geographical areas consistent with local law. The product range helps address the challenges of accessibility, affordability and availability of quality medicines to patients in remote villages. In addition, a new distribution model with emphasis on availability of drugs to the most rural interiors is being established. The next step is to adapt this model to the fight against diabetes, which is also on the rise in rural areas.

“Champions” advocate positive attitude to manage diabetes

In India, the objective of the “I Am A Champ” program is to help people living with diabetes to reach out to others with their inspiring testimonials. Through the program, patients and caregivers learn that a positive attitude and few lifestyle changes to support their treatment regime can help to empower them to contribute to the improvement of their health and well-being.

India’s first ever Diabetes Awards Ceremony was the first step to kick start the “I Am A Champ” program, which is based on the model of peer-to-peer counseling. Champions from various regions in the country will be the face and voice of this awareness program in their respective cities. Sanofi provides the 42 (seven national and 35 regional) ‘champs’ with platforms to share their testimonials, create awareness among other diabetes patients in their respective cities and help address their concerns on managing the disease. These individuals symbolize triumph over diabetes and give hope to countless other diabetics who may initially negatively react by thinking “life is over” once they are diagnosed with diabetes.

#### Other initiatives worldwide

Through a wide range of programs around the globe, Sanofi is actively involved in informing, educating and supporting patients to help better control the spread of diseases and increase access to healthcare.

Please see example of some of these initiatives:

| Country   | Program Name                       | Summary   |
|-----------|------------------------------------|---|
| Australia | Fighting Child Mortality           | Sanofi's consumer healthcare brand collaborated with Australia's Vitamin Angels to donate proceeds from sales of Nature's Own products towards promoting child nutrition. |
|           | Juvenile Diabetes Information Kits | Information kits providing practical guidance to Type 1 diabetes patients and their families, distributed to patients upon diagnosis.                                     |
| Brazil    | Fun Centers                        | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.  |



| Country              | Program Name                          | Summary   |
|----------------------|---------------------------------------|---|
| China<br>(Hong Kong) | Liver Health Awareness                | Awareness-raising program focusing on liver health to educate high-risk workers in the Macau gaming industry.   |
|                      | Thank You Doctor Day                  | Event created to allow cardiac patients to recognize their doctors' efforts, serving to promote quality doctor/patient relationships.   |
| Columbia             | Patient Support Program               | Program that includes education plans for diabetes patients and their families to help patients manage diabetes and comply with treatment.  |
| Dominican Republic   | Give More Against Diabetes            | Educational program providing diabetes patients with tools and knowledge to help them in their efforts to control their diabetes, improve quality of life and alleviate the long-term complications of their illness. |
| Egypt                | I Can Survive                         | Cancer advocacy and education for patients and their families through counseling and media forums, as well as improved access to medicines.   |
|                      | Patient Support Programs              | Support, education and a 24-hour hotline for diabetes, cardiac and rheumatology patients to ensure patient understanding and compliance with physician instructions.  |
| France               | Drop-in and Information Centers (ERI) | In-hospital centers where patients and their families come for support, information and referrals on a walk-in basis.   |
| India                | Certified Diabetes Counselors         | Diabetes management guidance, psychosocial support and educational materials provided to patients during home visits for their first six months of treatment.   |
|                      | Fun Centers                           | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.  |
|                      | I Am a Champ                          | Program based on sharing experiences and positive attitudes. Champions' goal is to inspire and motivate fellow diabetics by   |

| Country     | Program Name              | Summary   |
|-------------|---------------------------|---|
|             |                           | talking about how they manage the challenges of their disease.  |
| Indonesia   | Cancer Awareness Events   | Annual events organized for patients to promote breast and colon cancer awareness and education.  |
| Japan       | Diabetes Summer Camp      | Summer camp program for children with Type 1 diabetes. Indoor and outdoor recreational and educational activities emphasize problem-solving and daily self-care.                      |
|             | Pink Ribbon Campaign      | Raising awareness about breast cancer and the importance of early screening and diagnosis.  |
| Kazakhstan  | Children's Hospice        | The first hospice to provide palliative care specifically for children. A collaborative project with the Health Asia Foundation, the Ministry of Health and local organizations.      |
| Korea       | Reading Hospital          | An in-hospital library for cancer patients offering quality books and medical information, with the goal of providing support and facilitating doctor/patient communication.          |
| Malaysia    | Diabetes Camps in College | Diabetes education and awareness program for young adults focusing on diabetes treatments and healthy lifestyle strategies.   |
| Philippines | Fun Centers               | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.  |
|             | Innovation for Life       | Program to help lower-income diabetic patients and their families through adapted pricing and services, thus helping to alleviate some of the long-term cost burden of their disease. |
| Russia      | Fun Centers               | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.  |

| Country       | Program Name                      | Summary  |
|---------------|-----------------------------------|--|
| Taiwan        | Mental Illness Mobile Application | A free smart phone application developed for use by psychiatrists and their patients and families to calculate metabolic risks associated with prescribed medicines.           |
| Thailand      | Fun Centers                       | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.   |
| Ukraine       | Cardio Patient Support Program    | Cardiac patient education and awareness program with the goal of reducing additional ischemic events and resulting hospitalizations.   |
| United States | Oncology Dinner Gatherings        | Sanofi Oncology Sales professionals participate in evenings that include dinner, bingo and crafts with patients at American Cancer Society Hope Lodges across the country.     |
| Vietnam       | Diabetes Patient Education        | Printed educational materials and sponsorship of Patient Club educational workshops aimed at increasing awareness and improving treatment maintenance among diabetes patients. |
|               | Fun Centers                       | Recreational areas within pediatric oncology units providing children with a wide variety of games and activities.   |
|               | Patient Clubs                     | In-hospital workshops and activities providing healthcare education to cancer patients and their families.   |

## Rare diseases

### Background

#### What is a rare disease?

A disease is recognized as rare when it affects a limited number of people in the general population. The pertinent number varies in different regions of the globe:

- In Europe: Fewer than 5 people out of 10,000
- In the United States: Fewer than 200,000 people out of the entire U.S. population
- In Japan: Fewer than 50,000 out of the entire Japanese population

#### Orphan drugs

Nearly 7,000 rare diseases have been reported worldwide, yet new rare diseases are reported on a regular basis.

Health authorities recognize certain rare diseases as being serious, chronic and evolving. They may be life threatening. Nearly 7,000 rare diseases have been reported worldwide, yet new rare diseases are reported on a regular basis. Eighty percent of them are inherited diseases.

According to the definition from the European Medicines Agency, orphan drugs are those used for the diagnosis, prevention and treatment of diseases that are rare, very serious and life threatening.

Despite the economic pressures associated with developing orphan drugs, they are an important part of Sanofi's growth strategy to endeavor to provide a response to the public health need in both developed and developing countries.

## Actions

- ▼ [The Genzyme Business Unit: Sanofi's growth platform for rare diseases](#)
- ▼ [The Oncology Business Unit](#)
- ▼ [The Ophthalmology Business Unit](#)

### The Genzyme Business Unit: Sanofi's growth platform for rare diseases

With the acquisition of Genzyme, Sanofi is committed striving to develop treatments for rare and severe diseases for which there are currently no treatments available, or for which existing treatments are not satisfactory.

With this new ally, Sanofi R&D is expanding our portfolio and ability to provide treatments and innovative medical devices for patients.

Genzyme has developed a treatment for Type 1 Gaucher disease and is developing a second-generation treatment for Types 1, 2, 3 Gaucher disease. Other areas of development are focused on Fabry disease, Mucopolysaccharidosis type 1 and Pompe disease (lysosomal storage disorders).

*Sanofi global Portfolio management approach selects innovative product which target patients' needs with controlled development risk. Sanofi fully supports Genzyme's new approach to treating lysosomal storage disorders: treatments for ASM-deficiency Niemann-Pick disease, degenerative and fatal lysosomal storage disorders, and age-related macular degeneration (AMD) which have been considered as high priority projects for Sanofi portfolio. \**

#### For additional information:

- ▼ [Supporting patients with rare diseases](#)

### The Oncology Business Unit

The Oncology Business Division is working on mechanisms involved in the potential treatment of certain rare forms of cancer, in particular:

- Antivascular agents to inhibit vascularization in soft tissue sarcomas. For this very rare type of cancer, results with existing treatments are random.

- Multikinase inhibitors implicated in tumor angiogenesis for the treatment of acute myeloid leukemia, a cancer characterized by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with blood cell production (hematopoiesis).
- Inhibitors of Janus kinase 2 (JAK-2), a protein tyrosine kinase involved in several signaling pathways that are primarily responsible for cellular survival and proliferation for the treatment of primary and secondary myelofibrosis, a disease that is characterized by the invasion of the spinal cord by fibrous tissue. Because the cause of this disease is unknown, it has been designated as a rare disease.

### The Ophthalmology Business Unit

In collaboration with Fovea Pharmaceuticals, the Ophthalmology Business Unit is working on the development of drugs for the potential treatment of ophthalmological diseases, with a special focus on retinal diseases:

- Usher syndrome, a genetic disorder in which patients are born deaf and experience gradual vision loss due to retinitis pigmentosa, a degeneration of the retinal cells. It is the leading cause of deaf-blindness in adults.
- Stargardt disease, characterized by a combination of bilateral vision loss and specific retinal lesions. It is the most common form of inherited macular degeneration.
- Exudative AMD (the “wet” form), found in 10% of age-related macular degeneration patients.

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Humanitarian emergencies

### Background and Policy

Healthcare is one of the most vital needs when a humanitarian disaster occurs, and the Sanofi Group considers assisting in responding to such emergencies to be one of our missions.

Depending on local requirements and applicable law, in the aftermath of a disaster, our response may consist of donating medicines and vaccines in compliance with a charter based on the guiding principles of the World Health Organization, or financial donations to field organizations setting up emergency and post-emergency operations.

The Group created the Sanofi Espoir Foundation in 2010 with the explicit aim of contributing to reducing health inequalities. Responding to humanitarian emergencies to help ensure that victims of natural disasters and conflicts have access to healthcare is one of the Foundation's missions.

#### **Donation of medicines and vaccines**

The Sanofi process for the donations of medicines and vaccines aims to ensure the quality, coordination and consolidation of donations made within the priority scope of humanitarian emergencies, according to rules contained in the WHO guiding principles. It makes both the donor and the beneficiary accountable for the appropriate use of these donations.

## Actions

In 2011, 700,000 boxes of medicines and more than 900,000 doses of vaccines were donated to 60 countries.

Thirteen countries benefited from the Group's assistance in emergency situations: Australia, Brazil, New Zealand, Japan, Pakistan, Thailand, Turkey, Côte d'Ivoire, Libya, Ethiopia, Somalia, Djibouti and Kenya.

Here are some examples of humanitarian emergencies that struck all corners of the globe and Sanofi's response as a global healthcare leader.

### Haiti, two years after the earthquake

The magnitude 7.3 earthquake that struck the Haitian capital of Port-au-Prince and its three million inhabitants on January 12, 2010, was one of the largest natural disasters of the twenty-first century and it occurred in one of the world's poorest nations. Within days, Sanofi set to work with 6 different humanitarian partners to provide emergency financial assistance and donations of medicines and vaccines, sending 440,700 boxes of medicines worth a total of nearly €1.9 million and 300,000 doses of vaccines. In addition to these immediate responses, Group employees demonstrated their generosity, and a special budget of €2,015 million was allocated to support long-term efforts for the reconstruction of Haiti.

### Earthquake and tsunami in Japan

On March 11, 2011, the Tohoku region of Japan was hit by an earthquake of magnitude 9 on the Richter scale, followed by a devastating tsunami. One week later, Sanofi announced the donation of €1 million to support the aid relief efforts of the Japanese Red Cross through the Sanofi Espoir Foundation.

The Group also appealed to all countries and affiliates worldwide for generosity, inviting employees to join in this solidarity effort. A total of €250,000 was collected in over 20 countries and donated to the Japanese Red Cross. This amount, plus a matching sum of €250,000, was added to the €1 million already donated to the association.

In the most devastated areas, Sanofi provided emergency supplies of essential medicines during the first few days after the earthquake.



## Emergency measures to protect Sanofi employees in the Tohoku region

Sanofi has 3,100 employees in Japan working at five sites and various sales offices. When the earthquake struck, approximately 2,000 employees were working at Sanofi offices in eastern Japan – in Tokyo and Kawagoe. These offices felt the earthquake and its aftershocks for several weeks.

Three days after the quake, the Group sent food, water and basic necessities by helicopter to employees in the Tohoku region, in addition to Lantus® and Apidra® (insulin) for patients.

Sanofi provided support to 36 employees and their families in Fukushima who had to evacuate to Tokyo for two to three weeks. The homes of several employees were damaged and the Group provided assistance for them to move to other accommodations or gave support in the form of cash. Following the earthquake and tsunami, the Group put into effect a stay-home policy for employees within a 300 km radius. They also offered monitoring of employees' radiation levels three times a day.

## Tropical storm in the Philippines

**In December 2011, a deadly tropical storm struck the Philippines**, killing over 1,250 people. The storm, known as Washi, caused multiple flash floods and mudslides, affecting more than 65,000 families and damaging and destroying thousands of homes. Over 60,000 people sought shelter in evacuations centers.

Immediately following the disaster, Sanofi sent out an appeal for generosity to employees. Their donations, including budgets intended for year-end celebrations, were directed to the Philippine Red Cross and other relief organizations. Sanofi's Human Resources released an emergency fund for employees affected directly by the flooding to buy water, food and other critical supplies. In addition, Sanofi Pasteur made flu and tetanus vaccine doses donation while the Sanofi Espoir Foundation earmarked €40,000 for the Philippine Red Cross to assist in medical relief efforts.

## Flooding in Pakistan

**Torrential rains began in Pakistan in August 2011.** Compounded by damage to the country's water infrastructure that had occurred during the floods of 2010, particularly to dams, the situation quickly worsened and by mid-September the United Nations reported that 5.3 million people had been impacted by the monsoon rains across the country.

The Sanofi affiliate in Pakistan has donated 3,800 boxes of Nivaquine® to the Sidh government for healthcare programs to benefit nearly 200,000 patients. In addition, the Sanofi Espoir

Foundation provided financial support to Première-Urgence-Aide Médicale Internationale (PU-AMI) for activities in the Sindh Province, supporting access to primary healthcare and helping to make drinking water available.

### Flooding in Thailand

**In response to ongoing flooding during the 2011 monsoon season in Thailand, affecting over 12 million people**, Sanofi products were donated to Thai health officials for distribution in the most severely hit areas. Up to 30,000 doses of tetanus vaccines were mobilized to meet the needs of the Ministry of Public Health. Over 64 Sanofi employees were directly affected by the disaster, and many of their homes were flooded. The company provided temporary accommodation for these employees, and Sanofi Thailand launched an internal call for generosity. All contributions were doubled by the affiliate, and completed by the Sanofi Espoir Foundation financial support and transferred to the Friends in need (of “Pa”) Foundation Thai Red Cross.

### Earthquake in Turkey

**On October 23, 2011, a strong earthquake (magnitude 7.3) shook eastern Turkey**, causing 573 deaths and injuring 2,600 people. The Sanofi Espoir Foundation provided financial support to the Turkish Red Crescent’s first aid activities to support access to primary healthcare, water and shelter.

The affiliate donated 4,200 boxes of medicines as well as more than 30,000 doses of influenza vaccine to the National Medicine Rescue Team.

The Turkish affiliate organized the collection of tents, blankets, clothing and food to be sent to the affected region. An appeal for solidarity was also made among employees. Their donations, which were doubled by Sanofi, were allocated to emergency operations conducted by the Ministry of Health and partner humanitarian organizations.

### Drought in the Horn of Africa

**The worst drought in 60 years is plaguing the Horn of Africa** (Somalia, Djibouti, Kenya and Ethiopia). There has been no rain for four years in some localities, leading to a severe food crisis and soaring prices for basic foodstuffs. In these countries, 13.3 million people are in need of humanitarian aid, and over 840,000 people are refugees. These populations are affected by problems of access to safe water and food in general, and malnutrition in particular.

The assistance provided by the Sanofi Espoir Foundation to UNICEF in the healthcare field has been mainly focused on Somalia, the epicenter of the crisis. In addition, support from the

Foundation to AMREF has supported the development of healthcare activities in the Makueni District of Kenya. Several months after the beginning of the humanitarian crisis, UNICEF and AMREF (the leading African public health NGO) are still on the ground trying to help those most affected by malnutrition and lack of care, especially children.

### Displaced persons in Côte d'Ivoire and Liberia

Following the presidential election in Côte d'Ivoire on November 28, 2010, the country found itself in the midst of a civil war, which soon led to a humanitarian crisis. Nearly one million people were displaced, 60% of them women and children, and some 112,000 inhabitants fled to Liberia. The Sanofi Espoir Foundation chose to support UNICEF in organizing actions to aid victims of the crisis in Côte d'Ivoire and Liberia for an initial period running from March to June 2011. This aid was earmarked for medical activities with a focus on:

- A joint UNICEF-WHO campaign of vaccination against measles among 654,936 children, and the distribution of 115 gas cylinders to help avoid interrupting the cold chain,
- Distribution of 220 mosquito nets in displaced persons' camps, 20,000 bars of soap, and 60,000 sachets of oral rehydration salts,
- Delivery of essential medicines to two camps for displaced persons in Abidjan.

### Earthquake in New Zealand

**On February 22, 2011, a large 6.3 magnitude earthquake struck Christchurch, New Zealand.** Sanofi made a NZD100,000 donation to the Red Cross New Zealand Earthquake 2011 Appeal. A donation to the relief effort was also made through the Sanofi Espoir Foundation, amounting to €40,000 (NZD 75,000).

### Storm in the southeast and Midwest United States

To aid victims of the 2011 June storms in the southeast and Midwest United States, Sanofi Pasteur donated 5,500 doses of vaccine designed to confer protection against tetanus, including 500 doses of Tdap (tetanus, diphtheria and acellular pertussis) vaccine to Direct Relief International.

## Supporting patients and their families

### Background

As a global healthcare leader focused on patients' needs, Sanofi believes our mission goes beyond making medicines available. With our collaborators, we endeavor to act to protect health, enhance life and respond to healthcare needs. One of the ways the Group translates this commitment into reality is by collaborating with patient associations all over the world on mutual priorities that benefit patients. We are committed to listen and foster a dialogue to learn and to enhance our understanding of patients' expectations, to strive to:

- Find better healthcare solutions for patients
- Take into account and respond to the broader needs of patients and their families/loved ones throughout the patient's journey

### Working with patient associations

Patient associations have many roles: They help people by providing information about conditions and raise awareness about screening and prevention. They may also provide their members with a platform to meet with each other and share their experience and provide ongoing support for patients, relatives and friends during illness. Patient associations deliver benefits to the patient communities they represent, by enabling them to shape the current and future healthcare environment by making their collective voices heard, including by making public authorities aware of the importance of access to the most appropriate treatments.

The relationship between Sanofi and patient associations is guided by a spirit of collaboration, while respecting the independence of the association. This type of collaboration represents an opportunity for the Group, for the associations and, most of all, for patients by:

- Facilitating exchange of know-how
- Helping to make it possible to provide effective support to the patient and, on a larger scale, to the community, which may take different forms: support groups, hotlines, information centers, websites, educational programs, etc., all of which may improve the quality of life for patients

- Helping to enable patient associations to have a voice in current and future healthcare policy

Sanofi supports patient associations devoted to a number of different diseases in over 60 countries. The Group also collaborates with international and regional associations operating in 160 countries.

For more information:

- [List of patient associations](#)

The Group's support primarily involves associations that are active in conditions about which the Group has expertise, or is in the process of developing expertise. In parallel, the Group supports associations that, rather than focusing on a specific condition, strive to respond to the broad needs of patients.

## Policy

To ensure the integrity of relationships between Sanofi and patient associations, the Group has a worldwide policy in place, including a standard operating procedure and global principles governing interactions with patient associations. Ever mindful of the importance of transparency, the Group decided voluntarily to publicly publish the amounts of support it provides to European-based patient associations for activities undertaken in 2010 onwards. Subsequently, additional geographies, as well as amounts of support were added from other continents for collaborations in 2011 to further enhance the transparency of our activities on a voluntary basis.

### Ethics, responsibility and transparency: Enhancing Group policy

Approved at the end of 2010, the worldwide policy adopted by Sanofi is designed to:

- Ensure that interactions between the Group and patient associations take place in an ethical, responsible and transparent manner
- Establish standards for the Group
- Confirm that all the Group's actions worldwide must be undertaken with the ultimate aim of bringing benefit to patients

## Six global principles

### To guide interactions between the Group and patient associations: 6 global principles

The policy adopted by Sanofi concerning interactions with patient associations is based on six global principles that guide all the Group's actions and are part of the operating procedure established at Group level.

- 1. The independence of patient associations with respect to their policies and activities (including political decisions) shall be assured.
- 2. Collaborations between patient associations and Sanofi must be based on mutual respect and trust.
- 3. Sanofi shall not ask or encourage any patient association to promote any of its products.
- 4. Transparency of interactions must be ensured consistent with Sanofi Group and affiliate policies and procedures, legal requirements and local standards (e.g., industry codes).
- 5. Sanofi supports broad funding from multiple sources, and may not seek to be the sole funder of any patient association or major program.
- 6. All interactions including funding should comply with Sanofi Group and affiliate policies and procedures, patient association rules, legal requirements and local standards (e.g. industry codes).

These global principles are consistent with Sanofi's commitment as a sustainable healthcare provider. They are designed to apply the highest standards of ethics and integrity to the Group's stakeholder relations.

### Transparency – A deliberate choice

Sanofi is committed to be compliant with all applicable rules and regulations governing transparency, as well as voluntary collaborative undertakings by the pharmaceutical industry that seek to continuously improve transparency and ensure ethical, responsible conduct.

Recognizing the importance of transparency and its role in developing trust-based relationships with stakeholders, the public and, more importantly, patients – the ultimate recipients of

healthcare, in 2011, Sanofi took another step towards further enhancing transparency, with our decision to publicly publish amounts of support provided by the Group in 2010 for patient associations based in Europe, exceeding EFPIA (European federation of Pharmaceutical Industries and Associations) mandatory requirements, as well as for 2010 Medical Education Grants to patient associations in the US. This disclosure has subsequently been expanded to include far-reaching geographies (Australia, Brazil, Canada, Japan, All USA activities) for 2011 activities as part of a move towards enhanced transparency worldwide.

For more information:

- [List of patient associations](#)



## Actions

Here are some examples of initiatives that the Group initiated or continued in 2011, either directly or in collaboration with stakeholders:

- ▼ Supporting patients with multiple sclerosis
- ▼ Supporting patients with diabetes
- ▼ Supporting patients with cancer
- ▼ Supporting patients with rare diseases
- ▼ Supporting patients with their medications as they leave the hospital

### Supporting patients with multiple sclerosis or Parkinson's disease

In July 2011, Sanofi supported climbers with multiple sclerosis (MS) or Parkinson's disease who conquered Mount Kilimanjaro, the highest peak in Africa.

Sanofi sponsored communication activities for this special expedition, which was organized by one of the climbers, called "Kilimanjaro Leap of Faith Adventure," which was designed to challenge the body, expand the mind and foster courage in dealing with the diagnosis of a neurodegenerative disease. By supporting the climb, Sanofi wished to raise awareness of neurodegenerative diseases and help give a message of hope to people living with MS or Parkinson's disease and their families.

Seven men and women with MS and four with Parkinson's disease, along with nine climbing companions, reached Mount Kilimanjaro in Tanzania, which stands at 19,340 feet, the highest free-standing mountain in the world. The climb symbolized that neurodegenerative diseases need not represent the end of 'normal' life, and that people living with the diseases can achieve impressive feats.

## Supporting patients with diabetes

Information, education and prevention are essential to combat diabetes. Sanofi supports a number of programs worldwide to improve patient awareness. Here are just two examples:

### Korea

In 2011, Sanofi and the Korean Diabetes Association organized an original campaign to improve people's awareness about diabetes. This campaign featured a truly innovative artistic creation – a hope tree designed by a young sculptor and built from thousands of used insulin pens.

The “Green Star Campaign” was designed to raise awareness of insulin treatment options among patients with diabetes, while sending a message of environmental protection by organizing the collection of used insulin pens and needles.

Supported by 110 healthcare providers across the nation, the initiative encouraged patients to drop off their used insulin pens by providing special recycling boxes at the hospitals and clinics. Participants received educational information about the correct use of insulin treatments, including pens. During the campaign, about 2,200 patients collected 15,000 insulin pens, which the young sculptor Ha Tae-beom turned into a hope tree for patients.

The tree's roots and the trunk, made from used insulin pens, symbolize patients' willingness to receive treatment, while the white tree trunk and branches encourage environmental protection. The green leaves express patients' hope for improved quality of life through treatment. The hope tree is currently being displayed on Nami island. This initiative is just one of the CSR programs that our Korean affiliate has organized for patients since 2008.

### The Philippines

In the Philippines, Sanofi supports “Innovation For Life,” a patient access program intended to provide the Group's innovative diabetes medications to eligible patients who are unable to afford them. The program includes an adapted pricing policy consistent with applicable law and services for healthcare professionals and people with diabetes. In collaboration with key stakeholders (e.g., the Institute for Studies on Diabetes Foundation and the Philippine government) “Innovation for Life” seeks to provide direct assistance for eligible lower-income diabetic patients and their families by helping to alleviate some of the long-term cost burden of their health condition. By 2011, some 2,200 new patients had benefitted from the program, which was launched in June 2009.

“Innovation For Life” is a regional Asia Pacific initiative that was also introduced in Indonesia, where it met with similar success.

## Supporting patients with cancer

### Egypt

In Egypt, Sanofi hopes to be a source of support and inspiration for those whose lives are affected by cancer. Because it is important to improve awareness of the needs and challenges facing cancer patients, in 2011 Sanofi initiated a collaboration with "CanSurvive," one of Egypt's leading groups for cancer patients and survivors. The aim of their collaboration is to provide cancer advocacy, resources, education and support to patients. The program is designed for three target groups:

#### Patients:

- Provide information to help patients better understand their disease and treatment options
- Offer tools for self-advocacy empowering patients, survivors and enabling them to educate others
- Connect patients and survivors to share experiences on coping with cancer
- Offer access to medical and psychological support to reduce emotional distress associated with diagnosis
- Provide transportation for cancer patients to their treatment centers

#### Family, Friends and Caregivers:

- Educate those caring for cancer patients on how to best support them
- Offer expert support to help cope with the impact of learning that a loved one has cancer

#### Community:

- Campaign for better cancer care and support patients' fair access to treatment
- Offer opportunities to support cancer patients through volunteer work
- Raise awareness on prevention and early detection where applicable

#### For more information:

- [www.icansurvive.com](http://www.icansurvive.com)

- The Gaucher Initiative is Genzyme's partnership with Project HOPE that brings Cerezyme therapy to eligible Gaucher disease patients who live in developing countries where reimbursement is not yet a reality. Since the program began in 1999, more than 250 patients who otherwise would not have had access to Cerezyme have received it free of charge.
- Genzyme runs the European Cerezyme Access Program (ECAP) which provides free treatment to eligible Gaucher patients in Eastern Europe.
- Patients who live in countries where reimbursement is available can still face circumstances in which they cannot access treatment. The International Charitable Access Program (ICAP) provides Genzyme's four enzyme replacement therapies at no cost to eligible patients who live outside of the United States.
- Similar to the ICAP program, the Charitable Access Program (CAP) provides Genzyme's four enzyme replacement therapies free of charge to eligible U.S. patients who are not covered by any insurance program and lack the financial resources to obtain treatment.
- In partnership with the American Kidney Fund, Genzyme created the Renal Patient Assistance Program (RPAP), which provides Renagel and Hectorol to eligible patients who have no other means of access. Since the program was launched in 2001, nearly 16,000 patients have received free treatment through RPAP.

For more information:

- [www.genzyme.com](http://www.genzyme.com)

## Supporting patients with their medications as they leave the hospital

In the U.S., partially-used multi-dose medication containers such as inhalers, insulin vials or pens, ophthalmic/optic products (e.g., drops, ointments), topical preparations (e.g. creams, lotions) dispensed to patients in the hospital are often discarded when the patient is discharged despite the need for continued therapy; the patient is provided with a prescription at the time of discharge and incurs a copayment to obtain a new container of the same product.

In 2011, Sanofi US collaborated with the American Society of Health-System Pharmacists to develop a Multi-dose Medication Dispensing for Discharge (MMDD) program, which provides a framework to help interested institutions evaluate the potential implementation of the practice of labeling/relabeling partially-used multi-dose medications and providing them to patients to use after hospital discharge. In general, where available, MMDD is a service that can help reduce pharmaceutical waste, optimize limited health care resources, and increase patient satisfaction.

This program is offered as a resource to hospital pharmacists to help them make the case to implement a MMDD practice at their hospital in accordance with state applicable law and regulations. The resource website offers a comprehensive toolkit including: background and rationale, resources to reference state law, rule, and regulation information, as well as legal and regulatory information, waste calculator, slide kit to obtain relating to administrative consideration, tools to plan and implement such as sample policies and procedures, tools to educate key personnel, and tools to evaluate compliance.

- Dispensing partially used multidose medications for discharge helps to ensure the patient has a continued initial supply
- Also allows more time for patients taking new multidose medications to fill prescriptions post-discharge
- Provides opportunity for focused medication teaching and potentially increase patient satisfaction
- MMDD is a nationally recommended practice to reduce pharmaceutical waste (Hospitals for a Healthy Environment. Pharmaceutical waste minimization. [www.practicegreenhealth.org / topics / waste](http://www.practicegreenhealth.org/topics/waste))
- A 50% waste reduction of returned multidose medications was observed when studied at two hospitals affiliated with the same health-system (Conzelmann J, King K, Sarnicola S et al. MedWise: preventing medication waste while promoting safe administration. November/December 2009. [www.psqh.com / MedWise: Preventing Medication Waste](http://www.psqh.com/MedWise:PreventingMedicationWaste))

**For more information** on MMDD and to view the resources available visit:

- [www.multidose.org / Multidose medical dispensing for discharge](http://www.multidose.org/Multidose_medical_dispensing_for_discharge)

## Transparency

**Note:** Activities with patient associations supported by Genzyme, a Sanofi company are listed at:

- [www.genzyme.com / Our commitment / Patient organizations](http://www.genzyme.com/Our_commitment/Patient_organizations)



[Our Global Principles for Interacting with Patient Associations](#) (PDF, 18Kb)



[Sanofi-aventis Support in 2010 to Patient Associations based in Europe \(and Medical Education Grants to patient associations in the US\)](#) (PDF, 153Kb)



[Sanofi-aventis Support in 2009 to Patient Associations based in Europe](#) (PDF, 146Kb)



[Sanofi-aventis Support in 2008 to Patient Associations based in Europe](#) (PDF, 271Kb)

## Innovation for patients

Solidly rooted in Sanofi's values, innovation is one of the drivers of our transformation process. The Group's actions are guided by the goal of providing patients with solutions for unmet therapeutic needs. They rely on innovation as a mindset, and on continuously asking questions. From research to marketing, production to sales, and medicines to vaccines, all Group functions are developing new approaches to reach this shared objective.



Addressing the challenges at hand will require innovation in products, devices, the provision of health services and the ways these services are funded, as well as in the organization and management of medical facilities.

**Elias Zerhouni,**  
President of Global Research & Development, Sanofi

## Managing innovation



## Innovation management structures

### iPCS: Integrated Patient Centered Solutions

The Group has adopted a new organization to manage innovation with a renewed emphasis on the customer. The Sanofi iPCS network is wholly focused on providing solutions to patients while promoting a culture of innovation. One of iPCS's key objectives is to design initiatives that encourage the development of services to improve patients' day-to-day lives and the care they receive. Our teams also promote innovation by evaluating, prototyping and sharing cutting-edge projects and approaches in areas such as digital business, advocacy and stakeholder engagement.

The new iPCS organization hit its stride in 2011 by accelerating a patient-centered approach. Our goal is to provide solutions for people, rather than simply deliver products. We make this possible by combining services, products and innovative market access schemes. All Sanofi business units are in charge of innovative projects, with the aid of two support functions: Customer Solutions & Innovation and Digital Communications.

We are convinced that the key to sustainable success in the healthcare industry is to provide solutions for patients so that we can address the needs of our customers in emerging countries and more established markets.



« The 'i' in iPCS stands for 'integrated,' which speaks to the way we work collaboratively with our colleagues in R&D and Industrial Affairs to create value for the customer. The 'i' also refers to our commitment to digital innovation in all areas of our work. »

**Jean-François Brin,**  
Senior Vice President, iPCS

### Industrial Affairs: Optimizing our product portfolio

Sanofi created the Industrial Development and Innovation Department in 2009 to act as interface between R&D and industrial processes. This department plays a key role in enabling Sanofi to better respond to customers' needs and patients' expectations. It aims to improve the dynamics of product life cycle management thanks to process and technology innovations for medicines and medical devices.



In a constantly changing environment, our organization works in close, sustained cooperation with internal and external partners. We look to people to generate innovation and pilot our projects.

**Jean-Philippe Santoni,**

Senior Vice President, Industrial Development and Innovation Department, Sanofi

## R&D: Modernizing our organization to stimulate innovation

Recent developments challenge traditional models of research, which form the basis of R&D. They require close collaboration between multidisciplinary basic research and clinical research teams. To meet this challenge, R&D has undergone extensive reorganization, including:

- The creation of business units dedicated to diabetes, cancer, aging and auto-immune diseases. This type of organization brings research and development closer together so that scientific discovery can benefit patients more quickly.
- Partnerships acquisitions and other ventures, leading us to fertile ground where new ideas and ways to apply them will flourish including the development of state-of-the-art tools to further our understanding of biomedicine.

This new R&D organization moreover facilitates a change in culture. It opens the doors to innovation thanks to improved management of medical knowledge.

## BUSINESS CASE



### Adopt a more global and multi-disciplinary approach

Sanofi is working to develop a multi-disciplinary approach to finding innovative solutions for aging patients to help them live longer in good health and remain autonomous. The Group's approach includes a new R&D model and a pharmaco-epidemiological observatory for persons over age 65.

- *Business case: The Aging Patient*

## Partnerships, acquisitions and other ventures

Sanofi is growing internally, as well as through partnerships, selective acquisitions, and other ventures to meet evolving healthcare needs today and in the future. We understand that such ventures, like ideas, do not flourish on assembly lines. Sanofi's partners are not obliged to fit into rigid or inappropriate structures. Instead, we personalize each business relationship to meet the unique needs of each project and team.

This open, strategic relationship approach has attracted some of the best innovators in the world – indeed, Sanofi announced 30 in-licensing and mergers and acquisitions (M&A) transactions in 2011. We entered into research collaborations with leading public, private and government organizations around the world.

Sanofi's partners enjoy the benefits of our global collaboration network and the opportunity to connect with world-renowned experts in their field. They gain immediate access to the mature markets of Europe, Japan and North America, as well as to the fast-growing emerging economies of Asia Pacific, Latin America, Africa and the Middle East, where Sanofi holds a premier position in the industry.

### Sanofi Pasteur: Stepping up exploratory vaccine research

To make sure we are equipped to bring our ambitious projects to fruition, Sanofi Pasteur has stepped up exploratory research for the development of our portfolio of new vaccines. This approach involves a particular focus on two centers of excellence: Marcy L'Etoile (France) and Cambridge (United States).

The vaccines that Sanofi Pasteur develops today are anticipated to be a source of growth tomorrow. We are well aware that future vaccines will very likely require the use of novel technologies that need to be developed and emerging targets that need to be assessed. For this reason, Sanofi Pasteur is strongly committed to R&D in collaboration with major universities, research institutes, government bodies, biotechnology companies and contract research organizations worldwide. We increased the number of such collaborations in 2011 to tap into external innovation and expand the Group's areas of expertise.

#### For more information:

- [Acquisitions / agreements](#)

In 2011, Sanofi Pasteur worked on portfolio segmentation for new vaccines in order to define priority portfolio projects for the Group and adapt resources accordingly. The two leading

priorities in the Sanofi Pasteur portfolio – which correspond to currently unmet health needs – are the dengue fever and *Clostridium difficile* vaccines.

- [\*Clostridium difficile\* candidate vaccine](#)

## BUSINESS CASE



### Develop a safe, effective vaccine to prevent dengue fever

Dengue fever is the second most widespread disease in the world after malaria, causing epidemics in many countries of Latin America and Asia. It also affects travelers. In response to a genuine public health challenge, Sanofi Pasteur is working on the world's most advanced candidate vaccine, currently in Phase III clinical trials.

- [\*Business case: Dengue Fever\*](#)

## Internal initiatives to foster a culture of innovation

In 2011, Sanofi launched a number of creative in-house initiatives to foster a culture of innovation, develop our expertise and design new solutions for patients

### Marketing

#### Comparing diverse perspectives to enhance innovative approaches

Bringing together talented individuals from diverse backgrounds was the driving force behind an internal initiative to develop an enriched approach to innovation. The iPCS team believes that combining different profiles and areas of expertise helps accelerate cross-fertilization of ideas. Participants from Marketing, R&D and Industrial Affairs took part in training sessions worldwide in 2011.

The Business Innovation Forum provides a platform for virtual exchanges among internal and external experts with a series of “webinars” on innovative business topics. This forum, launched in 2010, is open to employees from all Sanofi affiliates worldwide. The employees who took part in 2011 reported a high level of satisfaction. In 2011, a total of 14 sessions were held, providing an efficient way to share best practices on innovative and strategic topics for the Group.

Training programs to promote a culture of innovation are available for Sanofi affiliates via LINKS, the worldwide business platform. In 2011, the Asia region organized several meetings with affiliates to develop and accelerate innovation knowledge by setting up training programs. In addition, a new tool developed by iPCS was tested in Asia. Based on a questionnaire to facilitate self-assessment, this tool is designed to identify tangible steps toward developing innovation expertise. It will be rolled out worldwide in 2012.

The LINKS platform, which was upgraded in 2011 to a 2.0 platform to enable interactions among users, played a central role in bolstering a culture of innovation at Sanofi. LINKS is the Group’s only cross-functional and cross-business platform. Open to all employees worldwide, it invites users to share knowledge and innovative best practices to provide improved services for patients and healthcare professionals.

The LINKS Awards were launched recently by the iPCS Department. At a global event in May 2011, Sanofi senior management awarded 16 initiatives coming from Group affiliates. The Awards Program will be rolled out to Genzyme and all Sanofi businesses in 2012.

Developing solutions to satisfy unmet needs

**The Customer Solution and Innovation Board** was formed to provide external expertise in support of innovation projects at Sanofi. Board members come from outside the pharmaceutical industry and possess expertise in innovation, customer centricity, digital technologies, etc. They share their knowledge and international perspective with the Group in order to help forge ties and generate strategies for innovation topics focused on the customer.

iPCS worked closely with these experts in 2011 and began setting up services for patients – for example, people with chronic kidney disease. An “ideation” session – a creative process for developing new ideas – was conducted with a worldwide expert on innovation and design thinking who is also one of the members of the Customer Solution and Innovation Board.

In addition, a dedicated Customer Solutions and Innovation Team was formed at the global level. Team members come from a wide range of backgrounds (marketing, medical devices, etc.).

A collaboration with the Wireless Life Science Association was also established, providing many opportunities to interact with companies involved in wireless technologies.

A strong digital strategy

To strengthen the Group’s digital strategy and determine priorities, Sanofi created a Digital Steering Committee composed of representatives from all functions. We also developed the worldwide Sanofi Digital Community, intended specifically for the Group’s digital experts worldwide. Beyond providing a forum to share digital knowledge and experiences, this community represents a resource center for research and educational materials. Its primary objective is to break down silos and increase networking to more efficiently manage digital risks and potential crises.

The Senior Management Business 2.0 Community (SMBC) is available to affiliate General Managers as a means to accelerate information sharing, especially about innovative projects, and identify solutions that promote access to healthcare and better treatments for more patients. Working groups were formed in 2011 on topics such as biosimilars. Senior Managers can now access the SMBC website from a smartphone.

## Research & Development

### The Innovation Center: Liberating the pioneering spirit

Launched in 2011, Sanofi designed the Innovation Center in an effort to respond to innovators' need for funders willing to take on early-stage risk for research that has the potential to create "disruptive" technologies – i.e., technologies that could make leaps, instead of incremental steps, in providing healthcare solutions. Candidates for financing from the Innovation Center are assigned an internal R&D sponsor, who manages rapid decision-making processes at the highest levels of the company.

### Industrial Affairs

Connecting and communicating with collaborators are key skills for innovation leaders. To provide an opportunity for such skills to develop, the Industrial Affairs Department organizes innovation seminars. The second "Innovation Booster" seminar took place in October 2011 in the Paris area. It was attended by 30 innovation leaders from 14 countries that are part of our industrial site network.

To share our sites' innovations, we modeled another initiative after the on-line shopping cart concept. Since 2010, each site has been invited to create an "Innovation Cart" on the internal platform ShareYourInnov.com, which was developed to facilitate the application of innovations that are part of the Innovation Awards.

### The applicant pool continues to grow for Innovation Awards

Launched in 2009, the Innovation Awards have become a much-anticipated event within Industrial Affairs to celebrate and share the most promising innovations. A multidisciplinary jury which includes members from Sanofi Pasteur – selects the winners. Today the Innovation Awards have become an essential part of Sanofi's industrial culture. Encouraging innovation as a daily mindset helps expand its scope and elicits new ideas. It also contributes to promoting the entrepreneurial spirit and teamwork, which are essential assets in the industrial sector. In 2012, the fourth Industrial Innovation Awards will be expanded to include Genzyme's and Merial's industrial activities. For the first time, the entire Sanofi industrial network will take part in this collective adventure to promote innovation.

## Industrial Affairs Innovation Awards – 2011 Highlights

The number of Innovation Awards applications grows each year. In 2011, the jury received 350 applications, up from 330 in 2010, and 280 in 2009.

Three finalists and 1 prizewinner were selected in each of the following 5 categories:

- Entrepreneurship
- Value Creation
- Technology & Process
- Simple & Clever
- Talented Innovative Team

For more information:

- [\*The Industrial Innovation Awards\*](#)



Beyond our fundamentals, HSE, Quality and Performance, our ambition for our site network, is to be recognized as the best supply solution for our patients and our markets.

**Alain Peychaud,**  
Industrial Affairs, Pharmaceutical Solids



## Our innovations in 2011

## Innovations in industrial processes

In 2011, the following projects were selected to be finalists in the Industrial Innovation Awards:

- ▼ Medicine inserts redesign: Information made easy
- ▼ Ready-to-drink Oral Rehydration Salts: The taste of success in Vietnam
- ▼ Techniques to counter the misuse of medicines

### Medicine inserts redesign: Information made easy

Unfortunately, medicine inserts are often associated with waste. According to an internal survey, 39% of French patients never read them. And as information and font sizes expand, leaflets have increased in size, which has a dramatic impact on packaging costs. The Pharma Solids team at Lisieux, France, along with its French affiliate, decided it was time for a total revamp. They designed a new insert for the French market – to be piloted with Doliprane 500 mg – that presents information in a clearer manner, without repetition, and offers titles, tables and even colored drawings for easier use.

### Ready-to-drink Oral Rehydration Salts: The taste of success in Vietnam

Patients suffering from diarrhea or fluid loss due to high-energy activities use Oral Rehydration Salts (ORS) to replenish their body. In Vietnam, however, the leading competitive ORS had a number of disadvantages. In addition to the unpleasant taste – particularly problematic for children – the product comes in an inconvenient powder-sachet format, which requires mixing with water. An innovation team in Vietnam decided it was time to transform these shortcomings into strengths. Leveraging an existing formula within the Group, they created Enterolyte, a convenient ready-to-drink ORS with a delicious strawberry flavor and innovative new packaging that's ideally suited to the market in Vietnam

### Techniques to counter the misuse of medicines

The innovation team at Sanofi's pharmaceutical site in Tours, France, works on developing techniques to combat the misuse and abuse of medicines in a way that gives Sanofi a competitive advantage. One key component of this initiative is an effort to aid in the prevention of drink tampering. Responding to a request by customers in Japan, the team created an

orodispersible Zolpidem tablet, a sleeping medication, which incorporates anti-abuse technology. If a malefactor breaks open the tablet to drug someone's drink, the potential victim will be alerted by an opaque color and floating insoluble particles, as well as effervescence in acidic beverages.

Another initiative by the Tours innovation team focuses on combating drug addiction by incorporating elements to help prevent drug addicts from misusing oxycodone, which is found in powerful painkillers. The team developed a new bi-layer tablet that incorporates anti-misuse technologies, such as a gelling agent to prevent extraction for intravenous injection and an irritant agent to make snorting unpleasant. These innovations can assist in combating narcotics abuse.

## New services for patients

In 2011, a number of projects were developed to improve services that bring a true benefit to patients. These new services concern the therapeutic areas covered by the Group's medicines as well as those covered by Sanofi Pasteur's vaccines. The following innovations are described below:

- ▼ Data Matrix: Modern technology improves access to information for all
- ▼ iBGStar®: Sanofi's innovative blood glucose meter receives FDA clearance
- ▼ Virtual promoter in Russia
- ▼ "Living-Proof" stickers to fight counterfeit drugs
- ▼ The African Pain Club develops e-Training to reach more professionals
- ▼ Connecting Nurses: Social media provide an innovative way to champion nurses' work
- ▼ New initiatives for healthcare professionals
- ▼ Multiple Sclerosis - Assessing patients, healthcare practitioners and payers needs

### Data Matrix: Modern technology improves access to information for all

In France, the Data Matrix identification system uses a two-dimensional barcode on drug packaging, which contains important information. Data Matrix codes are read when drugs are dispensed, improving traceability and enabling the detection of falsified or expired products.

This technology is being harnessed in a new innovation developed by Sanofi's Diversity and Information Systems Departments to provide improved accessibility to medical information for patients with disability, including blind patients and those with a visual or dexterity impairment.

Notiris software can read the information contained in the Data Matrix code by connecting to a specific database that provides the drug's name, dosage and expiration date. The information is given orally and in writing. The product leaflet will also be accessible thanks to the software, which will be available to PC, Mac and smartphone users in 2012. A dedicated website is in preparation to provide more information about this innovative tool.

In the near future, Sanofi plans to expand this option to countries such as Turkey, where the Group has already started using Data Matrix codes on packaging.

## iBGStar®: Sanofi's innovative blood glucose meter receives FDA clearance

In December 2011, the Food and Drug Administration (FDA) granted 510(k) premarket clearance for one of Sanofi's most innovative products, the iBGStar® Blood Glucose Monitoring System was co-developed by Sanofi with its partner AgaMatrix. As a global leader in diabetes, the Group is pleased to introduce iBGStar® as Sanofi's first blood glucose monitor in the U.S. It is already available in Germany, France, Switzerland, the Netherlands and Italy.

The iBGStar® is the first and only FDA-cleared blood glucose meter that directly connects to a smartphone, a key innovation that the diabetes community had been waiting for. It was designed with patients in mind, to allow them to more seamlessly integrate accurate blood glucose monitoring into their daily lives. This innovation expands our diabetes portfolio to include even more comprehensive diabetes management offerings.



*Sanofi*

## Virtual promoter in Russia

In Russia, Sanofi has launched a large-scale innovative project to put virtual promoters in the country's leading pharmaceutical networks. This innovation project was designed for the promotion of products in the Consumer Healthcare portfolio, including Essentiale® Forte N, No-Spa® and Magne B6® products.

The virtual promoter, developed specifically for Sanofi Russia, reproduces a video model of a woman. Images can be changed to address different audiences and promote several different products in succession. Currently, 90 pharmacies in Moscow and St. Petersburg are taking part in the virtual promoter pilot project. Feedback from customers indicates that this innovation has a number of advantages over conventional promotion tools because it can reach a broad audience to provide consumer information in an unusual format, including audio-visual effects and 3D animation.

## “Living-Proof” stickers to fight counterfeit drugs

Preventing counterfeit drugs from entering the supply chain is a top priority for Sanofi. Our innovation teams work to help develop ways to preserve patients' safety by ensuring the quality of our products. “Living-Proof” stickers are one example of this type of innovation.

Living-Proof stickers have been introduced in Lebanon for Plavix® and will be expanded to other products and to neighboring countries where the phenomenon of counterfeit drugs poses a significant threat. Living-Proof stickers cannot be removed from packaging without being destroyed, thereby creating a void label. These stickers are part of an interactive system that includes a hotline that patients and providers can contact to immediately verify the product's authenticity in case of doubt.

## The African Pain Club develops e-Training to reach more professionals

Pain is one of the most under diagnosed, neglected and undertreated medical problems in Africa.

In light of the Group's broad portfolio of analgesics, Sanofi created the African Pain Club, a multidisciplinary scientific committee composed of experts from seven countries in Africa, which meets twice a year under the leadership of Professor Alain Serrie (Lariboisière Hospital, Paris), Chairman of the African Pain Club and President of Douleurs Sans Frontières (Pain without Borders).

The objective of the African Pain Club is to improve pain management through the development of specific training on topics tailored to the African environment. Initially nine modules were developed, followed by case studies and modules on patient education. Each member of the Pain Club is responsible for training "trainers" who will in turn train healthcare professionals in their own country at meetings organized by Sanofi.

To date, more than 10,000 healthcare professionals (doctors, pharmacists, dentists, nurses in health clinics, etc.) have thus been trained. Given this success, Sanofi, in partnership with an African health e-magazine, decided to create the African Pain e-Club. The site was launched on October 17, 2011, during the World Day Against Pain.

For more information:

- [www.clubdouleurafrique.com](http://www.clubdouleurafrique.com)

This original tool enables healthcare professionals to train at home 24/7, which is particularly appreciated by professionals who are far from major African towns. Several events were held in the African affiliates to promote this new Sanofi service.

Connecting Nurses: Social media provide an innovative way to champion nurses' work



Connecting Nurses was designed as an initiative to champion nurses, who are at the forefront of healthcare. Supported by Sanofi, it brings nurses together both on-line and in the real world.

Nurses unquestionably play a key role in today's healthcare world, in particular in patient education and chronic disease self-management. In the future, they are expected to become increasingly influential healthcare stakeholders. In addition, many nurses show a keen interest in using social media.

Based on combining these trends, Sanofi's iPCS Department developed the Connecting Nurses project, launched in January 2011. The project initially focused on two initiatives: Care Challenge and Information Shareapy.



**Care Challenge** is an online contest that highlights innovative care solutions developed by nurses from all over the world. The contest got underway in mid-2011, and 20 winners will be announced in 2012.

For more information:

- [www.care-challenge.com](http://www.care-challenge.com)



**Information Shareapy** is a prototype patient education service for nurses, allowing them to share links to websites with their patients and provide access to quality sources of information. Information Shareapy was first tested in 2011.

Thanks to these initiatives, nurses will be able to improve their practice and share knowledge with their patients. They will be able to share their experience and preferred websites and communicate with other nurses worldwide.

Patients will benefit from improved quality of care and more direct communication with nurses. Last but not least, the Connecting Nurses initiative enhances Sanofi's reputation as a preferred partner.

#### New initiatives for healthcare professionals

In 2011, Sanofi's integrated iPCS team developed many innovations for healthcare professionals.

In the field of atrial fibrillation (AF), innovations included an awareness campaign with the World Heart Federation (WHF): a new long-term initiative on disease management; and involvement with local World Heart Federation chapters to deliver patient information and provide an AF primary care support tool for healthcare providers to better manage AF.

Also in 2011:

- The International Society for Holter and Noninvasive Electrocardiology organized the Worldwide Internet Symposium on the management of Atrial Fibrillation, which received funding from Sanofi. The fourth session was made available in October 2010 for one year via the Internet thanks to funding from Sanofi. The on-line symposium includes the latest data and opinions from internationally recognized faculty of around 30 experts from across the globe, new ESC AF guidelines, genetics, ablation systems, anti-arrhythmic drugs, devices and clinical cases, to name a few topics. It includes video and audio streams and downloadable materials. It is available in English, Chinese, Spanish and Russian. There



- were over 13,044 visits to this web symposium in the first month and 3,700 from December 2010 to December 2011.
- Innovative means of communication with healthcare practitioners were introduced, including virtual medical visits using an iPad. In addition, a Multaq® pilot initiative was organized in Austria (Europe).
- The Thrombosis Global Team introduced a new initiative with the EAHP (European Association of Hospital Pharmacists). The main objective was to reduce the use of paper (zero paper) for the launch of a promotional Lovenox® / Clexane®.

#### Multiple Sclerosis - Assessing patients, healthcare practitioners and payers needs

In France, in Canada and in the United States, Sanofi undertook the evaluation of service needs for patients, healthcare practitioners and payers using innovative approaches, including:

- A patient survey among the “Patients Like Me” multiple sclerosis community in the US
- Benchmarking of service offerings in the multiple sclerosis field
- A study of service shortcomings for healthcare providers and payers in multiple sclerosis continuum of care
- Assessment of a telemonitoring solution for cardiac insufficiency with the development of a pharmaco-economic model

In addition, the Group undertook a worldwide landscaping of health services to evaluate business opportunities in greater depth.

## Innovative acquisitions, partnerships, and other business ventures

### Recent Trends in Business Development

In 2011, Sanofi announced 30 in-licensing and M&A transactions and the Genzyme acquisition was completed. The Group entered into an R&D agreement in oncology with Merck Serono, demonstrating a willingness to explore co-development / risk-sharing approaches in late-stage clinical trials. Two other Business Development transactions concerned “disruptive” innovation: a new approach via the Innovation Center will be taken following the agreement with Kahr Medical (oncology and immuno-inflammation, Israel) and the agreement with Esperance Pharmaceuticals (oncology, U.S.). On January 10, 2012 Sanofi announced the launch of Warp Drive Bio, an innovative biotechnology company in which Sanofi is co-investor, focusing on proprietary genomic technology to discover drugs of natural origin. Sanofi will give Warp Drive Bio access to its strains library and natural product expertise and will be granted certain access rights to Warp Drive Bio’s technology and products.

- 69% of Sanofi products in clinical development are innovative because they are either first in class or among first in class
- 79% of these innovative projects resulted from Business Development activities (in-licenses or acquisitions)

### Innovative acquisitions, partnerships, and other business ventures in 2011

#### **Genzyme: taking a decisive step toward biotechnology**

Sanofi’s rare disease division includes Genzyme, one of the world’s leading biotechnology companies. Dedicated to making a major positive impact on the lives of people with serious diseases, Genzyme is a leader in efforts to develop and apply the most advanced technologies in life sciences, with products and services focused on treating rare inherited disorders, kidney disease, orthopedics, cancer, immune and transplant-related diseases.

The acquisition of Genzyme completed in April 2011 has strengthened Sanofi’s sustainable growth strategy and expanded the company’s presence in biotechnology. As a Sanofi company,

Genzyme benefits from the reach and resources of one of the world's largest pharmaceutical companies, with a shared commitment to improving the lives of patients.

For more information:

 [Business Overview \(extract from 2011 Form 20-F\)](#) (PDF, 287Kb)

### **Sanofi Pasteur contributes to public-private partnership to develop HIV vaccines**

Sanofi Pasteur upholds a long-standing commitment to HIV vaccine research and development efforts by collaborating with academia, governments, non-governmental organizations, and other vaccine companies. In the nearly 20 years since Sanofi Pasteur's HIV vaccine development program was established, we have taken part in a number of collaborations that have led to major advances in research, clinical study design and implementation.

A follow-up study to the Phase III clinical trial in Thailand, completed in 2009, provided new clues in 2011 about the types of immune responses that may have played a role in the protection seen in 2009 with our ALVAC-HIV vaccine, the first concrete evidence since the discovery of the HIV virus in 1983 that a vaccine against HIV is potentially feasible.

Last year, Sanofi Pasteur entered into a public-private partnership with Novartis Vaccines, the Bill & Melinda Gates Foundation, the U.S. National Institutes of Health (NIH), the HIV Vaccine Trial Network, and the Military HIV Research Program to substantiate and extend the vector prime / protein subunit boost regimen used in Thailand. This collaboration is expected to further the field of HIV vaccine development by sharing resources and combining the forces of vaccine manufacturers, funding agencies, research organizations, governments and experts in the field of HIV vaccine development.

### **Collaboration between CureVac and Sanofi Pasteur to develop prophylactic and therapeutic vaccines**

#### **Logo Curval**



In 2011, CureVac and Sanofi Pasteur signed several collaboration agreements to further develop and apply CureVac's proprietary RNAActive® technology to the development of vaccines against several infectious diseases. They will also further advance key aspects of CureVac's

RNActive technology platform and evaluate several vaccine candidates in a number of relevant disease models.

Sanofi Pasteur and CureVac, the global leader in mRNA based vaccination technologies, have also entered into an option agreement with pre-agreed license terms for several pre-defined pathogens. Messenger RNA (mRNA) vaccines are an alternative technology to DNA-based vaccines and have shown safer features<sup>1</sup> Sanofi Pasteur's option rights are linked to fulfillment of certain agreed acceptance criteria relating to the above project. Under the license agreements, Sanofi Pasteur will fund all research and development activities and will have exclusive marketing rights worldwide for RNActive vaccines against the pathogens for which Sanofi Pasteur has exercised the option.

**For more information:** Methods in Molecular Medicine, 2006, Volume 127, I, 23-40

- [www.springerlink.com / content](http://www.springerlink.com/content)



Regulus is very pleased to have formed an alliance with Sanofi, a leader in innovative healthcare solutions meeting patients' unmet needs. Regulus is committed to scientific excellence and advancement of novel microRNA medicines, and our alliance has been a seamless interaction with creative input and expertise offered on both sides.

**Kleanthis G. Xanthopoulos, PhD**

President and Chief Executive Officer of Regulus



By combining Warp Drive Bio's unique proprietary technology and Sanofi's extensive drug development capabilities, we are convinced that this open and creative model of a pharma-biotech alliance will boost innovation for the benefit of patients.

**Elias Zerhouni, President,**

Global Research & Development of Sanofi

<sup>1</sup> (Source: Methods in Molecular Medicine, 2006, Volume 127, I, 23-40

[www.springerlink.com / Abstract](http://www.springerlink.com/Abstract), on March 30, 2012.

## Innovative products

The following products illustrate the Group's innovation strategy for both medicines and vaccines:

- ▼ Lyxumia®
- ▼ Multaq®
- ▼ Jevtana®
- ▼ Innovative vaccines
- ▼ Clostridium difficile candidate vaccine

### Lyxumia®

On October 26, 2011, Sanofi's Global Regulatory Affairs Department submitted a marketing authorization application (MAA) to the European Medicines Agency for Lyxumia®, a combination medicine and injection device, with the hope of receiving E.U. approval in 2012. This is the first time in the Group's history that we have submitted an MAA for a new medicine and a new injection device developed in-house.

The injection device was designed specifically to improve the lives of people with diabetes. Lyxumia® is a pen containing 14 fixed doses, for one injection per day. Several thousand patients and healthcare professionals took part in its development in order to take into account patients' needs and thus be able to offer tangible benefits for improved diabetes management.

Consistent with Sanofi's patient-centered philosophy and the Group's interest in developing easy-to-use injection devices, this new pen offers a very simple pressure-activated mechanism.

### Multaq®

Multaq® is the only anti-arrhythmic drug that offers comprehensive treatment for the symptoms of atrial fibrillation by controlling cardiac rhythm and reducing cardiovascular events. Atrial fibrillation (AF) is an irregular and often rapid heart rate that generally causes poor blood flow to the body. It is a serious medical condition that may lead to complications and sometimes requires emergency treatment.

For more information:



[Business Overview - Multaq \(extract from 2011 Form 20-F\)](#) (PDF, 41Kb)

## Jevtana®

In 2010, Sanofi received marketing authorization for Jevtana® (cabazitaxel injection), another recent innovation developed to respond to patients' unmet needs.

In combination with prednisone, this is the first therapy that brings a significant survival benefit in the treatment of patients with metastatic hormone-refractory prostate cancer treated previously with docetaxel-based therapy.

This new drug fills an important therapeutic need. Following the approval of Jevtana®, healthcare professionals may now consider utilizing a new treatment for patients with the most advanced form of prostate cancer, for which there are few therapeutic options. For this patient population, Jevtana® is the only drug that brings about significant improvement in overall survival.

Jevtana® is the result of 14 years of Sanofi research. Marketing authorization for this drug highlights the success of the Group's new R&D strategy within the Oncology Division. Nearly ten other oncology projects are under development in Sanofi research laboratories.

## Innovative vaccines

To sustain our global leadership in the development of influenza vaccines, the Group's R&D efforts concentrate on innovative methods to assess new formulations and new means of administration with an eye to meeting specific patient needs.

- **Intanza® / IDflu®: The first influenza vaccine to be administered via intradermic micro-injection**

Sanofi Pasteur has licensed microinjection intradermal influenza vaccines, marketed as Intanza® or IDflu® vaccines, in more than 40 countries including Australia, Brazil, Canada and countries in Europe. Since 2010, we have marketed the first influenza vaccine to be administered by means of a new intradermic micro-injection. In light of the advantages it offers – comfort and ease of administration – this vaccine aims to improve immunization coverage rates.

This innovation brings benefits to both patients and the Group. Patients welcome the minimal invasion of a small needle and the innovative means of administration (intradermally), while the Group is able to offer an innovative product.

- **Fluzone® ID: New intradermal influenza vaccine with 90 percent smaller needle in the US licensed in 2011**

The new formulation of Fluzone® Intradermal vaccine is the first influenza vaccine licensed in the U.S. that uses a novel microinjection system for intradermal delivery: Fluzone Intradermal vaccine, indicated for active immunization of adults against influenza, features an ultra-fine needle that is 90 percent shorter than the typical needle used for intramuscular injection of influenza vaccine.

Fluzone® Intradermal vaccine is expected to be an attractive new immunization option for adults 18 through 64 years of age, a broad age group that is often overlooked but still at risk of contracting influenza.

- The Fluzone® High Dose vaccine (influenza virus vaccine) was designed specifically to induce a stronger immune response among persons aged 65 and older. This new vaccine was successfully launched in the United States in 2010.
- **Our future quadrivalent Fluzone® and Vaxigrip® influenza vaccines reach important development milestones.**

By increasing the number of viral strains contained in the vaccine, the Group should be able to enhance protection against the most prevalent seasonal influenza viral strains. A Phase III clinical trial was completed in 2011 for Fluzone®. Vaxigrip® QIV IM, targeting the European market, entered Phase III clinical trials in October 2011.

#### Clostridium difficile candidate vaccine

Nosocomial infections continue to represent a major public health concern in many industrialized countries. Vaccination and immunotherapy are novel and very promising approaches to prevent these infections.

Clostridium difficile, an anaerobic spore-forming bacterium, is a major public health concern in North America and Europe. It is the leading cause of infectious diarrhea among adults, particularly the elderly, in hospital settings. *Currently there is no vaccine available to prevent this hospital-acquired infection, and the ACAM-Cdiff™ vaccine under development by Sanofi Pasteur, is a toxoid-based vaccine and is the most advanced candidate vaccine under development.* \*

After receiving approval from the Food and Drug Administration (FDA) for a fast-track evaluation, Sanofi Pasteur U.S.'s candidate vaccine to prevent Clostridium difficile entered Phase II clinical trials in the United States in late 2010, marking a major step in its development.

This trial is focused on evaluating prevention of the first episode of Clostridium difficile infection (CDI) in at-risk individuals, which includes adults with imminent hospitalization or current or

impending residence in a long-term care or rehabilitation facility. Results from the first stage of this study showed the vaccine was safe and immunogenic and provided important information for dose selection. The ongoing stage two of the study is evaluating the dosing schedule.

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)



## Business Case: Valuable progress in dengue fever vaccine program in 2011

### The challenge

Dengue fever threatens nearly half the world's inhabitants, especially the most disadvantaged populations. Sanofi Pasteur's challenge is to complete the development of a safe and effective tetravalent vaccine targeting the four viral serotypes to prevent dengue fever and its serious complications, such as hemorrhagic fever.

Developing and testing the vaccine in clinical studies throughout dengue-endemic regions of the globe involves a number of challenges, including creating vaccination policies and addressing access issues and financing mechanisms for people most in need. Last but not least, raising global awareness about dengue fever is a pressing issue.

### Our response

Dengue fever is the second most widespread disease in the world after malaria. Sanofi Pasteur is working on the world's most advanced candidate vaccine.

### Clinical trials

To date, no other potential dengue fever vaccine has reached Phase III clinical trials. Our vaccine is currently in Phase III trials with large-scale testing. By October 2011, over 22,500 volunteers had joined our clinical trials, which involve 43 different clinical sites in ten Latin American and Asian countries.

This is the largest clinical trial program ever undertaken by Sanofi Pasteur, the results of which are anticipated to be available in 2014. Ultimately, nearly 45,000 volunteers in 15 countries will have participated in all of our dengue vaccine clinical trials.

### A new production plant

Sanofi Pasteur decided to build a plant for the production of this potential vaccine, which entailed transforming a chemical production facility into a biotechnology site. When it is completed and operational, the plant in Neuville-sur-Saone (France) will be the Group's third European production center devoted entirely to vaccines.

### Regulatory approval approach

To reach populations in need as quickly as possible, Sanofi Pasteur's clinical and regulatory expertise is being applied to an innovative approval approach. It is based on a sound understanding of each country's needs and the ability to adapt to different national health organizations and cultures. Each country will receive a customized approval application pursuant to applicable law, which is being prepared in close cooperation with local and regional teams.

## Benefits for stakeholders

Successful development of the world's first dengue fever vaccine would first and foremost benefit patients.

For Group employees, the dengue fever vaccine program supports jobs at the Neuville-sur-Saone site. More than 1,000 employees are being trained to make the switch from chemical to biotechnology production. Moreover, employees are proud to contribute to developing such a critical candidate vaccine for global public health.

For other stakeholders such as the World Health Organization, national governments, healthcare authorities, sponsors, NGOs and foundations – all of whom collaborate with Sanofi Pasteur – it is important to be able to anticipate the health challenges related to access to vaccines. Our cooperation with these stakeholders focuses on accelerating the adoption and introduction of dengue vaccination and on making it accessible to those who are most at risk.

## Opportunities for the Group

The new candidate vaccine bolsters the Group's image and reputation. The Sanofi Pasteur candidate dengue fever vaccine was distinguished in April 2011, winning the "Best Prophylactic Vaccine" award at the World Vaccine Congress. In June 2010 it was designated "Best vaccine under development in Asia."

The dengue fever vaccine project is wholly in line with the Sanofi access to healthcare strategy. In addition, this program is a growth driver for the Group.

## The Future

The plant at Neuville-sur-Saone will be a new showcase for the Group's public health mission, with state-of-the-art facilities to produce dengue fever vaccine in the quantities required to support vaccination needs and to help combat this devastating disease.

If approved, the first vaccine is expected to be available in 2015 at the earliest.

## Business Case: The aging patient

### The challenge

Aging in today's world is, in part, a matter of living in good health. Elderly and aging patients must be considered from a global, multi-disciplinary perspective that goes beyond merely providing medical treatment for diseases that affect individuals as they grow older.

### Our response

Sanofi is committed to working with public authorities and healthcare professionals in an effort to better understand diseases and conditions that may affect the elderly patient, as well as their treatment. The Group strives to combat disorders caused by medical treatments and procedures or exposure to healthcare facilities. We wish to stand with all those in the healthcare network who support the aging patient.

The Group takes a multi-faceted approach to meeting this challenge.

### **Creating a new R&D model**

Understanding age-related disorders requires adopting a different R&D model and taking a cross-sector approach. In an effort to develop innovative solutions, Sanofi created an entirely new unit within our R&D organization, which focuses on the medical challenges related to aging. The objectives of this R&D unit are centered on four priorities:

- Developing a line of research devoted to quality of life for the elderly, in particular issues such as pain and preserving their independence so that they can live at home for as long as possible,
- Adapting pharmaceutical formulations for the elderly,
- Designing new therapeutic solutions that make use of new technologies – such as intelligent medical devices that are able to combine electronics and pharmacology,
- Understanding the mechanisms behind the aging process by determining the causes of cellular aging and the channels they involve as well as endeavoring to discover new targets for drugs to treat osteoarthritis, Alzheimer's disease and Parkinson's disease.

## **A pharmaco-epidemiological observational study for aging patients**

In France, Sanofi has teamed up with researchers from the University of Paris XI to collect pharmacological and epidemiological data about three major diseases that affect aging patients: type 2 diabetes, atrial fibrillation and chronic pain. They are conducting a study to monitor 3,600 patients over age 65 for three years. Thanks to the participation of 809 primary care physicians, who most often treat elderly patients, the study aims to gather information about both medical and non-medical care given to these patients.

## **Promoting the proper use of medicines in France**

One of the Group's priorities is to promote the proper use of medicines. Carefully maintained patients' records are critical to reaching this goal because they help to ensure that key information is shared and coordinated among different healthcare professionals. In France, the carnet de liaison for seniors was designed to improve all aspects of their care – medical, paramedical and social.

## **Benefits for stakeholders**

The primary beneficiary of this coordinated initiative is the aging patient. Our other stakeholders – the scientific community, public health organizations, medical and paramedical personnel, and so forth – will benefit from new data and an improved understanding of conditions affecting the elderly, as well as potential development of specific tools designed for aging patients.

## **Opportunities for the Group**

One of the clear results of the cross-disciplinary approach adopted by Sanofi has been to open up certain departments and bring together teams that rarely have the opportunity to work together, such as certain R&D and business teams. Such cooperation is not only a potential catalyst for innovation and synergy; it also can help save time.

## **The Future**

Whether scientific, sociological, economic or medical, initiatives will continue to be developed to help elderly people remain autonomous for as long as possible and to help delay the onset of disease. Alongside the healthcare community and patients themselves, Sanofi is working to innovate and to discover improved healthcare solutions for persons over age 65.

## External recognition

In 2011, a number of awards distinguished Sanofi's innovative products and services. This external recognition confirms our ability to live up to the conviction that innovation is a key driver for success in our industry.

### Sanofi Pasteur dengue fever vaccine designated "Best Prophylactic Vaccine"

With five other nominees in the running for this category, Sanofi Pasteur's dengue fever vaccine received the "Best Prophylactic Vaccine" award at the World Vaccine Congress held on April 12, 2011, in Washington, D.C.

The 2011 Vaccine Industry Excellence (V.I.E.) Awards were presented in 10 categories. This event was the occasion for various players from the international vaccine community – manufacturers, biotech companies, research institutes – to recognize outstanding achievements in the field.

In 2010 Sanofi Pasteur's dengue fever vaccine received the V.i.E. Award for "Best Vaccine in Development for Asia."

**For more information:** The Vaccine Industry Excellence Award

- [www.terrapinn.com/awards/vaccine-industry-excellence](http://www.terrapinn.com/awards/vaccine-industry-excellence)



We are certainly excited to have been recognized for the groundbreaking work we are carrying out in the field of dengue fever vaccine development. This achievement only adds to our belief in this promising candidate and to the benefits it can bring to so many individuals around the world. It recognizes the efforts by everyone involved.

**Allan Jarvis,**  
Vice President, Corporate Development, Sanofi Pasteur

## BUSINESS CASE



### Develop a safe, effective vaccine to prevent dengue fever

Dengue fever is the second most widespread disease in the world after malaria, causing epidemics in many countries of Latin America and Asia. It also affects travelers. In response to a genuine public health challenge, Sanofi Pasteur is working on the world's most advanced candidate vaccine, currently in Phase III clinical trials.

- *Business case: Dengue Fever*

### Dengue Fever Vaccine Program

To conduct clinical trials, a global program is expected to ultimately enroll approximately **45,000** participants in Asia, Latin America and the United States. Both children and adults will be included in the studies.



We will be able to develop the vaccine and obtain the approvals only thanks to the culture of urgency and innovation instilled within the team. We have come to thoroughly understand the success factors associated with the political, strategic and execution aspects of our program, while adhering to our ambitious timetable. The vaccine could provide a real public health benefit and at the same time be a source of long-term profitability for the company.

**Jean Lang,**  
R&D Dengue Program Leader

### VaxDesign group wins Florida's "Company of the Year" award

Our VaxDesign group was honored at BioFlorida's 14th Annual Conference, where it received the David J. Gury "Company of the Year" Award.

BioFlorida represents more than 3,000 companies and 61,000 Floridians working in research organizations in the biotechnology, pharmaceutical and medical device fields. This award is intended to honor a significant technological advancement or achievement of a major product development milestone.

The award acknowledges VaxDesign's work designing, developing and manufacturing in vitro biomimetic models of the human immune system (MIMIC®, which stands for Modular IMMune In-vitro Construct), and continuing business and science advances.

With MIMIC®, our scientists can predict the effectiveness of different adjuvants and antigens, along with dosing and timing of administration. This innovation also allows us to predict cross-protection against other strains, determine the potency of stockpiled vaccines, and compare the effects of different manufacturing methods on vaccine potency.

For more information:

- [Ethics section / Use of laboratory Animals - Actions](#)

Sanofi Pasteur receives the "Best Vaccine R&D Pipeline" VIE Award. Our C. Difficile vaccine also received accolades in the "Best Prophylactic Vaccine" category.

The 5th annual Vaccine Industry Excellence (ViE) awards ceremony was held on April 11 at the World Vaccine Congress in Washington, DC. These awards recognize accomplishments and positive contributions of companies and individuals in the vaccine industry.

Sanofi Pasteur received two honors:

- Sanofi Pasteur received the top award as the winner in the "Best Vaccine R&D Pipeline" category—thanks to our innovative portfolio including 13 vaccines in clinical development. Christian Steber, R&D Project Leader, from Swiftwater, accepted the award on the company's behalf.
- Our Clostridium Difficile vaccine was commended as "Highly recommended" in the "Best Prophylactic Vaccine" category.

## Elias Zerhouni receives transatlantic innovation leadership award

Dr. Elias Zerhouni, President, Global Research and Development and former director of the U.S. National Institutes of Health (N.I.H.), received the European Institute's prestigious Transatlantic Innovation Leadership Award on December 5, 2011. The award, which recognizes "uncommon commitment to the renewal of the transatlantic relationship," was presented during the Ambassadors' Gala Dinner in Washington, D.C.

Also attending the event, Sanofi CEO Christopher A. Viehbacher shared elements of the company's strategy and his thoughts on what the United States and Europe must do to move forward through difficult economic times.

**Dr. Elias Zerhouni and Christopher A. Viehbacher**





## Product risk management

One of Sanofi's principal missions is to ensure the safety and quality of the Group's products. We aim to provide the best possible risk management associated with the utilization of our products.

## Pharmacovigilance

- ▼ Pharmacovigilance: commitment to the safety and quality of our products
- ▼ When does Pharmacovigilance come into the picture?
- ▼ A solid regulatory environment

### Pharmacovigilance: commitment to the safety and quality of our products

Sanofi's Pharmacovigilance Department plays a vital role in patient safety by monitoring the risks associated with the use of our products. This division is in charge of endeavoring to ensure the safety and quality of our products during all development phases and after products have received marketing authorization.

Pharmacovigilance is broad in scope, monitoring all products from Sanofi Pharma, Genzyme, Fovea and Sanofi Pasteur as well as our generic medicines and consumer health (OTC) products.

The Pharmacovigilance Department seeks to constantly optimize the benefit / risk ratio by monitoring prescription practices to prevent or reduce treatment risks and alert patients about safety issues. To accomplish this, we work in close collaboration with healthcare professionals, relevant health authorities and the patient community.

The purpose of Pharmacovigilance is three-fold:

- To detect, evaluate and monitor risks related to the use of all Sanofi medicines and vaccines
- To seek and implement measures to reduce such risks as well as to prevent adverse events
- To promote the proper and safe use of medicines

### When does Pharmacovigilance come into the picture?

The diagram below shows the different phases in a drug's life cycle, from research to marketing. Pharmacovigilance plays a role from the first time a compound is administered to human subjects (clinical trials) and continues throughout the entire development and product marketing cycle.

| RESEARCH  |  | TERM         | MOLECULES        |
|---|--|--------------|------------------|
| <b>Research into chemical starting points</b> <ul style="list-style-type: none"> <li>• Conception</li> <li>• Target selection</li> <li>• Test development</li> <li>• Synthesis</li> </ul> <b>Screening (+ high throughput screening)</b><br>Active molecules (lead compounds)                         |  | 2 years      | 5,000 to 500,000 |
| <b>Optimization</b> <ul style="list-style-type: none"> <li>• Intrinsic activity</li> <li>• Selectivity</li> <li>• Oral absorption</li> <li>• Duration of action</li> <li>• Efficacy in relevant animal models</li> </ul>  |  | 1 to 2 years |                  |
| DEVELOPMENT   |  |              |                  |
| <b>Preclinical evaluation in vitro and in animals</b> <ul style="list-style-type: none"> <li>• Chemical development</li> <li>• General pharmacology</li> <li>• Analytical methods</li> <li>• Stability</li> <li>• Safety</li> <li>• Formulation</li> <li>• Metabolism and pharmacokinetics</li> </ul> |  | 1 to 2 years | 30               |
| <b>Clinical evaluation in man</b><br><b>Phase I</b><br>• Tolerance and pharmacokinetics   |  |              | 10               |
| <b>Phase II</b><br>• Biological activity and research of a therapeutic effect<br>• Determination of the optimal dose  |  | 6 to 8 years | 3                |
| <b>Phase III</b><br>• Confirmation of the therapeutic effect and tolerance  |  |              |                  |
| BIRTH   |  |              |                  |
| Preparation and submission of a new drug application dossier  |  | 1 year       | 1                |
| LIFE  |  |              |                  |
| <b>Marketing</b><br>• LCM (Life Cycle Management)   |  | Contin.      | Production       |

## A solid regulatory environment

Monitoring the risk of adverse events resulting from the use of drugs and products for human use takes place in a highly regulated environment. Product development in compliance with regulations provides a safeguard that demanding standards of medical practice are applied to protect patient safety.

In the European Union, new Pharmacovigilance legislation was adopted on December 31, 2010, and will go into force in July 2012. It provides for a new EU legislative framework to strengthen safety monitoring and ensure clear communications about product safety through transparent and immediate data collection and data analysis, which contribute to improving public trust. This legislation also streamlines the review and assessment process for product marketing authorizations and maintenance on the market by requiring drug profiling recommendations and post-marketing studies.

For more information:

In Europe: EMA (European Medicines Agency)

- [www.ema.europa.eu](http://www.ema.europa.eu)

In the United States

FDA (*Food and Drug Administration*)

- [www.fda.gov](http://www.fda.gov)
- [www.accessdata.fda.gov](http://www.accessdata.fda.gov) / *Code of Federal Regulations*

## Internationally

CIOMS (*Council for International Organizations of Medical Science*)

- [www.cioms.ch](http://www.cioms.ch) / *About Us*
- [www.cioms.ch](http://www.cioms.ch) / *Benefit-Risk balance for marketed drugs: evaluating safety signals*

ICH (*International Conference on Harmonisation*)

- [www.ich.org](http://www.ich.org)

## Policy

Sanofi complies with applicable regulations and recommendations in force in Europe and the United States as well as internationally. Compliance with these regulations guarantees that the highest standards of practice are maintained for patient safety.

In other contexts, the Group's Pharmacovigilance policies are mandatory and routinely applied, such as for:

- studies in countries that have no compulsory safety / product development regulations
- studies not directly sponsored by Sanofi
- collaborative projects with non-governmental organizations

▼ [A global organization with local support](#)

▼ [A new Pharmacovigilance compliance monitoring system](#)

### A global organization with local support

Sanofi's commitment to product safety requires the implementation of the appropriate global and local organization. The Group Pharmacovigilance Department is in charge of monitoring all pharmaceutical products, from the first time a compound is administered to human subjects (Phase I clinical trials) to the end of the product's life cycle.

The Pharmacovigilance organization has created a safety information network between expert groups assessing and validating product safety and local teams operating worldwide to ensure the transparent collection of safety information. In addition to enabling the coherent and transparent flow of information, this organization promotes clear communications with health authorities, healthcare professionals and the patient community.

### A new Pharmacovigilance compliance monitoring system

In response to a rapidly changing and increasingly demanding regulatory environment, Sanofi developed a new and improved compliance monitoring system. Today the Group's Pharmacovigilance team has better control of tasks and activities pertaining to the management of timelines to speed up reporting to health agencies, in particular for Individual Case Safety Reports (ICSR).

## BUSINESS CASE



### New Pharmacovigilance monitoring system enhances worldwide compliance

In a rapidly changing and increasingly demanding regulatory environment, the challenge for Sanofi's Pharmacovigilance organization was to implement a compliance enhancement program.

- *Business case: Pharmacovigilance*

## Actions

- ▼ Ensure ongoing control of Pharmacovigilance processes and continuously supporting our affiliates
- ▼ Innovative product safety governance
- ▼ Providing Pharmacovigilance training and improving product safety awareness
- ▼ Contributing to Pharmacovigilance training programs in African countries

### Ensure ongoing control of Pharmacovigilance processes and continuously supporting our affiliates

In addition to inspections and audits conducted, respectively, by the health authorities and by the Sanofi Quality R&D Department, the Countries and Regions Interface created within the Pharmacovigilance and Epidemiology Department pays regular visits to the affiliates to ensure they have adequate means and resources.

The affiliate Pharmacovigilance teams provide monthly activity reports to the central team. The corporate Pharmacovigilance Quality and Compliance Department makes regular checks to verify compliance with health authorities' reporting deadlines. Thanks to its network, warning system and rigorous standards, the Pharmacovigilance Department is able to fulfill its mission and ensure that Sanofi provides advanced risk management associated with the use of medicines.

A global Safety Database (Pharmacovigilance / epidemiology) gathers information about all products from Sanofi Pharma, Genzyme Fovea, Sanofi Pasteur and Generic and Consumer healthcare affiliates. Safety data integration for Sanofi Pasteur and Genzyme is ongoing and should be finalized in 2012.

**For more information** about how Pharmacovigilance database management upholds high standards, in particular as concerns data protection:

- [Personal data protection](#)

**For more information** about inspections and audits conducted

- [Global Quality](#)

## Innovative product safety governance

*The Pharmacovigilance Department has implemented innovative and transparent global product safety governance supporting a continuous signal detection process to identify emerging safety issues as well as the proactive assessment of product safety risk during all product development phases and maintenance to the market to improve products' benefit / risk ratio.\**

Identified signals are analyzed within the Group's Pharmacovigilance Quality Training and Compliance team. Subsequently identified safety issues or risks are then contextualized and the product benefit / risk ratio is evaluated. A senior management governance body reviews recommendations, establishes and communicates the Group's positions concerning safety and, if necessary, subsequent product label changes or risk mitigation activities. Through this process, a systematic, reliable, reconcilable review of a product's safety information is achieved that meets high ethical standards, is consistent with regulatory obligations and remains robust when it comes to inspections.

A specific committee, the Benefit/Risk Assessment Committee (BRAC), is in place to review on an on-going basis the Benefit/Risk profile of the product during all development phases and after products have received marketing authorization. Moreover an internal Alert procedure is in place to monitor critical safety signal and propose mitigation plan with the appropriate experts on a cross functional approach.

## Providing Pharmacovigilance training and improving product safety awareness

Throughout 2011, a training program was successfully introduced in different countries to increase employee awareness about the importance of Pharmacovigilance and related processes. The training program was rolled out internationally for the entire Group, including medical sales representatives. This awareness-building initiative reviews basic safety rules, presents the organization and describes available tools as well as procedures to follow. Specific training is also available for all employees working for the Group's Pharmacovigilance teams to ensure they update their knowledge on a regular basis. Among other benefits, the training program helps facilitate the Group's commitment to comply with all mandatory reporting of adverse events within required time limits. In 2011, a total of 19,942 employees successfully completed Pharmacovigilance awareness training.

## Contributing to Pharmacovigilance training programs in African countries

In response to recommendations from the Global Fund and within the scope of our Access to Medicines program, Sanofi promotes the implementation of Pharmacovigilance systems and structures in several African countries. In September 2011, Sanofi took part in Pharmacovigilance training initiatives conducted in French-speaking countries, organized under



the auspices of the Moroccan National Pharmacovigilance Center. The Group also contributed to supporting the implementation of Pharmacovigilance structures through meetings and workshops organized by the French Pharmaceutical Companies Association (LEEM) with representatives of French-speaking African country healthcare systems (Gabon, March 2011).

The Global Fund to **Fight AIDS**, Tuberculosis and Malaria is a unique public-private partnership created to dramatically increase resources to fight three of the world's most devastating diseases, and to direct those resources to areas of greatest need.

For more information:

- [www.theglobalfund.org](http://www.theglobalfund.org)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Business case

### The challenge

In a rapidly changing and increasingly demanding regulatory environment, the challenge for Sanofi's Pharmacovigilance organization was to implement a compliance enhancement program.

### Our response

The Sanofi Pharmacovigilance Quality Training and Compliance team developed an improved, scalable compliance management system for the Group's entire Pharmacovigilance community. They wished to demonstrate full control over tasks and activities pertaining to the management of timelines in order to speed up reporting to health agencies, in particular for Individual Case Safety Reports (ICSR).

The team established a Quality Enhancement Compliance program, taking a holistic and proactive approach as the key to improvement. This program allowed them to define several milestones:

In the short term, to:

- Implement compliance reports and tools so that global and local stakeholders can provide reliable metrics and Key Performance Indicators (KPIs) on international compliance.
- Provide a fast, integrated and technical solution allowing the global compliance team to collect, document and track root cause investigations. This solution makes it possible to identify deviations and communicate appropriate corrective and preventive actions (CAPA) to agencies such as the U.S. Food and Drug Administration (FDA) and EudraVigilance, which is in charge of pharmacovigilance in the European Economic Area.
- Develop an improved monitoring process to ensure that Sanofi teams maintain ongoing oversight of compliance. The process involves corporate and local stakeholders within the scope of expedited reporting to the European Medicines Agency (EMA) and to the FDA.

In the long term, milestones included:

- Improved performance and full control of the system
- Stronger global compliance governance
- A corporate tool to enable the Pharmacovigilance team and local stakeholders to manage compliance in a coordinated, integrated way.

### Benefits for stakeholders

In the short term, both the Pharmacovigilance team and U.S. affiliate Pharmacovigilance stakeholders now have consolidated oversight on compliance deviations and root causes pertaining to the timing of submissions of expedited Individual Case Safety Reports (ICSR).

A weekly compliance process has been set up to review and act on any timeline deviations for ICSR reporting, making it possible to take appropriate corrective and preventive actions. The Pharmacovigilance team director and management, as well as all concerned stakeholders, take part in this review.

This project will allow us to communicate information with the health authorities in a more complete manner, both on a regular basis and when an incident arises.

### Opportunities for the Group

In the long term, meeting this challenge enabled Sanofi to build the foundation for a worldwide compliance monitoring system that benefits both the Pharmacovigilance team and the affiliates. This system shows regulators that the Group is in full control and bolsters Sanofi's reputation as a company that is committed to ensuring patients' safety.

This ambitious global compliance program created many opportunities for Sanofi because it:

- Allows all stakeholders to speak in one voice based on using the same data
- Gives the Group harmonized oversight and an IT solution
- Eliminates gaps between local and corporate systems
- Provides an assessment approach to identify root causes
- Supports the production of compliance KPIs and the assessment of corrective and preventive actions
- Ensures ongoing compliance control for expedited Individual Case Safety Reports

This system also benefits our business by making the Pharmacovigilance organization more efficient. In 2011, our overall performance demonstrated sustained and continuous global compliance improvement.

### The future

In 2012, the next phase of the plan will be worldwide piloting of a global communications campaign with training and documentation to ensure effective implementation of the new compliance program worldwide.

## Global quality

Sanofi is a global healthcare company focused on patients' needs. We develop, manufacture and market a broad range of essential healthcare assets across the globe, including a broad-based product portfolio of prescription medicines, consumer healthcare products (OTC), animal health products, vaccines and generics. We are fully committed to making the quality and safety of our products as an absolute priority.

## Compliance with pharmaceutical regulatory requirements

For several decades, the pharmaceutical industry has been operating in a highly regulated environment. Before products can be brought to market, numerous clinical trials and laboratory studies must be conducted to assess and, where applicable, improve their risk / benefit ratio. Such trials and studies must be carried out in compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).

In addition, at each step of product development it is necessary to adhere to Good Manufacturing Practices (GMP), which seek to guarantee that marketed products will meet demanding quality standards.

Compliance with Good Distribution Practices (GDP) is also essential to ensure quality and guarantee the traceability of products – from the distribution center to the final point of delivery: wholesaler, dispensing pharmacy, hospital pharmacy.

In addition to these “good practices,” a number of statutes and regulations define legal requirements concerning pharmacovigilance, medical information and sales and promotional practices.

Together, these requirements are continuously improved and updated in line with scientific and technological developments, taking into account market globalization as well as the needs of stakeholders: patients, healthcare professionals, health authorities, etc.

## A commitment for the patient

Patient safety is an absolute priority for Sanofi. With this in mind, the Group's approach consists of implementing guidelines to ensure quality and continuous improvement to cover each phase of the product's life cycle, as well as services associated with our products.

Sanofi's senior management is committed to providing safe and effective products worldwide, which are developed, manufactured, distributed and marketed in full compliance with statutory and regulatory requirements and the Group's corporate values.

The same high quality standard is applied worldwide to guarantee patient safety and to satisfy stakeholders' expectations.

This commitment appears in Sanofi's [Global Quality Policy](#), which is distributed to all employees in all countries (in 11 languages) and is upheld by the Group's senior management.

## How Global Quality is organized at Sanofi

At every operational unit, site or affiliate involved in activities having a potential effect on product quality, patient safety or data integrity, Quality Managers conduct and coordinate quality and compliance activities. They contribute to safeguarding compliance through regulatory requirements and continuous improvement of the Group's performance.

Since 2009, our Global Quality organization has been working at Group level to coordinate the various Quality teams and to ensure the consistent implementation of the Quality Policy throughout products' life cycles.

The scope of Global Quality was expanded in 2010 to include the commercial affiliates and in 2011 to new entities such as Genzyme and Merial, through the creation of dedicated Operational Quality Units.

“Quality is a core value of the company that must be implemented at all levels. A consistently high standard of quality, applied worldwide, allows us to ensure patient safety and meet customer expectations.”

For more information:



[Excerpt from the Global Quality Policy](#)



« Patient safety is a must: We deploy the principles of Quality and continuous improvement all across the life-cycle of the products to all entities of the Group. »

**Thierry Bourquin,**  
Chief Quality Officer

## Actions

The Sanofi Quality Policy is implemented in many different ways, including:

- ▼ Quality systems covering the entire product cycle
- ▼ Controls relating to the quality of vaccines
- ▼ Inspections by regulatory authorities
- ▼ Quality risk management
- ▼ Quality across the entire Supply Chain
- ▼ Managing supplies of life saving drugs

### Quality systems covering the entire product cycle

Sanofi welcomed the International Conference on Harmonization (ICH) Q8, Q9 and Q10 guidance established by regulatory authorities because it marks substantial progress to encourage innovation and process effectiveness.

#### What is the ICH?

The mission of the International Conference on Harmonization, created in 1990, is to achieve greater harmonization to ensure the development and registration of safe, effective, and high quality medicines. It is unique in bringing together the regulatory authorities and pharmaceutical industry in Europe, Japan and the US to address the scientific and technical aspects of drug registration.

For more information:

- [www.ich.org](http://www.ich.org)

## Q8, Q9, Q10

ICH topics are divided into four categories. Within each of the four categories there are guidelines numbered:

Q8: Pharmaceutical Development

Q9: Quality Risk Management

Q10: Pharmaceutical Quality System

For more information:

- [www.ich.org](http://www.ich.org)

The Group uses ICH guideline Q10 (Pharmaceutical Quality System) in particular to complement ISO quality management standards as a key reference to ensure the effectiveness of quality systems already in place.

Sanofi's quality systems are structured in such a way as to cover all processes in connection with product development, manufacturing and distribution, starting with early research phases through the application of the internal rules of Good Research Practices (GRP).

They also cover cross-functional support processes such as personnel qualifications, documentation and management of third parties.

Each Sanofi division monitors the effectiveness of our quality systems by setting objectives and performance indicators and by organizing periodic reviews involving senior management and internal partners.

## Controls relating to the quality of vaccines

Manufacturing vaccines is a complex process that requires very strict controls at every stage. It can take up to 22 months to produce a vaccine, and approximately 70% of this time is spent on quality controls.

For manufacturers like Sanofi Pasteur, satisfying global demand while meeting the requirements of strict quality and regulatory controls represents an ongoing challenge.

Our goal is for Sanofi Pasteur to be a benchmark when it comes to quality. We have therefore developed a strong quality culture and take great care to see that all employees focus on quality as part of their day-to-day mindset. In an effort to maintain this level of quality, Sanofi Pasteur has taken specific measures governing sound industrial management as well as marketing practices, management principles and performance measurement. To constantly improve customer satisfaction and meet regulatory demands, while also keeping our business highly competitive, the quality teams work closely with the heads of industrial operations. Together they define quality policies and guidelines and guarantee that our processes correspond to good manufacturing practices.



## Inspections by regulatory authorities

Inspections by regulatory authorities provide an independent assessment of Sanofi's quality system, Standard Operating Procedures and current practices. We see inspection outcomes as an opportunity for continuous improvement and we implement corrective and preventive actions as necessary.

Regulatory authorities also conduct inspections as part of the evaluation of new product registration submissions. Sanofi has a cross-functional process to prepare and manage these pre-approval inspections and ensure that products are marketed in compliance with their registration file.

Sanofi also has a comprehensive quality management approach designed to ensure that the Group is optimally prepared, at all times and at all levels and functions within the Group, for any health authority inspection to assess compliance with regulatory requirements.

Preparedness for inspections is one of the pillars of our quality system. Sanofi created a Global Quality Audit Program to support periodic self-assessments by all Sanofi internal and external pharmaceutical sites. In addition, our Quality Department works with an international consultant to evaluate our quality system and enhance our internal approach from an even broader perspective. Our goal is to instill a sustainable compliance culture to satisfy all regulatory requirements.

In 2011 a total of 193 inspections\* were conducted at Sanofi sites by regulatory authorities (see table).

| Activity / Relevant Good Practices               | Number of inspections |
|--|-----------------------|
| Pharmacovigilance                                | 5                     |
| Clinical research (GCP)                          | 41                    |
| Pre-clinical research (GLP)                      | 4                     |
| Manufacturing and distribution sites (GMP / GDP) | 143                   |
| <b>TOTAL</b>                                     | <b>193*</b>           |

\*Scope: Includes Genzyme and Merial entities, from Q3 2011.

The Group is fully committed to meeting all applicable regulatory requirements and proactively ensuring readiness for health authority inspections

### Inspection in Frankfurt, Germany

In February 2011, Sanofi received a warning letter from the US Food and Drug Administration (FDA) due to violations related to certain aspects of current Good Manufacturing Practice (cGMP) regulations for finished pharmaceuticals. The FDA issued the warning letter following a routine inspection of Sanofi's pharmaceutical manufacturing facility in Frankfurt, Germany. Sanofi implemented comprehensive corrective and preventive action plans to address the violations that led to the warning letter. In late October, Sanofi advised the FDA that the site would be ready as of December 1, 2011, for a follow up inspection to verify implementation of the corrective action plans.

### Inspection in Bridgewater, N.J. (US)

Following a routine pharmacovigilance inspection of Sanofi's US affiliate in Bridgewater in Spring 2010, the FDA issued a warning letter in January 2011 citing inadequate procedures for the surveillance, receipt, evaluation and reporting of adverse events in a timely manner, and failure to include all required post-marketing studies in NDA Annual Reports to the agency.

The warning letter refers to compliance with reporting requirements, not to specific safety concerns related to a particular medication. We implemented immediate short-term corrective and preventive actions and developed a long term Quality Enhancement Plan to address the observations and to align efforts, company-wide, to ensure sustainable compliance. We shared our action plans and implementation status with the FDA on a regular basis.

In June 2011, the FDA conducted a follow-up inspection to assess Sanofi's commitments and corrective / preventive actions. The inspectors indicated that the 2010 FDA observations had been adequately addressed and in July the FDA issued a close-out notification stating Sanofi appeared to have addressed the violations mentioned in the warning letter.

It is important to note that the violations cited in the two mentioned warning letters did not impact the safety, efficacy, quality and purity, or continuity of supply of Sanofi's products.

### Inspection in Genzyme Allston Facility (US)

On May 24, 2010, Genzyme entered into a consent decree with the FDA relating to the Allston facility following FDA inspections at the Allston facility that resulted in a FDA Form 483 observation and a warning letter raising current Good Manufacturing Practice (cGMP) deficiencies. A consent decree is a court order entered by agreement between a company and a government (in this case the FDA) that requires the company to take certain actions as set out in the decree. A work plan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. The work plan is expected to take approximately four more years to complete. To

date, all requirements of the consent decree, are being met by Genzyme in accordance with the work plan timetable.

For more information:

 [Business Overview \(extract from 2011 Form 20-F\)](#) (PDF, 287Kb)

### What is a warning letter?

When the FDA finds that a manufacturer has significantly violated FDA regulations, the FDA often sends a warning letter to notify the company. A warning letter identifies the violation and makes clear that the company must correct the violation. It provides directions and a timeframe for the manufacturer to inform the FDA of its correction plans before checking to ensure that corrections are adequate.

For more information:

- [www.fda.gov / About FDA](http://www.fda.gov/AboutFDA)

## Quality risk management

A structured Quality risk management approach facilitates better decision-making and may increase authorities' confidence in the Group's ability to address potential issues.

Our integrated Quality risk management process aims to identify, assess, control and report risks relating to quality and in particular that potentially could generate one of the following consequences:

- Recall of marketed product or recovery of product used in clinical trials due to quality defect
- Non-compliance with regulations or regulatory files that have been submitted
- Discontinuation of a study, for example, due to a product supply interruption
- Suspended or cancelled authorization to manufacture or market products
- Loss of customer confidence, or harm to the company's image
- Shortage or inventory depletion of life saving products

In 2011, no Sanofi product was recalled from the market for what the regulatory authorities consider to be a defect that could potentially threaten patients' lives or be a serious risk to patient's health (Class 1 recall).

## Quality across the entire Supply Chain

In a global economy, the quality of Sanofi's products is determined not only by the final link in the chain, but also by the quality of the raw materials manufactured by suppliers as well as services provided by third parties at each step of the process.

All materials, equipment and services (e.g., transport) that may have an impact on product quality are purchased from approved sources according to predefined acceptance criteria, which include compliance with technical specifications and quality requirements. All these materials are tested at reception in our plants.

The quality of the subcontractors with whom the Group works is audited by a formal process that includes an initial assessment, qualification and routine assessment of compliance with regulatory requirements as well as Sanofi's internal standards.

In 2011 Sanofi conducted a total of 284 audits of active pharmaceutical ingredient manufacturers

The frequency with which audits are performed is determined following a risk analysis taking into account several factors, such as the criticality of the product or service and the history of Quality performance of the third party. For example, in 2011 Sanofi conducted a total of 284 audits of active pharmaceutical ingredient manufacturers, including 112 audits located in India and China.

The table below shows the number of audits performed for suppliers of active pharmaceutical ingredients in 2011.

| Regions   | Number of audits performed for suppliers of active pharmaceutical ingredients in 2011 |
|---|---|
| Europe  | 106 audits  |
| North America   | 32 audits   |
| South America   | 9 audits  |
| Africa – Middle East  | 5 audits  |
| Asia – Pacific<br>• China (40 audits)<br>• India (72 audits)<br>• Other (20 audits) | 132 audits  |
| <b>TOTAL</b>  | <b>284 audits</b>   |

In addition, Sanofi voluntarily elected to strengthen Quality controls of ingredients provided by suppliers located in less regulated countries, where cases of fraudulent products were recently reported.

Since the creation of the Rx-360 consortium in 2009, Sanofi has been a member of this non-profit organization whose mission is to improve pharmaceutical supply chain security and ensure product quality and authenticity across the entire supply chain.

For more information:

- [www.rx-360.org](http://www.rx-360.org)

To reduce the risk of fraud, falsification and diversion of our products, Sanofi adopts innovative technological solutions to facilitate traceability, identify fake products and secure the supply and distribution chain. These include the use of tamper-evident packaging aimed at guaranteeing the integrity of the packs, anti-counterfeit security labels to authenticate our products and Data Matrix codes and serialization tools to improve the traceability and the identification of our products. In addition, the Group created the Central Anti-Counterfeit Laboratory, which opened in 2008 in Tours, France. This Sanofi laboratory dedicated to the analysis of medicines or products suspected of being counterfeit.

For more information:

- [\*Patient / Safety and Product Risk Management / Fight against counterfeit\*](#)

## Managing supplies of life saving drugs

For several years, the Group's Global Quality organization has worked with affiliates to identify life saving drugs in each country where Sanofi operates. These are Group medicines and vaccines that have no therapeutic equivalent or for which substitutes would be difficult to find.

In 2011, we extended this approach to most Sanofi affiliates, in more than 80 countries.

On the basis of this list, it is possible to define production priorities in the event of a major accident at one of our production sites (fire, natural disaster, etc.) or a pandemic. Contingency plans can then be drawn up based on these priorities.

Following the earthquake and tsunami that struck Japan in March 2011, this list was very useful in helping determine where to focus our efforts to prevent shortages of products containing active pharmaceutical ingredients supplied by Japanese factories.

Sanofi undertook actions to determine the quality and safety of the raw materials, analyzing each ingredient's specific context as well as the distance between the factory that produces this ingredient and the Fukushima nuclear power station. In some cases, alternative suppliers were sought. This approach also made it possible to provide timely answers to questions raised by regulatory authorities about the risk of radioactive contamination of products.

In addition, a management plan to anticipate potential risks in connection with certain products (involving complex manufacturing processes, difficulties obtaining active ingredient supplies, etc.) has been established and will be further enhanced to determine which medicines are concerned, in order to be able to offer solutions for different markets – such as increasing inventories or seeking to identify back-up solutions for the production of active ingredients or finished products.

## Continuity of activities and supplies

### Background

As a global healthcare leader fulfilling a public health mission, Sanofi considers safeguarding the Group's supply chain and business continuity to be some of the most important of the Group's responsibilities.

The Group is committed to making every effort to ensure the Supply Chain will continue to deliver medicines and vaccines to the market without interruption, with the goal of protecting patients' health, every day.

As part of this mission, the Group endeavors to ensure that:

- There is no interruption of programs to develop new medicines
- Monitoring of adverse reactions (pharmacovigilance) is uninterrupted
- Continuity of our business activity is safeguarded and protected
- Continuity of activity for Group employees is also ensured
- Continuity of products Supply Chain

Moreover, in the event of a pandemic or major crisis (natural disaster, nuclear accident, humanitarian emergency, health-related risks, etc.) the Group is committed to:

- Reacting as quickly as possible to bring to market vaccines to prevent pandemics
- Taking all necessary measures to safeguard the continuity of the Group's activities, ensuring that the production of medicines and vaccines will not be interrupted

To reach these goals, the Group must be capable of evaluating and assuring preparedness for accidents or health-related risks that could have a negative impact on our activities – in particular, on the production of medicines and vaccines.

Sanofi is strongly committed to safeguarding business continuity as one of the Group's leading priorities and key responsibilities. Sanofi is committed to the principle that pharmaceuticals be available when and where they are needed by an individual or a healthcare service.



Sanofi distribution centers are now entering a new technological era. We are implementing the “Goods to Man Technology” which represents a strong breakthrough in the way we operate our activity. This new technology is also a significant savings provider at a time when Supply Chain has to positively contribute to the gross margin of Sanofi.

**Bernard Amoury,**  
Vice President, Global Supply Chain



## Policy

### ▼ Supply Chain

### ▼ Continuity of activities

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## Supply Chain

Sanofi's Supply Chain strategy focuses on endeavoring to guarantee the continuous supply of drugs and vaccines to our patients, without any interruptions. Our goal is to meet a "zero Out of Stock" objective, meaning that no link in the chain must be missing or deficient.

The Supply Chain Management has defined a set of guidelines, tools and processes for all stakeholders to apply our strategy. The team is in charge of implementing the various processes effectively.

In its efforts to attempt to guarantee the continuity of the entire supply chain, our Supply Chain Management relies on teams working everywhere the Group operates to ensure controlled processes and compliance with our continuous improvement policy.

The Supply Chain is aligned with the Group's organizational structure, in particular because our Supply Chain expertise is present in each region where we operate and works closely with Commercial Operations. For example, our expertise in Asia is located in Shanghai and Singapore, Bridgewater and Boston for North America, Dubai for Middle-East, etc. Local organizations may also include Supply Chain expertise relative to a specific product or business unit, which enables us to take into account the commercial aspects in our Supply Chain decisions.

The goal of the "zero Out of Stock" policy is to protect patients and attempt to ensure they will have access to our products at all times. Many processes must come together to support this goal, and they involve various stakeholders.

- At each affiliate, the Supply Chain, Finance and Marketing functions work together to produce two kinds of highly reliable sales forecasts:
  - Short-term forecasts (~ up to 14 months) are for the most part operationally driven; when combined with appropriate inventory policies from each affiliate, these forecasts are the key to meeting the "zero Out of Stock" goal.
  - Long-term forecasts (~ 14 months to 5 years) provide the basis for investment decisions because they give an accurate idea of long-term sales for a given geographical area or for specific technologies.

- At site level, sales forecasts are used to determine manufacturing needs for each product. For this purpose, it is essential to carefully analyze resource requirements: operators, equipment and working hours.
- After our products have been manufactured and released, they are shipped through the Group's Distribution organization:
  - Directly, when the manufacturing site produces for the local market,
  - Via an export platform, which allows grouping and transportation cost optimization.
- Once the products arrive in each domestic distribution center, they are delivered through our three principal distribution channels:
  - Direct to pharmacies
  - Direct to hospitals
  - Deliveries to wholesalers

Measured on a regular basis, Sanofi's customer service rate is between 99% and 100%, a best-in-class result of which the Group is proud. To maintain this level, several indicators are monitored and constitute an alert system to notify the different functions of any potential incident.

**For more information:**

- *Patient / Product risk management / Continuity of activities and supplies / Actions / Guaranteeing supply continuity on a daily basis / Proven results*

The processes involved in preserving supply continuity include the following activities, for which the Supply Chain Division is directly responsible:

- Defining product inventory levels, taking into account the criticality, manufacturing times and volatility of products from the viewpoint of commercial forecasts
- Activating back-up solutions as needed for certain products
- Coordinating and supervising crisis situations when necessary

## Continuity of activities

In the event of a pandemic or major crisis, Sanofi has developed specific continuity plans for Group activities. In such a situation, the Group's plans make every effort to achieve the following goals simultaneously:

- Guarantee and safeguard the continuity of our business activities,
- Ensure that all Group products meet the same quality standards,
- If a pandemic occurs, react as quickly as possible to bring a pandemic vaccine to market,
- Maintain the capacity to continue development, production and distribution of the medicines and vaccines needed to prevent or cure pandemic-related infections as quickly as possible,
- Safeguard the continuity of Group activities to supply all other Group medicines and vaccines for all patients,
- Continue to provide assistance to patients and healthcare professionals, in particular by setting up alternative solutions, such as call centers open 24 hours a day, seven days a week, monitoring of adverse reactions (pharmacovigilance), etc.

## Actions

- ▼ Guaranteeing supply continuity on a daily basis
- ▼ Managing supplies of life saving drugs
- ▼ Implementing a Business Continuity Plan
- ▼ Coordinating and supervising crisis situations: two examples in 2011

### Guaranteeing supply continuity on a daily basis

Quality of service, the Supply Chain's leading priority, is assessed using a specific indicator – the average customer service rate.

#### Proven results

Some of the indicators we use include:

- **Indicators of sales forecast accuracy for affiliates and adherence with standard manufacturing timelines** for production sites. The following table shows the quality of our forecasts in 2011, measured at one of our leading affiliates (pharmaceutical business). This information is broken down by product group: Ethical products (Rx), Consumer Health Care products (CHC) and Generics (Gx). The figures shown here are yearly averages.

|  | Rx  | CHC | Gx   |
|--|-----|-----|------|
| Forecast accuracy (%) <sup>(1)</sup>   | 101 | 102 | 89   |
| Forecast dispersion (%) <sup>(2)</sup> | 7.5 | 7.9 | 15.8 |

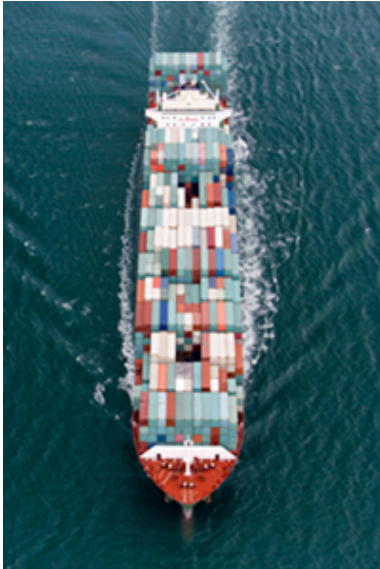
(1) Measured as sales divided by forecast / Lag 3; Targets: Rx 100/103; CHC + Gx: 100/105

(2) Measured as statistical dispersion. Targets: Rx: <10, CHC:< 12, Gx: <15

- **Low inventory indicators:** Our inventory policy for finished goods is two to three months depending upon the product, country, market context, manufacturing process and the distance between the manufacturing site and the market. For products that are listed as Life Saving Drugs, average inventory levels are set at six months.

In the event of a supply crisis, the Supply Chain Management creates a task force to manage the crisis. The principal task force members include a product specialist, a representative of the manufacturing site, and a regional or affiliate counterpart.

### Transporting medicines



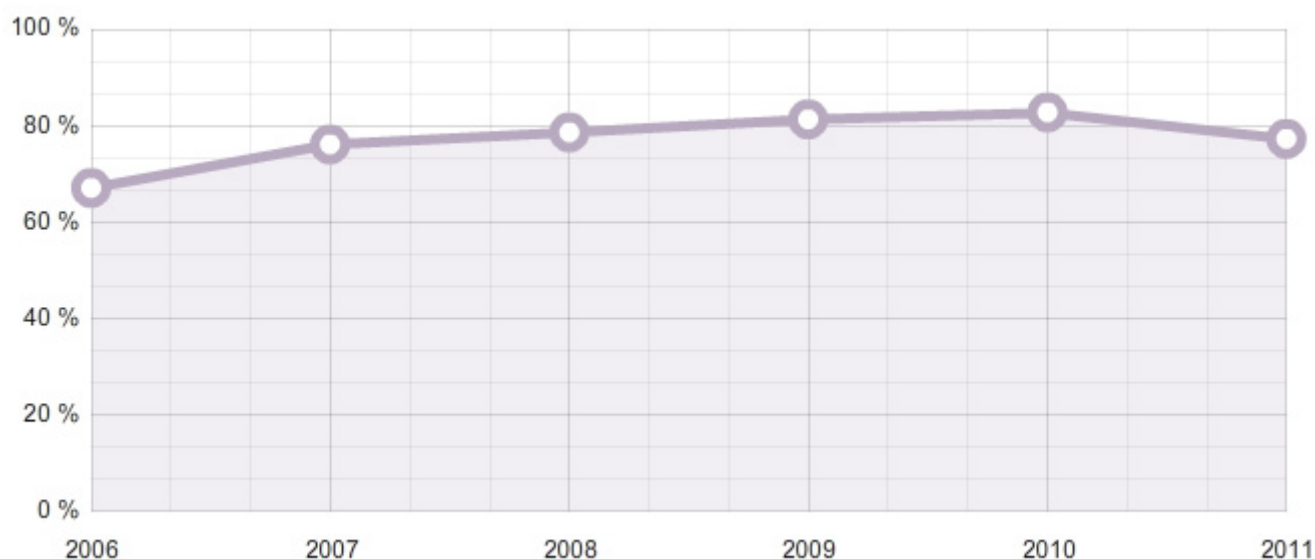
Transportation in the distribution chain clearly has an environmental impact. We are actively and fully committed to implementing sustainable business practices where feasible, which in addition to preserving the environment contributes to limiting our supply risk. For all our export activities, we have made sweeping changes in an effort to attempt to reduce greenhouse gas emissions. We now generally ship products by sea (or full trucks) rather than by plane, which is costly from both a financial and an environmental viewpoint. We currently use air shipments for emergencies only. Sea freight has allowed a saving of 35,000 tons of CO<sub>2</sub> per year (since 2005). Another factor we take into account: during weather-related crises, such as Iceland's volcanic ash cloud in 2010, sea freight is not adversely affected, whereas air shipping may be disrupted.

For more information:

- [\*Planet / Energy and carbon footprint / Transporting Medicines\*](#)

The following graph illustrates the increase in the use of sea freight relative to total freight for our export activity (in %).

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In countries where the Group has distribution centers, contingency plans are activated in the event of an interruption in the Supply Chain.

All materials, equipment and services (such as transport) that may have an impact on product quality are purchased from approved sources according to predefined acceptance criteria, which include compliance with technical specifications and quality requirements.

### For more information:

- [\*Global Quality / Quality across the entire Supply Chain\*](#)

As an example, Sanofi has three distribution centers in France and manages domestic distribution to conventional channels (wholesale distributors, hospitals and pharmacies). All the Group's distribution centers use the same information system and can easily provide back-up support for one another – for example, if one center is temporarily down. To guarantee the supply of Group products to French hospitals, an initiative was developed specifically for situations where the Group's primary transporter cannot ensure delivery.

Export is handled by a Sanofi center or is managed directly from Group factories when volumes allow it. The management system is identical to that used for the domestic market so that necessary operations can be streamlined from all sites.

In countries where outside service providers are in charge of distribution, the Group generally prefers to work with a single service provider per zone (covering one or more countries). Such

service providers are carefully selected for quality of service as well as their financial health and compliance with CSR principles. If a potential risk is detected, Sanofi enters into an agreement with another provider on the market that can act as a back-up should difficulties arise with the main service provider.

In France, transporters are selected via a “Request For proposals”. They undergo an audit process before they can begin working with the Group and for their entire period of service. The Supply Chain Management is directly responsible for the delivery of medicines. Transporters are subject to routine and careful monitoring for pharmaceutical quality as well as quality of service.

The most sophisticated techniques are used during transport to trace shipments and confirm customer deliveries (GPS tracking, GPRS real-time tracking, electronic signatures, etc.). Each center has developed a back-up plan, including a list of transporters that can be activated at any time and will be operational within 24 hours.

## BUSINESS CASE



### Create a back-up system to guarantee product deliveries to hospitals

In France, the Group implemented a rapid back-up plan so that continuity of supplies of Group products to hospitals will be ensured. This Business Case describes the back-up system created at Sanofi's Marly-la-Ville distribution center, which is activated in the event the primary transporter cannot ensure delivery.

- *Business case: Continuity of supplies*

## Managing supply shortages

In July 2011, Sanofi experienced a temporary worldwide supply shortage of Apidra® SoloSTAR® following a technical incident which occurred at the Group's manufacturing site in Frankfurt, Germany.

This incident caused temporary shortages worldwide. Sanofi proactively notified the appropriate health authorities, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). The Group made every effort to resolve the issue and anticipated that normal supply levels would resume in early 2012.

In light of the shortage, Sanofi advised healthcare professionals that one option for patients would be to consider switching to Apidra® vial and syringes. Sanofi offered to provide support and education for patients and healthcare professionals to facilitate the appropriate handling of Apidra® vials and syringes during the shortage.

## Managing supplies of life saving drugs

For several years, the Group's Global Quality organization has worked with affiliates and the global medical department to identify life saving drugs in each country where Sanofi operates. These are Group medicines and vaccines that have no therapeutic equivalent or for which substitutes would be difficult to find. The Group's philosophy is that these medicines should always be available in adequate quantities.

On the basis of this list, it is possible to define production priorities in the event of a major accident at one of our production sites (fire, natural disaster, etc.) or a pandemic. Contingency plans can then be drawn up based on these priorities.

### For more information:

- [\*Global quality / Managing supplies of life saving drugs\*](#)

## Implementing a Business Continuity Plan

In recent years, Sanofi has implemented a Business Continuity Plan (BCP) and organized several important initiatives:

- Implementation in 2009 of a specific Supply Chain plan to respond to the risk of an influenza pandemic as part of the Group's global VIGIFLU program.
- Mapping of alternative distribution centers in each country, or in a nearby country, including extremely precise requirements (i.e., number of pallets, GDP, etc.). In addition, as of mid-2012, Sanofi's centers in Germany and France will begin using cutting-edge technology, known as "Goods to Man" systems. In the event of an emergency they will facilitate the exchange of products between different centers.

In addition, the Business Continuity Plan also addresses the role of Information Systems (I.S.) to ensure there are no interruptions in the Supply Chain. Our I.S. infrastructure includes equipment such as servers, communication switches and hard disks. The Group keeps back-up of critical equipment, in addition to back-up HVAC, electricity and monitoring facilities. Both



external and internal I.S. risks are reduced thanks to technological improvements to the Group's equipment and systems.

### Coordinating and supervising crisis situations: two examples in 2011

The Group is at times faced with crisis situations due to natural disasters and must manage them effectively and quickly to protect Sanofi employees, take all necessary measures to safeguard the continuity of the Group's activities and avoid interruptions in the production of medicines.

The following table provides information about the measures that were taken to ensure continuity of activities and supplies following natural disasters in Australia and in Japan in 2011.

| Country                  | Sanofi Site                                   | Disaster | Actions for Continuity of activities and supplies   |
|--------------------------|---|----------|---|
| Australia<br>(Toowoomba) | Virginia<br>(Manufacturing;<br>189 employees) | Flood    | <p>Sanofi's Operations, Supply and Sales were affected by loss of utilities. The central business district (10 km from Virginia) was seriously affected. In accordance with our flood response plan, we:</p> <ul style="list-style-type: none"> <li>● Prioritized manufacturing / packaging</li> <li>● Used air freight where possible</li> <li>● Identified external packing / manufacturing opportunities</li> <li>● Re-routed phone calls to the Sydney Customer Service</li> </ul> <p>The Downfall Creek catchment area was saturated, with a risk of flash flooding. As a result, we:</p> <ul style="list-style-type: none"> <li>● Monitored levels frequently</li> <li>● Moved higher value stock to Mezzanine level</li> </ul> <p>When Virginia faced a loss of power due to electricity companies progressively shutting down power, the site risked having air-conditioning / IS infrastructure cut off. We took</p> |

| Country           | Sanofi Site                 | Disaster                                    | Actions for Continuity of activities and supplies   |
|-------------------|-----------------------------|---|---|
|                   |                             |   | <p>measures to ensure availability of a generator to provide a back-up power supply.</p> <p>Personnel were unable to return home from work. Measures taken included:</p> <ul style="list-style-type: none"> <li>● Using makeshift sleeping facilities (fold-out sofas, sick bay)</li> <li>● Asking staff for support in providing accommodations</li> </ul>   |
| Japan (Fukushima) | All sites (3,100 employees) | Earthquake, tsunami, nuclear radiation risk | <p>The crisis management team was made up of 15 members representing: Health, Safety and Environment, Business Development, Business Continuity Management, Communications, Controlling, Diabetes Business Unit, Finance, General Manager, Human Resources, Industrial Affairs, Information Systems, Public Affairs, Regulatory, Research &amp; Development, Sales, Security Officers. In Kawagoe site, following a power outage, production operated at 50% of capacity in the factory, increasing the need to develop a prioritized production plan. It was necessary to obtain information about inventories on the market to determine production priorities.</p> <p>Due to gasoline shortage, office staff was asked to use bicycles, car pooling, etc. Distribution sites continued to operate to make critical medicines available. Products were still being sold and distributed. To help stabilize production and distribution, night shift began on time despite</p> |

| Country | Sanofi Site | Disaster | Actions for Continuity of activities and supplies   |
|---------|-------------|----------|---|
|         |             |          | <p>planned blackouts.</p> <p>In Japan, the following decisions were made to help protect public health. A power shortage plan had been prepared for Sanofi Japan to allow activity planning at minima and ensure continuity in the production of life saving medicines (in particular, Lasix® and SoloSTAR®). Lantus® and Apidra® have been delivered to the affected area three days after the earthquake struck. In addition, Sanofi made donations (Amaryl®, Lasix®, Plavix®, Rythmodan® and Allegra®) to the Japanese Ministry of Health, Labor and Welfare.</p> <p>Company messages have been posted to patients about stable production and distribution on Sanofi website homepage. Moreover, 24/7 patient call centers have been implemented.</p> |

To find out more about Sanofi's response to the earthquake and tsunami in Fukushima, see the PEOPLE and PLANET sections of the 2011 CSR Report.

**For more information:**

- [\*Patient / Humanitarian emergencies / Earthquake in Japan\*](#)
- [\*Patient / Humanitarian emergencies / Emergency measures to protect Sanofi employees in the Tohoku region\*](#)

## Business case

### The challenge

The Group needed to set up a back-up plan so that the supply of Group products to French hospitals would be guaranteed in situations where the Group's primary transporter cannot ensure delivery.

### Our response

Based on our collective experience, we developed a system at the Marly-la-Ville (France) distribution center. It operates simultaneously on many levels to:

- Harmonize computer and information systems: Today the Marly-la-Ville site and the distribution centers in St. Loubès, Croissy and Amilly all use the same information system.
- Draft calls for tender to include a tariff agreement: Each transporter is now able to cover at least two sites – one of which is “dormant” for that specific transporter.
- Activate a customer support system: As soon as we are informed of a problem with one of our transporters, we take steps to monitor each delivery. We work with customers to identify the most urgent products and quantities. The urgent portion of a new order is shipped by an express transporter referenced at the Marcy site, while the rest of the order is delivered later.
- Notify the back-up transporter immediately: At the same time we activate the customer support system, we notify the back-up transporter. This step is facilitated by the fact that the back-up transporter already works with another of our sites on a daily basis. Because all sites use the same information system, no extra operations are necessary (for example, there is no need to print special labels).

### Benefits for stakeholders

For hospitals: This system guarantees continuity of service with the same level of quality because the transporters delivering our products have been vetted and approved by Sanofi for this specific service.

For the customer support system: In the event of a problem with a transporter, the back-up solution is rapidly implemented, which significantly decreases the burden of extra work, given that the transition phase is short.

For the distribution center: The swift activation of the back-up transporter also decreases additional work generated by dividing orders in two categories: priority vs. less urgent. It does not affect the center's organizational system for the preparation of orders, labels or loading.

For the transporters: Because tariffs are negotiated ahead of time, unexpected quotes and billing issues are avoided.

### Opportunities for the Group

In addition to the many benefits of harmonizing information systems, this approach has enabled the Group to develop closer ties with our partners. It has also led to greater synergy among our distribution centers.

The rapid use of a back-up transporter at tariffs negotiated ahead of time has led to the cost reductions during the transition phase (cost of shipping and cost of preparation) as well as during the delivery phase (cost of back-up transport).

### The future

This system could be a model for other Group sites and activities – for example, transporting vaccines to wholesalers and distribution centers.

## The fight against counterfeit drugs

### Background

- ▼ A public health challenge
- ▼ A global mobilization
- ▼ More stringent legislation

### A public health challenge

Eliminating counterfeit drugs represents a substantial public health challenge.

The figures most commonly cited by international organizations indicate that counterfeiting involves, on average, 10% of the global pharmaceutical market, although this figure may reach up to 70% in certain African countries. Counterfeiting is most rampant in areas where regulatory and enforcement systems for medicines are weakest. The Pharmaceutical Security Institute revealed that the number of counterfeit medicines in the world has increased by 9% within the last two years.

According to the WHO, approximately 50% of drugs sold on illegal websites have been found to be counterfeit, and trafficking in counterfeit medicines is estimated to generate a total of several hundred million Euros in sales each year.

Counterfeit medicines give rise to multiple risks because they:

- Endanger patients' health (according to the WHO, counterfeit medicines may be responsible for a large number of deaths worldwide)
- Feed a parallel and freeloading economy, which is contrary to sustainable development and may present risks to safety, hygiene, environment, ethics, human rights, etc.

### A global mobilization

The fight against counterfeit drugs mobilizes an increasing number of stakeholders, governments and healthcare authorities as well as police organizations and customs officials.

## WHAT IS A COUNTERFEIT MEDICINAL PRODUCT?

A counterfeit medicine is deliberately and fraudulently mislabeled with respect to its identity and / or its source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

Source: *WHO Fact Sheet n°275 (2010)*

**For more information** about what constitutes a counterfeit drug:

- [www.who.int / Medicines: spurious / falsely-labelled / falsified / counterfeit \(SFFC\) medicines](http://www.who.int / Medicines: spurious / falsely-labelled / falsified / counterfeit (SFFC) medicines)

## WHAT IS A FALSIFIED MEDICINE?

Falsified medicines are medicines with false representation with respect to their identity, source or history. The European Directive on Falsified Medicines of June 2011, most provisions of which must be transposed into national law in European member states before January 2013, aim to prevent the entry of falsified medicines into the legal supply chain.

Falsified medicines do not reach patients only through illegal means. They may also come into a patient's hands via the legitimate supply chain for drugs, which not only represents a threat to human health but may undermine public trust in the pharmaceutical supply chain.

 [Falsified medicinal products](#) (PDF, 822Kb)

## More stringent legislation

### The European Union

Recent legislation in the EU introduces tougher rules to protect public health with new harmonized measures to ensure that medicines are safe and the sale of medicines is rigorously

controlled. Directive 2011/62/EU contains measures to ensure easier identification of falsified medicines as well as improved verifications and controls at borders and within the EU, including:

- An obligatory authenticity feature on the outer packaging of some medicines
- A common EU-wide logo to identify legal online pharmacies so that it will be easier to distinguish between legal and illegal online pharmacies throughout the EU
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients
- More stringent record-keeping requirements for wholesale distributors

As one of the first companies to call for specific legislation on this critical public health issue, Sanofi welcomes this new development.

**For more information:** Directive 2011/62/EU of the European Parliament and of the Council dated June 8, 2011:



[\*Falsified medicinal products\*](#) (PDF, 821Kb)

## The Council of Europe

MEDICRIME is the Council of Europe's Convention on the counterfeiting of medical products and similar crimes involving threats to public health. It constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health. Adopted in December 2010, MEDICRIME has to date been signed by 12 countries (Germany, Austria, Cyprus, Finland, France, Island, Switzerland, Italy, Israel, Portugal, Russia, Ukraine).

The Council of Europe is an international organization comprising 47 member states in Europe whose aim is to promote democracy and protect human rights in Europe. For more information about MEDICRIME:

**For more information:** [Medicrime](#)

- [www.coe.int / MediCrime](http://www.coe.int / MediCrime)



## Policy

- ▼ Fighting counterfeit medicines and promoting access to safe medicines
- ▼ A proactive approach
- ▼ Supporting the distribution of quality medicines: the Cotonou Declaration

### Fighting counterfeit medicines and promoting access to safe medicines

Counterfeit drugs are a major concern for Sanofi.

The Group coordinates international efforts to combat counterfeit medicines in cooperation with many different health authorities and has developed a number of programs to promote access to medicines.

**For more information:** [Our Access to healthcare programs](#)

- [Patient / Access to Healthcare](#)

#### **SANOFI POSITION ON ENSURING THE QUALITY OF MEDICINES AND FIGHTING COUNTERFEIT DRUGS**

Sanofi ensures product quality for patients and medical personnel in all countries throughout the world.

The Group actively supports public authority's efforts to guarantee the highest standards of drug quality and safety and fight counterfeit drugs through the following actions:

- Working closely with local authorities and professional organizations to deliver information and educational program to create awareness and fight against counterfeiting drugs and their serious damage on patient's health.
- Centralizing all Sanofi suspected drugs and samples from market in our specialized Laboratory.

- Ensuring the quality of its medicines, securing the supply chain and pro-actively protecting its drugs with innovative solutions to prevent falsification and fight against counterfeiting.
- Reinforcing cooperation with official bodies (international agencies, customs, police...) to support their work in the fight against counterfeit.
- Fostering a dedicated and structured organization involving experts from Security, Legal, Industrial Affairs, Cybercriminality, Communication, Medical and Regulatory departments to coordinate at corporate and local level all activities regarding the fight against Counterfeit medicines.

In accordance with this position, it alerts health authorities of the risks of falsified medicines.

#### A proactive approach

Since 2005, the Group takes an increasingly coordinated and structured approach to combating counterfeit drugs:

- 2005: Creation of an anti-counterfeit organization.
- 2007: Creation of a Central Operational Coordination Team supported by an international network of teams within affiliates.
- 2008: Expansion of the correspondent network in over 70 countries.
- 2009: In-house initiatives to increase awareness of counterfeit drug incidents by organizing a number of information meetings for employees at various industrial sites.
- 2010: Expansion of awareness-raising initiatives for employees, mobilization with national and international public authorities.
- 2011: Stronger coordination to drive activities related to preventing counterfeiting by:
  - Leading and supporting the network of anti-counterfeit coordinators (within each affiliate) so that they can share their experience, knowledge and best practices

- Ensuring that each suspected sample is tested at the Central Lab and that confirmed cases of counterfeit are monitored until all appropriate public health, investigative and legal actions have been taken
- Developing initiatives to promote communication, information, awareness-raising and education for internal and external stakeholders (employees, patients, healthcare professionals, etc.)
- Working with public and private institutions and official organizations worldwide.

### Supporting the distribution of quality medicines: the Cotonou Declaration

In late 2009, at the request of the Chirac Foundation, the Cotonou Declaration against counterfeit drugs marked the launch of a campaign to instigate unprecedented international mobilization to halt the trade in counterfeit medicines. In collaboration with the Chirac Foundation, Sanofi played a large role in the preparatory work leading up to the declaration. *The Sanofi Group provides financial support to Chirac Foundation as a part of a three-year sponsorship agreement.\**

**For more information:** [The Cotonou Declaration](#)

- [\*The Chirac Foundation - The Cotonou Declaration, October 12, 2009\*](#)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Actions

Sanofi organizes a wide range of initiatives in support of a single, critical goal: contributing to the fight against counterfeit drugs and, when possible, preventing the phenomenon. Our approach pursues many different objectives at the same time: protecting the patient, preserving trust in the supply chain, cooperating with national and international organizations, using cutting-edge technology to ensure product quality and operating our own dedicated anti-counterfeit laboratory.

- ▼ An essential tool: The Central Anti-Counterfeit Laboratory
- ▼ Safeguarding the quality of our medicines using innovative technology
- ▼ Protecting the patient: the Data Matrix system
- ▼ Cooperation with national and international organizations
- ▼ Promoting investigations and legal actions
- ▼ Combating networks responsible for illicit sales of medicines on-line
- ▼ Developing awareness and education programs
- ▼ The International Institute against Counterfeit Medicines

### An essential tool: The Central Anti-Counterfeit Laboratory

Since 2008, the Sanofi Central Anti-Counterfeit Laboratory teams have analyzed over 17,000 products.

The Sanofi Central Anti-Counterfeit Laboratory, which opened in 2008, is located at the Group's pharmaceutical site in Tours, France.

The laboratory is an integral part of the program set up by the Group to combat counterfeit drugs.

With a dedicated team of specialists and state-of-the-art technologies, the Sanofi Central Anti-Counterfeit Laboratory, pursues a three-fold mission:

- Perform direct technical examinations of packaging and product inserts as well as the most sophisticated chemical analyses on suspected samples.

- Design new analytical methods, in part with the aim of sharing them globally to allow each industrial site worldwide to apply the same criteria when examining and performing analyses on all suspected products that correspond to products manufactured by Sanofi.
- Centralize so-called “identity cards” containing information about counterfeit products in a single, centralized database – the only database that enables Group-wide cross-referencing of different counterfeit drugs.

Video: “Fight against counterfeiting: Sanofi's commitment in ensuring patients safety”

### Safeguarding the quality of our medicines using innovative technology

Counterfeiters use increasingly sophisticated means to produce fake medicines. Consequently, the pharmaceutical industry must continuously update innovative technological solutions to ensure the protection and traceability of products, to identify fake products and to secure the supply and distribution chain.

To avoid falsification and rapidly establish the authenticity of our products, Sanofi has developed a specific label known as the Sanofi Security Label (SASL). It contains the means for visible verification (by distributors and patients) as well as invisible verification (which only Sanofi can determine). In 2011, the Group extended the use of the safety label to all new drugs, such as Multaq® and Jetvana®, as well as to specific pre-existing products that are sold worldwide, such as Plavix® and Taxotere®.

Moreover, Sanofi is working on the use of tamper-evident packaging, which guarantees the integrity of the original manufacturer's packaging.

## Protecting the patient: the Data Matrix system

Since January 1, 2011, in compliance with French legislation, all Sanofi products marketed in France are equipped with a Data Matrix identification system, a two-dimensional barcode printed on each box that contains traceability information: product code (CIP code), batch number and expiration date. Data Matrix codes are read when drugs are dispensed, improving traceability and enabling the automatic detection of falsified or expired products. They also facilitate batch recalls.

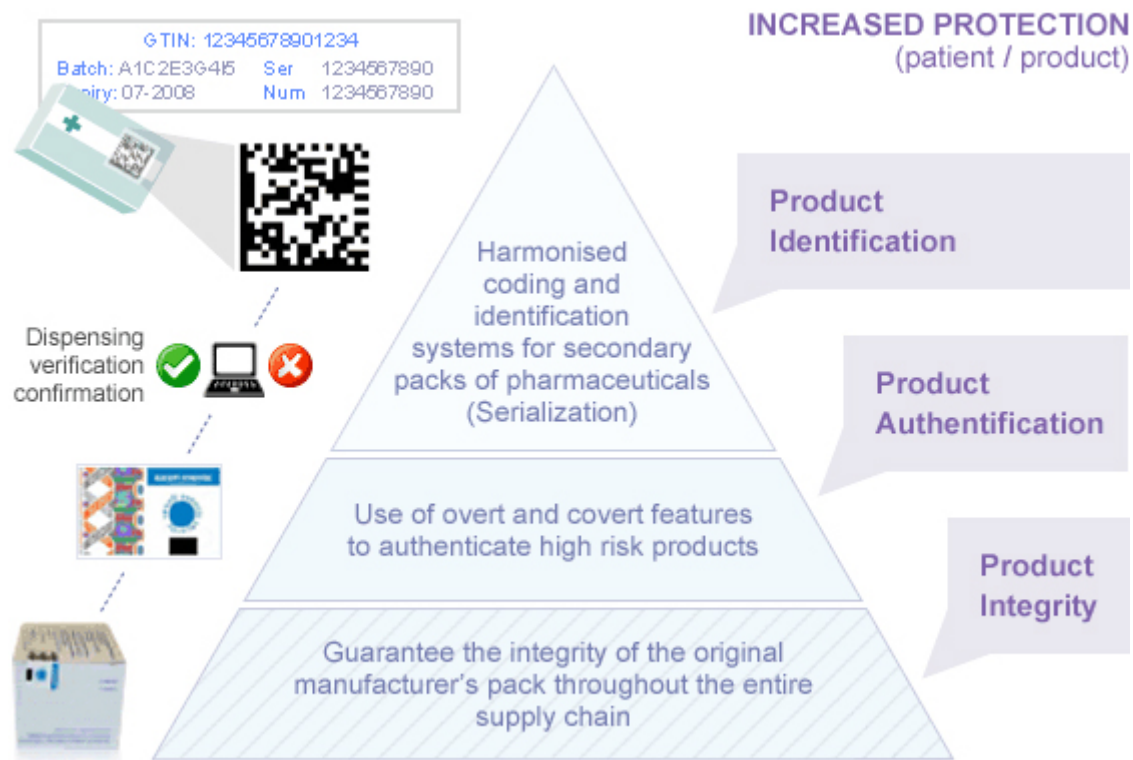
Sanofi actively supports a project from the European Federation of Pharmaceutical Industries and Associations (EFPIA) to create a harmonized codification and verification system for medicines based on the use of Data Matrix codes, mass serialization and systematic controls at the time of dispensing by pharmacies and hospitals. The current objective is for all European countries to adopt this system, particularly in light of the new EU Directive published on July 1, 2011.

- [Background / More stringent legislation](#)

In Turkey, Sanofi has used a Data Matrix code on all secondary packaging since January 2010, in line with Turkish laws. Throughout 2012, Sanofi will continue to expand its policy of identification of its medicines based on Data Matrix technology and industry-recommended international standards, in compliance with the legislation in force in various countries.

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Cooperation with national and international organizations

Convinced that public / private cooperation is essential to effectively fight counterfeit drugs, Sanofi participates actively in international and local organizations.

Internationally, the Group collaborates with:

- Organizations such as the WHO, the United Nations, the World Customs Organization (WCO), the World Trade Organization (WTO), the International Criminal Police Organization (INTERPOL)
- National and international health agencies
- Professional federations, such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Security Institute (PSI).

At the local level, the Group cooperates with:

- The National Anti-Counterfeit Committee (CNAC) and Union des Fabricants (UNIFAB), an organization of manufacturers in France
- Quality Brands Protection Committee (QBPC) in China
- The Pharmaceutical Research and Manufacturers of America (PhRMA) in the United States,
- National federations such as LEEM (the French Pharmaceutical Companies Association)

Sanofi takes part in public / private initiatives to promote the prevention of counterfeit medicines (i.e., *Comité Stratégique des Industries de Santé*).

These collaborative ties have made it possible for Sanofi to:

- Support the adoption of the EU Directive on falsified medicines;
- Take part in drafting the Council of Europe's MEDICRIME Convention, making counterfeiting of medicinal products a criminal offense;
- Sign charters supported by the French Ministry of Industry to facilitate prevention and contribute to the fight against counterfeit drugs sold on the Internet. These charters were signed with key players of e-commerce (2009) and classified ads and postal operators (2012);



[Charte de lutte contre la contrefaçon](#) (PDF, 375Kb)

- Support the PANGEA operations (see below) to dismantle counterfeiting networks on the Internet.

### Promoting investigations and legal actions

The day-to-day mission of Sanofi's Central Coordination Team, created in 2007, is to:

- Investigate every suspicious counterfeit product, whether it is reported by patients, healthcare professionals or the authorities
- Cooperate with customs officials
- Ensure tracking and routine intelligence on the Internet



- Test market surveillance operations in various countries throughout the world

We also participate in other important operations conducted by INTERPOL and the WCO.

In 2011, Sanofi teams collaborated with national and international authorities and contributed to several investigations that led to the seizure and destruction of more than 1.5 million counterfeit tablets of our products.

As regards legal action, Sanofi favors criminal prosecution when possible under applicable law because criminal prosecution is aimed at seeking coercive punishment against counterfeiters rather than compensation.

### Combating networks responsible for illicit sales of medicines on-line

Operation Pangea IV took place from September 20 to 27, 2011, when police, customs and health authorities from 81 countries joined forces with several pharmaceutical companies including Sanofi. During this weeklong operation, tighter controls resulted in the seizure of 2.4 million potentially harmful medicines, valued at €4.7 million. Nearly 13,500 websites were shut down and 55 people were arrested.

Pangea IV followed a similar operation one year earlier, in October 2010. Pangea III, in which Sanofi also took an active part, was coordinated by INTERPOL and the WHO with the participation of more than 40 countries. It led to the identification of 125 websites engaged in illegal counterfeiting activities.

This global initiative, which also relies on support from Internet Service Providers, postal services, and financial intermediaries, is aimed at educating Internet users about the dangers of buying medicines online.

According to the WHO, approximately 50% of drugs sold on illegal websites have been found to be counterfeit.

The Pangea operations clearly demonstrate the importance of cooperation between public authorities and private companies to identify and dismantle these networks.

## Developing awareness and education programs

In 2011, 5,380 people were trained by Sanofi, including 1,581 employees, 3,799 public health agents, customs officials and police officers from around the world

Raising awareness among Sanofi employees, healthcare professionals and the health authorities is an important part of Sanofi's anti-counterfeit actions.

The Group pursues a policy to actively promote information and education across the globe, based on:

- Distributing a tool kit for in-house training
- Creating a press kit about fighting counterfeit drugs
- Organizing regular information meetings and conferences at the Tours, France, site and throughout the world
- Offering training specifically for customs officials and police officers. In 2011, 5,380 people were trained by Sanofi, including 1,581 employees, 3,799 public health agents, customs officials and police officers from around the world.

## The International Institute against Counterfeit Medicines

Sanofi is committed to encouraging initiatives which aim to reinforce the fight against counterfeit. In that perspective, Sanofi has been very supportive to the creation of the International Institute against Counterfeit Medicine. The purpose of this independent institute is to provide training in the fight against counterfeit drugs. The institute was founded in October 2010 in compliance with French law governing not-for-profit organizations, and is located in Paris, France.

For more information:

- [www.iracm.com](http://www.iracm.com)

# ETHICS

## Respecting the rules of ethics.

Sanofi is committed to acting ethically and responsibly at all levels of its activities (R&D, production and marketing). Respecting the rules of ethics in relation to Group employees, patients, customers, suppliers and other stakeholders is one of the pillars of the Group's CSR approach.

## Ethics Indicators

- [Ethics in clinical trials](#)
- [Use of laboratory animals for research](#)
- [Corporate governance](#)
- [Responsible marketing](#)
- [Fighting corruption](#)
- [Responsible procurement](#)

## Ensuring Respect of Human Rights

### Background

#### A key challenge for businesses

Sanofi is committed to incorporating the principles of human rights into the Group's operating activities. We are convinced that these principles apply to people, nations and, by extension, to businesses.

Striving to ensure respect for human rights in companies has become a key CSR topic today, when international standards are becoming more stringent and stakeholders are putting more pressure on companies to provide information about their practices. The ISO 26000 standards contains the basic principles of social responsibility including the respect of human rights.

Beyond legal ramifications, human rights issues may pose a risk for a company's image or reputation, especially when violations are committed by others potentially within its sphere of influence (e.g., suppliers). For this reason, non-financial rating agencies and ethical investors take human rights issues into account in their evaluations and ratings.

In addition, the implementation of human rights principles is a major factor of motivation for the employees and helps companies to be an attractive employer on the job market.

In June 2011, the United Nations Human Rights Council endorsed a set of Guiding Principles for Businesses and Human Rights, based on extensive research and consultation by **Professor John Ruggie**, Special Representative of the UN Secretary-General for Business and Human Rights. For the first time, this set of principles introduced a global standard for business when it comes to human rights. Designed to provide tools to measure real progress in people's daily lives, the Guiding Principles outline how governments and businesses can better manage human rights challenges and live up to their responsibilities.

**Professor John Ruggie** of Harvard University is the UN Secretary-General's Special Representative for Business and Human Rights. He conducted research for six years to develop the Guiding Principles, which are based on consultations with governments, businesses, affected individuals and groups, investors and other stakeholders in more than 20 countries.

In line with the UN Guiding Principles to ensure respect for human rights, businesses must:

- ▼ Adopt a human rights policy
- ▼ Assess human rights impact
- ▼ Integrate human rights throughout the company
- ▼ Measure and report human rights performance

The Group's human rights policy and actions are designed to go above and beyond compliance with these four steps. Sanofi is considered a leader in this field thanks to our pro-active initiatives to ensure we apply the principles of human rights as comprehensively as possible across the entire Group.

For more information:

- [www.business-humanrights.org / Business & Human Rights Resource Center](http://www.business-humanrights.org / Business & Human Rights Resource Center)



[\*Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework\*](#) (PDF, 140Kb)



Respecting human rights is a priority for us. We have made a strong commitment to complying with international standards and principles, particularly the UN Global Compact.

**Gilles Lhernould,**  
Senior Vice President, CSR

## Policy

### Adopting a human rights policy

Respect for human rights forms the foundation upon which our CSR policy is built. By complying with international human rights standards and principles, Sanofi makes a formal commitment to incorporate human rights principles in the Group's operating activities. The principles of Human Rights are addressed in three Sanofi main reference documents:



[Code of Ethics](#) (PDF, 1.84Mb)



[Suppliers Code of Conduct](#) (PDF, 578Kb)



[Social Charter](#) (PDF, 299Kb)

These three documents cover the human rights principles defined in international texts. For instance, the references for the Group's Code of Ethics include:

- [The Universal Declaration of Human Rights](#)
- [The UN Global Compact](#)
- [The Organization for Economic Cooperation and Development directives](#)
- [International Labor Organization principles](#)
- National laws and regulations

Through its Code of Ethics, the Group also supports each person's right to health, as defined in the International Covenant on Economic, Social and Cultural Rights:

- [International Covenant on Economic, Social and Cultural Rights](#)

Sanofi has complied with the Ten Principles of the UN Global Compact since 2003. As part of this commitment, each year the Group issues a Communication On Progress, signed by our CEO, Christopher A. Viehbacher, to report to the UN Secretary-General about the Group's progress in human rights.

The Group's human rights policy and actions are designed to go above and beyond compliance with the UN Guiding Principles for Businesses and Human Rights.

For more information:

- [UN Global Compact](#)

Sanofi's Communication on Progress to the United Nations:

- [www.unglobalcompact.org / Participant Information](http://www.unglobalcompact.org/Participant%20Information)

The Group's Code of Ethics, Social Charter and Supplier Code of Conduct all comply with the Ten Principles of [United Nations Global Compact](#)

- [Human Rights](#)
- [Labor Rights](#)
- [Environmental Protection](#)
- [Anti-corruption](#)



## Actions

Sanofi's human rights policy is lived out through our actions and commitments, which take into account interactions with stakeholders as well as their expectations. Beyond compliance with international standards and principles, we believe it is important to implement a progress-based methodology and develop the tools necessary which take into account interactions with stakeholders as well as their expectations. Through the Sanofi CSR Excellence Direction, we have introduced an ambitious approach to ensure that human rights are integrated throughout the Group operations by initiating self-assessments of internal practices, employee training, and other initiatives.

- ▼ [Identifying and responding to the challenges facing the Group](#)
- ▼ [Implementing a progress-based monitoring approach](#)
- ▼ [Assessing human rights impact](#)
- ▼ [Integrating human rights throughout the company](#)
- ▼ [Measuring and reporting human rights performance](#)
- ▼ [Working alongside other companies](#)
- ▼ [Participating in developing the Guiding Principles](#)

## Identifying and responding to the challenges facing the Group

The following table outlines the human rights issues that Sanofi may address for different Group stakeholders. It illustrates both the diversity of our stakeholders and the different human rights issues related to them, with particular attention paid to each one. These issues must fall in line with the rules described in various internal reference documents, in particular the Group's Code of Ethics and Social Charter.

| Stakeholders | Human rights issues  |
|--------------|--|
| Employees    | <ul style="list-style-type: none"><li>● <a href="#">Fair compensation and working conditions</a></li><li>● <a href="#">Occupational health and safety</a></li><li>● <a href="#">Non-discrimination and respect for diversity</a></li><li>● <a href="#">Respect for privacy</a></li><li>● <a href="#">Freedom of association</a></li><li>● <a href="#">Abolition of forced labor</a></li><li>● <a href="#">Abolition of child labor</a></li><li>● <a href="#">Fighting corruption</a></li></ul> |

| Stakeholders      | Human rights issues  |
|-------------------|--|
| Suppliers         | <ul style="list-style-type: none"> <li>● <u>Abolition of forced labor</u></li> <li>● <u>Abolition of child labor</u></li> <li>● <u>Fair compensation and working conditions</u></li> <li>● <u>Respect for privacy</u></li> <li>● <u>Freedom of association</u></li> <li>● <u>Non-discrimination</u></li> <li>● <u>Health, safety and protecting the environment</u></li> </ul> |
| Patients          | <ul style="list-style-type: none"> <li>● <u>The right to health: Access to healthcare</u></li> <li>● <u>Respecting ethics rules specific to the pharmaceutical industry</u></li> </ul>   |
| Local communities | <ul style="list-style-type: none"> <li>● <u>Safety and protecting the environment</u></li> <li>● <u>Contributing to local economic development</u></li> <li>● <u>Respect for ethics rules for research and in business</u></li> </ul>  |

**The challenges related to human rights are largely covered in the following sections of our 2011 CSR Report:**

- **People:** Work practices, occupational health and safety practices, non-discrimination, respect for diversity, etc.
- **Ethics:** Human rights related to suppliers, fighting corruption, good practices for clinical trials, preventing biopiracy, etc.
- **Planet:** Environmental safety and protection, contributing to local economic development, etc.
- **Patient:** For issues related to the right to health, the Patient section covers several challenges specific to the pharmaceutical industry, such as improving access to health, pharmacovigilance, the fight against counterfeit drugs, etc.

## Implementing a progress-based monitoring approach

Through the Sanofi CSR Excellence Direction, the Group has introduced an approach to ensure the integration of our human rights principles in our operations. In 2011, initiatives were

developed to allow different functions to evaluate the impact of their own activities at both the corporate and regional levels, with a particular focus on identifying any potential human rights concerns.

## Assessing human rights impact

### Self-assessment at the Group level

Evaluation of Sanofi's practices at the corporate level is based on an international tool, the Business and Human Rights Matrix of the BLIHR (Business Leaders Initiative for Human Rights), allowing the Group to establish an inventory of practices, identify any areas for improvement and outline good practices for the following human rights areas:

- Child Labor
- Forced Labor
- Non-discrimination
- Freedom of association
- Remuneration and working conditions
- Security

#### **The Business and Human Rights Matrix is a dedicated tool used to:**

- Learn about human rights issues in companies
- Analyze the situation today
- Identify all the policies, practices, and initiatives aimed at ensuring respect for human rights and provide a basis for developing an action plan

Following this first self-assessment, good practices were highlighted and communicated internally. In addition, areas of improvement were also identified that include the need to update some existing Group policies and develop new guidelines.

### Self-assessment at the local level

*In 2011, the Group organized a self-assessment of practices in a pilot country, India, selected on the basis of potential risks of human rights concerns according to the Maplecroft methodology. The pilot assessment received support from an external human rights consultant*

and was performed using the Human Rights assessment tool for Pharmaceutical Companies created by the Danish Institute for Human Rights.\*

### What is the Human Rights assessment tool for Pharmaceutical Companies?

This evaluation tool was developed by the Danish Institute for Human Rights to detect human rights risks. It is designed to help businesses detect potential human rights concerns by looking at the impact of their operations for employees, local communities, and other stakeholders. This diagnostic tool contains questions tailored specifically for pharmaceutical companies.

For more information:

- [www.humanrights.dk](http://www.humanrights.dk) / *The Danish Institute For Human Rights*

*The results of the pilot program were encouraging and highlighted India as an example for other countries to follow. Many good practices were identified, as well as few shortcomings and a limited number of areas for improvement. Based on the outcomes of this pilot, our goal for 2012 is to develop an internal guide to sum-up human rights principles included in the Sanofi codes and charters, and to provide guidance and examples to Group employees in order to help them implement these principles in their daily activities.\**

By adopting this approach, Sanofi is one of the leading companies in the field of human rights. This process is fully consistent with the Group's commitments (i.e., the Global Compact) and reference texts in this field.

## BUSINESS CASE



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- [Business Case: Human Rights](#)

## Integrating human rights throughout the company

Since 2009, the Group provides external human rights training program developed for executives from companies that are members of EDH (Entreprises pour les Droits de l'Homme,

Businesses for Human Rights) to improve employees' understanding and to promote respect for human rights as an integral part of our business conduct.

In 2011, senior executives from various Sanofi functions took part in in-house training sessions held in different countries, to raise awareness of integration of human rights principles in business. This program made use of materials developed with Entreprises pour les Droits de l'Homme (EDH) tailored specifically to the pharmaceutical industry by the recognized experts in the field.

**68** Sanofi employees representing over **25** functions received human rights training

Since the initiation of this Human Rights program, a total of 68 Sanofi employees, representing more than 25 functions, have received one full day of Human Rights training.

**Excerpts from an employee survey following the pilot human rights training program:**

"What a good educational tool to increase CSR awareness. It brings an interesting, useful and pertinent perspective."

"Thank you for this excellent training day, also going behind the concrete horizon of our day-to-day responsibility/activity, needing to think beyond our immediate perimeter. Training could help to ensure respect of human rights and enhance understanding internally."

"The training allowed me to realize that human rights are the foundation of CSR. Now this concept is clearer although it remains complex. Very enriching."

## Measuring and reporting human rights performance of suppliers

To monitor how well human rights impacts are being addressed, the Group has developed since 2007, a robust methodology and process for the large-scale and targeted evaluation of our suppliers worldwide.

The suppliers' assessment process primarily relies on:

- The use of CSR questionnaires,
- The use of additional questionnaires, when relevant, depending on the procurement category (i.e. low-skilled workers, IT purchases, waste, etc.),
- Audits conducted on site.

In addition, the leadership of the Procurement function decided to leverage the new responsible procurement approach by launching a project pilot in 2011 with 50 suppliers. This project consisted of using a web-based responsible procurement platform, processed by an external provider, in order to:

- Standardize and improve efficiency of the process by creating a single, harmonized, and realistic process,
- Optimize our actions by avoiding time-consuming questionnaires and administrative burden,
- Focus on action plans and suppliers' performance,
- Comply with new regulations and policies,
- Deliver relevant KPI's including Human Rights to the procurement community, our business partners, and external stakeholders.

For more information:

▼ [Supplier evaluations](#)

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## Working alongside other companies

Sanofi was a founding member of EDH in 2007, alongside seven other French international groups: AREVA, BNP Paribas, Casino, EDF, Lafarge, STMicroelectronics and GDF SUEZ.

EDH in France is inspired by the work of the Business Leaders Initiative on Human Rights (BLIHR), an initiative launched in 2003 to provide companies with practical solutions to implement the Universal Declaration of Human Rights."

For more information:



[Overview of EDH](#) (in French)

- [www.blihr.org](http://www.blihr.org) / [Business Leaders Initiative On Human Rights](#)

## Participating in developing the Guiding Principles

As a member of EDH and an advocate of bringing together human rights specialists and stakeholders such as pharmaceutical companies, Sanofi participated in the preparation of a position paper to contribute to the first draft of the Guiding Principles developed by John Ruggie.

([\*Human Rights / Background\*](#))

For more information:

- [www.business-humanrights.org](http://www.business-humanrights.org)



[\*Towards an operational implementation of human rights in business practice\*](#) (PDF, 86Kb)



[\*Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework\*](#) (PDF, 140Kb)

- [www.business-humanrights.org / Guiding Principles](http://www.business-humanrights.org/GuidingPrinciples)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Our vision / CSR performance / Statutory auditors' report\*](#)

## Business Case

Increasing awareness and incorporate human rights into our business activity

### The challenge

Our challenge was to raise awareness of our human rights commitments among Sanofi employees and incorporate the principles of human rights into the Group's operations.

### Our response

As part of a human rights project spearheaded by the Sanofi CSR Excellence Direction, Sanofi implemented an innovative two-fold approach across the Group based on training and self-evaluation tools:

- **1) Human rights training** made use of materials developed with Entreprises pour les Droits de l'Homme (EDH) tailored specifically to the pharmaceutical industry. Since 2007, Sanofi has been committed to human rights as one of the founding members of EDH, along with several other French international groups.

At the end of 2011, a total of 68 employees representing more than 25 functions had received human rights training since the integration of the human rights program.

- **2) Self-assessment of the impact of our operations** focused on areas of potential human rights concerns at the corporate, regional and local levels. This approach is designed to ensure that human rights policies are implemented effectively and addresses potential areas of improvement by developing action plans. It also identifies good practices. More than 10 Sanofi functions participated in this initiative.

### Benefits for stakeholders

Sanofi is convinced that the human rights of all individuals may be affected by the Group's activities. Many of our stakeholders benefit from these programs.

#### Employees

The implementation of human rights principles is a major factor in employee motivation. Respect for human rights also helps Sanofi remain an attractive employer on the job market.



## Suppliers

Suppliers are an important focus of the self-evaluation. The objective is to ensure that suppliers' practices are in line with human rights principles and Sanofi's policies. This helps suppliers to identify potential concerns and to implement action plans.

## Opportunities for the Group

Thanks to this type of pro-active initiative, Sanofi is recognized as a leader in the field of human rights. Our awareness-raising activities (e.g., our pilot program in India in 2011) show that assessing the impact of our operations and addressing areas of potential human rights issues provides many opportunities for the Group, such as:

- "De-mystification" by making human rights in business more concrete for Sanofi employees
- Identifying good practices that can be shared internally and externally
- Identifying gaps and risks; developing action plans to remedy shortcomings
- Monitoring, reporting and communicating internally and externally on human rights
- Improving the Group's image and reputation by establishing Sanofi as a leader in the field of human rights

## The future

In 2012, we plan to expand this initiative by continuing to organize internal and external human rights training programs for employees from different Group functions. Based on the outcomes of this pilot, our goal for 2012 is also to develop an internal guide to sum-up human rights principles included in the Sanofi codes and charters, and to provide guidance and examples to Group employees in order to help them implement these principles in their daily activities.

## Ethics in R&D

Scientific and medical research is an essential part of preventing and combating disease. It demands transparency toward stakeholders, respect for individuals and compliance with regulations. It therefore involves far-reaching ethical considerations.

## Ethics in clinical trials

### Background

Clinical trials are a set of processes in medical research, drug development and marketing approval that are conducted to allow safety and efficacy data to be collected for health interventions. Clinical trials are mandatory both for approving new drugs and for developing new indications for marketed products. They can be conducted when non-clinical safety and efficacy profiles of the potential new drug meet expectations, and health authority and ethics committees have granted approval in the countries where the trial is to take place.

Depending on the type of product and the stage of its development, physicians working as private practitioners or in hospitals (also called “investigators”) enroll healthy volunteers or patients in small pilot studies initially, followed by larger scale studies that often compare the new drug with a treatment already marketed. Clinical trials may vary in size depending upon the number of patients enrolled, number of investigators and countries involved.

Sanofi sponsors Sanofi Pharmaceuticals, Genzyme, Fovea and Sanofi Pasteur clinical trials; we also have ventures with government organizations, other pharmaceutical companies and biotech firms. Since the diversity of roles may exceed the sponsor’s resources, clinical trial support can also be provided by a sub-contracted collaboration such as a contract research organization or a clinical trials unit in the academic sector.

For more information:

- [en.sanofi.com / RD / Clinical trials](https://en.sanofi.com/RD/Clinical%20trials)

## Policy

Respecting the ethics rules that apply to all types of human clinical trials

All clinical trials worldwide must be conducted in compliance with stringent ethics and quality rules. Applying internal directives throughout the Group, Sanofi seeks to design and conduct clinical trials that can provide solid and reliable data, focusing first and foremost on the rights, safety and welfare of clinical trial participants.

Sanofi follows the rules contained in the Declaration of Helsinki and the recommendations of the International Conference on Harmonization (ICH), particularly Good Clinical Practices (GCP).

### **Declaration of Helsinki:**

- [\*www.wma.net / Ethical Principles for Medical Research Involving Human Subjects\*](http://www.wma.net)

### **ICH recommendations:**

- [\*www.ich.org\*](http://www.ich.org)

In addition to these rules, for clinical trials conducted by the Group, Sanofi complies with all applicable national and international rules and laws including:

- European Directives 2001/20/EC and 2005/28/EC
- CFR21 regulations issued by the FDA
- Regulations issued by the Japanese Ministry of Health, Labor and Welfare (MHLW)

Sanofi commits to apply various additional worldwide regulations and standards where applicable to support research in this area and to encourage pediatric trials such as:

- The Best Pharmaceuticals for Children Act (United States)
- The European Directive on medicinal products for pediatric use (1986/609/CE), which went into effect on January 26, 2006
- ICH E11 (United States, Europe and Japan)

## Promoting transparency of information about clinical trials

Sanofi is committed to appropriate transparency in medical research and to providing healthcare professionals and patients with the information they need about our development projects and products to make informed medical decisions.

**For more information:** Disclosure of information on ongoing clinical trials and on trial results

- [en.sanofi.com / RD / Clinical trials / Our commitments](https://en.sanofi.com/RD/Clinical%20trials/Our%20commitments)

## Actions

- ▼ Establishing quality risk management in the medical field
- ▼ Applying a clinical development quality assessment strategy
- ▼ Implementing measures and procedures to guarantee ethics in clinical trials
- ▼ Conducting clinical trials worldwide
- ▼ Strengthening patient participation in developing countries and emerging markets

### Establishing quality risk management in the medical field

Quality risk management starts from the principle of allowing the efficient utilization of available resources by devoting more attention, time and effort to areas of higher risk where they are most needed – thereby enhancing trial subject protection and clinical data quality.

A consistent approach to risk-based management of all trial activity conducted by Sanofi has been systematically implemented in the clinical and medical fields. This was accomplished by extending and adapting the risk management approach already well established by Global Quality in the industrial and manufacturing sectors.

#### For more information:

- [Global Quality](#)

An approach to detect and address potential clinical trial deviations was defined, using the Group's risk management methodology. Based on the identification of potential risk factors in clinical trials, methods have been defined and implemented to detect, prioritize, assess and mitigate risks due to deviations, if any, from applicable ethical, quality or regulatory standards.

For example, methods for detecting and addressing deviations are systematically applied to all clinical trials using both in-house methods, such as central data surveillance, as well as on-site methods during trial site monitoring. These measures ensure early detection of signals indicating potential deviations leading to prompt corrective and preventive actions. In the event that a severe deviation were to be observed at the investigators' site levels, like data fabrication, malpractice or serious non-compliance, sanctions such as termination of the investigator site and notification to ethics committees and health authorities would need to be taken.

Another important aspect of quality risk management is the implementation of a risk-based audit strategy guiding our approach to auditing clinical trials and systems for an efficient quality

assessment of all clinical development activities. This approach also includes a systematic tracking and follow-up of any deviation-related mitigation plans (corrective and preventive actions).

**For more information:**

- *Applying a clinical development quality assessment strategy*

Within the scope of worldwide trials, including in developing countries and emerging markets, clinical operations may be outsourced to clinical research organizations (CROs). In this case, R&D Quality provides expertise and oversight to ensure compliance with Good Clinical Practices (GCP) with the objective of rapidly notifying the relevant managers, regulatory authorities and ethics committees, as appropriate, in the event of non-compliance, if any, and participating in related risk mitigation plans.

### Applying a clinical development quality assessment strategy

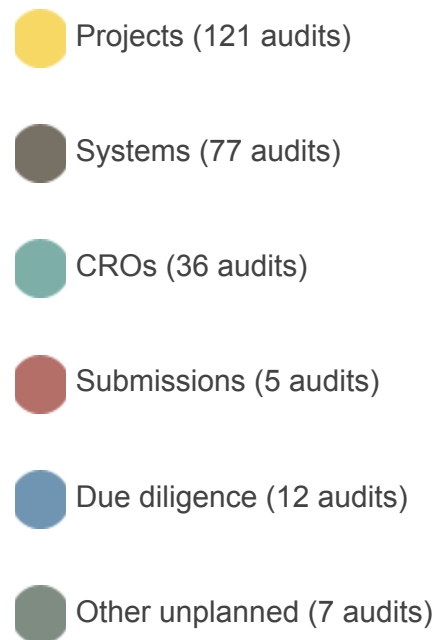
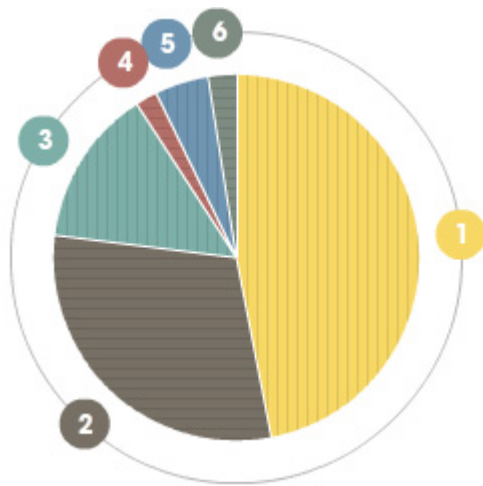
Sanofi seeks continuous improvement through audits in all areas of clinical development expertise (Clinical Study Operations, Medical Affairs, Global Regulatory Affairs, Global Medical Operations and Global Pharmacovigilance & Epidemiology).

As part of clinical development and life cycle management, clinical trials and the systems and processes involved in trial activities are audited by a specialized internal independent Quality department.

These audits are conducted based on our risk-based audit strategy and are designed to ensure appropriate coverage of projects and trials in different countries and regions worldwide.

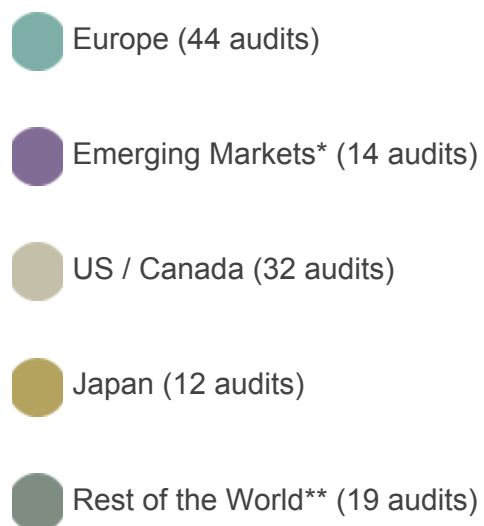
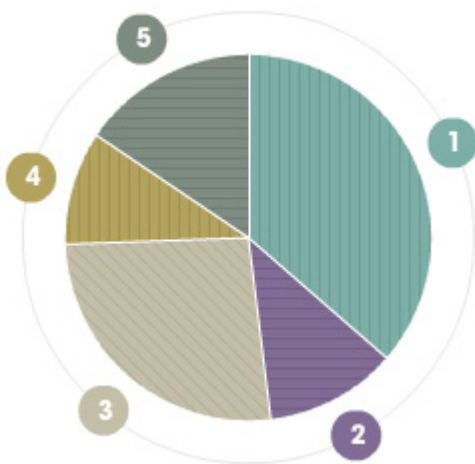
### Overview of the 2011 clinical activities audit program

In 2011, a total of 258 audits were conducted by Sanofi in the field of its clinical trials activities. The proportion of system and process audits (e.g., audits of country affiliate operations, research units or local and global pharmacovigilance units) has increased to 30% as compared to 2010, reflecting a stronger focus on global quality standards and systems. A significant part of audit resources was also devoted to oversight of sub-contractors (CROs). (see diagram below);



## Trial Audits

In 2011, Sanofi conducted 121 audits of clinical trials. About one-third (28%) of them took place in developing countries or emerging markets (see graph below).

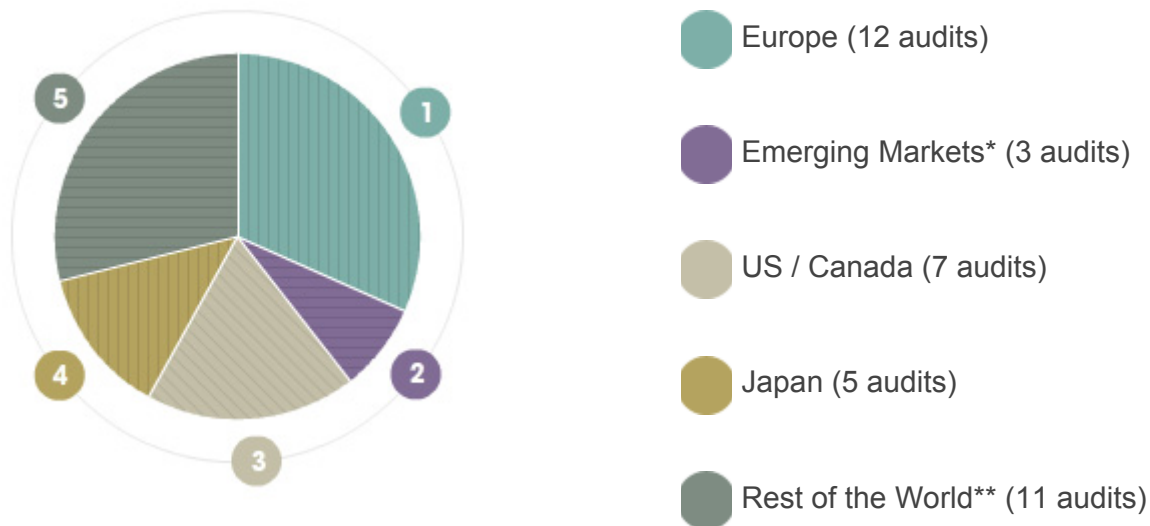


\* **Emerging Markets:** Countries of BRIC: Brazil, Russia, India and China

\*\* **RoW:** all other countries except EU, US, Canada, Japan and BRIC

The breakdown of Sanofi's internal audits (including clinical trials and pharmacovigilance activities for Sanofi projects) coverage is similar to that of worldwide regulatory agency inspections in different regions of the globe (see graph below).





## Implementing measures and procedures to guarantee ethics in clinical trials

Whether a trial focuses on products designed to cure or treat a disease or medical condition, or prophylactic products that act on risk factors and are directed towards preventing or delaying the onset of disease, the trial must be designed to protect the safety of participating patients and ensure their consent is based on clear, complete information, consistent with applicable law.

### Trial Ethics Committee

Before a clinical trial can start, it is routinely subject to multidisciplinary review by Sanofi R&D teams. Information about the trial is then submitted to the health authorities and to independent ethics committees (institutional review boards) in accordance with applicable local and international regulations.

The ethics committee is an independent body entrusted with the responsibility of protecting the rights, safety and well-being of human subjects involved in a clinical trial and providing public assurance of this protection, expressing an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial and the adequacy of facilities, and on the methods and documents to be used to inform enrolled patients and obtain their free and informed consent.

For trials involving vulnerable populations, such as children or patients unable to exercise their own free will, as well as trials in developing countries, qualified ethics committees need to review specific provisions addressed in the trial protocol, such as the procedures to obtain informed consent.

## Data Monitoring Committee

In addition to mandatory safety reporting obligations requested for the marketing authorization of a product, an independent expert group, or Data Monitoring Committee (DMC), is routinely involved in pivotal clinical trials. The role of the DMC is to ensure complete, independent assessment and surveillance of the safety of all patients participating in the trials. The DMC meets on a regular basis to analyze any safety alerts or signals, and make recommendations for mitigation plans. The committee may even decide to terminate a trial if it deems that trial subjects are exposed to unacceptable safety risks.

## Free and Informed Consent

The principle of freely given informed consent applies to all trial subjects and to all types of clinical trials.

All documents related to clinical trials, and in particular written information provided to potential participants, must comply with applicable legislation and regulations and be fully understood by potential participants.

Sanofi assures that all participants (or their legal representatives) enrolled in clinical trials conducted by the Group give free and informed consent to participate in the trial. Consent must be given prior to any procedure required by the study protocol and before any data is collected.

## Personal Data Protection

Personal data collection within the scope of a clinical trial must be clearly defined prior to commencing any trial and must be mentioned in the information submitted to relevant authorities.

All participants whose personal data is collected must be fully informed of the purpose of collecting this information and how it will be used, consistent with applicable law. Health-related data, which are considered sensitive data in some countries according to applicable data privacy regulations, can only be collected once participants have provided their consent. Specific consent may be required to collect genetic data, depending on local law. Participants must be clearly informed of their right to access and amend their personal data as defined by applicable law. Sanofi has put in place procedures and tools to protect the confidentiality of personal data collected during clinical trials.

For more information:

- [Protection of Personal Data](#)

## Conducting clinical trials worldwide

Clinical trials sponsored by Sanofi are conducted worldwide, including in developing countries and emerging markets.

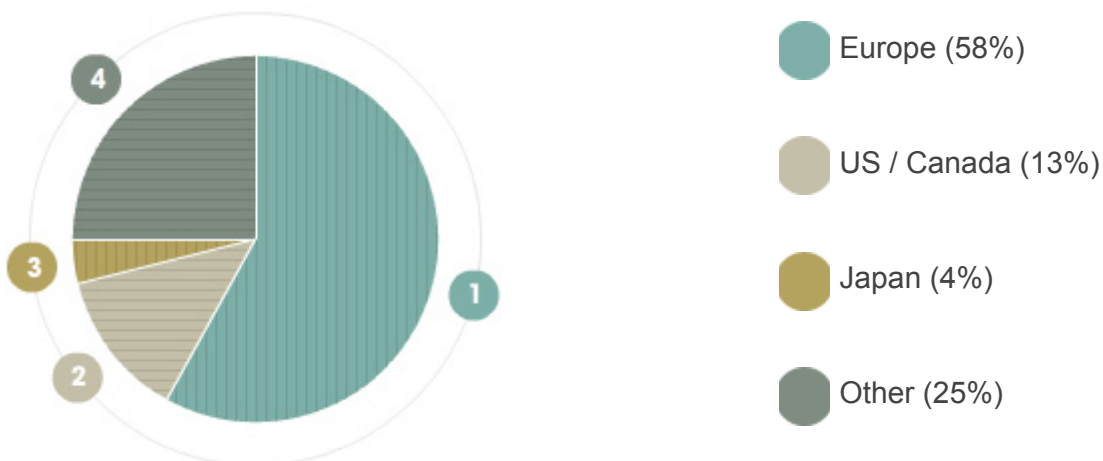
The goal of this worldwide approach is to take into account specific medical conditions and populations in the context of local healthcare systems, constraints and health authority requirements while respecting global requirements.

### BUSINESS CASE



- [Business case: Ethics clinical trials](#)

## Geographic breakdown of patients involved in clinical trials in 2011 (1)



(1) Phase I, II, III and IV trials to develop pharmaceuticals, including Genzyme, not including vaccines

With respect to clinical trials conducted outside the U.S., Europe and Japan, more than 50% are conducted in emerging countries.

## Strengthening patient participation in developing countries and emerging markets

For our industry, it is important to design and conduct trials to test treatments that are context-specific and socially relevant. Through cooperation and collaboration among sponsors, host-country investigators, government agencies and the local patient community, it is possible to address local specificities and overcome obstacles without compromising high standards. This approach develops medical services and strengthens local skills in connection with the Group's training about regulations and global standards.

Our goal is to enable investigators in developing countries to become true product development collaborators by providing valuable product development information covering safety and efficacy needs. We promote the development of malaria, dengue fever and tuberculosis products for use in developing countries and emerging markets while also providing training and support for local healthcare providers and professionals. Helping them stay informed about clinical development regulations and international standards can be an effective way to build local capacity. In addition, Sanofi continues to pay strict attention to compliance with applicable ethics and quality standards in these countries.

A number of international recommendations stipulate that projects carried out in developing countries by sponsors from industrialized nations should be reviewed by two ethics committees: a local committee (in the country where the study is being organized) and a committee in the industrialized country where the sponsoring entity is located. To date, French legislation has no provisions for independent ethics committees to review trials being organized outside of France. To address this issue, Sanofi has taken a proactive approach since 2007 and will submit its clinical trial protocols for malaria studies to a French ethics committee (CPP – Comité de Protection des Personnes), in addition to the ethics committee of the country where the trial is run. In an advisory capacity, the CPP reviews projects to ensure that the sponsor complies with the ethical requirements of its home country. Sanofi was involved in discussions regarding the potential revision of the French law regarding clinical trials, and supported the principle of a double ethical review for trials conducted in developing countries. The proposed revised law is expected to be submitted to Parliament for vote in 2012.

## Business case

### Conducting clinical trials in Africa without compromising global standards

#### The challenge

Today a growing number of clinical trials to assess the safety and efficacy of drugs and vaccines are conducted in developing countries. Such trials must respond to local health needs and address local characteristics. In addition, local healthcare providers should be involved from the early stages of protocol development designed to ensure trial data integrity and patient safety.

This is especially important because developing countries often have no local ethics committees to guarantee that clinical trials comply with Global Quality standards – yet it is essential to respect such standards regardless of where trials are conducted. Sanofi believes that, in emerging and developing countries, the interests of vulnerable patients and communities need to be protected, which is the role that local ethics committees can play.

#### Our response

In response to this challenge, Sanofi's R&D Quality Operations developed a program to provide guidance to healthcare professionals in developing countries who are involved in clinical trials. This program is designed to ensure compliance with ethics standards and respect for local medical practices, customs and beliefs.

In countries where the local environment and infrastructure may not be compatible with Global Quality standards, Sanofi's Quality Operations Department designed a program to provide support for organizing and conducting clinical trials.

*In response to this challenge, Sanofi's R&D Quality Operations conducted audits in several countries (Algeria, Morocco, Tunisia, Egypt, Lebanon, Gabon and South Africa) leading to specific and adapted action plans to provide guidance to healthcare professionals. These action plans are designed to ensure compliance with ethics standards and respect for local medical practices, customs and beliefs supporting the conduct of clinical trials.*

*For example in Tunisia and Gabon, action plans have been implemented in order to promote the protection of patients' health and safety as well as to support local healthcare professionals to comply with clinical trial standard:*

- *In Tunisia (Lantus® Diabetes) we developed an action plan to pay careful attention to the ethics committee's composition and areas of expertise as well as governance so that committees can play their role effectively*
- *In Gabon ( Ferroquine Malaria) we developed an action plan for implementing local standard operating procedures to obtain patients' informed consent in compliance with applicable international guidelines and regulations (adapted to local medical practices and cultural specificities)*
- *In Gabon (Ferroquine Malaria) we developed an action plan supporting data integrity of patients' medical records in accordance with international standards and local law ensuring accuracy of study results \**

For the successful implementation of these quality practices, Sanofi's teams worked with local teams to ensure monitoring and auditing with the aim of sharing good practices, providing information and developing action plans. Sanofi worked in close collaboration with local investigators, health authorities and community representatives.

## Benefits for stakeholders

Stakeholders in developing and industrialized countries include researchers, policy makers, communities and trial sponsors. They may all benefit from this collaborative approach because it is designed to help address the challenge of protecting vulnerable patients and communities. Furthermore, working collaboratively helps to ensure that research is compliant with applicable local and international standards while responding to the community's health needs.

This approach allows all concerned parties to be represented in assessing the value of research projects as well as health issues. At the same time, the host community's culture and social practices are taken into account in the trial's design and implementation.

The case of severe falciparum malaria is a good example: for residents as well as visitors to developing countries, valuable research may focus on preventing and treating malaria; and for everyone, a malaria vaccine would be valuable.

## Opportunities for the Group

Sanofi's collaborative approach may reduce disparities between sponsors in industrialized countries and host communities where clinical trials are conducted in developing nations. It allows developing countries to make a greater contribution to product development programs, as well as building local capacity to conduct clinical trials in compliance with applicable quality standards.

For Sanofi, genuine collaboration with stakeholders in developing countries helps to ensure benefits while enhancing transparency in product development and demonstrating potential value for the local community.

## The future

The implementation of clinical trials in developing countries raises complex ethical issues that should be addressed through transparent dialogue among relevant stakeholders.

Pharmaceutical companies need to strengthen this type of collaborative approach. Clinical trials that are conducted ethically and in compliance with global quality standards should benefit all stakeholders.

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Bioethics

### Background

Scientific advances over the past ten years have led the research community to work increasingly with human biological samples. Such research offers great hope for patients by pursuing potential treatment options for serious or incurable illnesses.

Nevertheless, innovative research using gene therapy, molecular biology, human tissues and, more recently, Human Embryonic Stem Cells (HESC), requires that the Sanofi Bioethics Committee take a firm position and define a clear statement ensuring that Sanofi Research will respect the basic principles established by international conventions and declarations: the UNESCO Universal Declaration on Bioethics and Human Rights dated October 19, 2005; the Declaration of Helsinki (2008 version); the Oviedo Convention (an international convention signed by most European States, which sets out the fundamental principles applicable in day-to-day medicine, as well as those applicable to new technologies in human biology and medicine); and relevant applicable national and international legislation and regulation.

### Policy

The Sanofi Bioethics Committee was created in 2010. This new committee allows the Group to take a position on current and emerging biomedical issues, such as those that are the focus of public debate. It also establishes Sanofi's Bioethics policy with respect to these positions and keeps up to date on current scientific advances.

The Sanofi Bioethics Committee is chaired by the Corporate Chief Medical Officer. The R&D Corporate Social Responsibility Correspondent acts as secretary. Other members of the Committee include the Director of Global Pharmacovigilance & Epidemiology, the Director of R&D Legal Affairs, the Asia Pacific Therapeutic Strategic Unit Director, the Benefit-Risk Assessment Committee Secretary, the Public Affairs Director and external experts and representatives.



## Actions

- ▼ [Defining a strategy for Human Embryonic Stem Cell \(HESC\) research programs](#)
- ▼ [Revising the Sanofi Bioethics Charter](#)
- ▼ [Monitoring the legal framework](#)
- ▼ [Participating actively in ethics-related initiatives](#)

### Defining a strategy for Human Embryonic Stem Cell (HESC) research programs

In 2011, the Sanofi Bioethics Committee gave its approval for research on HESC with a clear strategy: to focus research on the understanding of biological models only, supported by parallel research on adult stem cells, particularly those from the umbilical cord, and research on induced adult stem cells (iPS). IPS are obtained by adult cell reprogramming and exhibit characteristics close to those of HESC. Such research is in compliance with applicable ethical principles. Regardless of the type of stem cells used for research, Sanofi ensures the traceability of samples and complies with applicable data protection guidance.

### Revising the Sanofi Bioethics Charter

The Bioethics Committee is working on the adaptation of the Sanofi Bioethics Charter to provide practical guidelines in response to a changing legal environment. The French law relating to ethical and social bioethics questions raised by medical innovations involving human organ transplants and the use of human biological samples was enacted on July 7, 2011.

### Monitoring the legal framework

The Bioethics Committee and its experts are closely monitoring legal and regulatory statements and case law to ensure that research on human material and especially on HESC is conducted in full compliance with national and international ethics regulations and for the patient's potential benefit.

### Participating actively in ethics-related initiatives

In 2011, Sanofi sponsored a conference in Montpellier (France) devoted to exploring scientific responses to new access to healthcare challenges. This was the first multidisciplinary conference of its kind, providing an opportunity to specialists, scientists, healthcare

professionals and patient organizations to share their experiences through workshops and conference calls.

Sanofi also took part in the Multi-Regional Clinical Trials Center meeting held at Harvard University (U.S.). As one of the sponsors of this international initiative, Sanofi endorsed the overall project objectives focusing on various workstreams, in particular for the development of:

- Standardized contract language for clinical studies that all sponsors could use
- A standardized charter for ethics committees
- Standardized informed consent language
- Training curricula for ethics committees

In addition, Sanofi endorsed supporting the accreditation of clinical investigators.

## Use of laboratory animals for research

### Background

In the discovery and development of potential new medicines and vaccines designed to prevent and cure diseases in animals and humans, the use of animals is essential. As this is a privilege and a responsibility, demanding the utmost consideration and respect, Sanofi maintains a global “Culture of Care” for all of our animals.

Reducing animal experimentation has been an ongoing objective for Sanofi and the scientific community for many years. A new European Directive on the protection of animals used for scientific purposes was approved in 2010. It is now being transposed into national law in EU countries with implementation by January 1, 2013, at the latest. However, because currently available alternatives do not completely eliminate the need to use animals, Sanofi remains morally and legally obligated to conduct animal research and testing. In order to comply with ethics principles, the scientific community has embraced the “3 R’s principles” (Replacement, Reduction and Refinement with respect to the use of animals in research) designed to optimize animals’ health and welfare during all phases of animal testing.

## Policy

- ▼ [Adapting the new European Directive on the Protection of Animals used for Scientific Purposes \(2010/63/EC\) and other Sanofi positions](#)
- ▼ [Internal policies](#)
- ▼ [Accreditation of research laboratories](#)
- ▼ [3R's principles: Replacement, Reduction, Refinement](#)

### Adapting the new European Directive on the Protection of Animals used for Scientific Purposes (2010/63/EC) and other Sanofi positions

One of Sanofi's principal priorities for 2011 was to ensure that in each European country where the Group carries out in vivo research, European Directive 2010/63 on the protection of animals used for scientific purposes has been successfully adapted.

With the involvement of other experts, such as the U.S. National Association for Biomedical Research (NABR) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), Sanofi proactively implements measures designed to improve the welfare of animals without creating unnecessary administrative burden and while offering greater transparency about practices.

### Internal policies

#### Ethics committees for animal experimentation

Sanofi's internal ethics committees are established to make sure that:

- Animals are used only where there is an expectation that the results will contribute to the protection and / or improvement of human health and safety or the quality of medicines or vaccines
- Animals are used with the consideration that they deserve and when no suitable alternative exists

Absolutely all research protocols are validated by these ethics committees, whose position is decisive. Ethics committees are made up of senior animal researchers, personnel in charge of caring for the animals, including at least one veterinarian, and an independent member. The

presence of a biostatistician on ethics committees is designed to ensure that the lowest number of animals of each species required to generate statistically significant results is used.

#### Working with new Sanofi subsidiaries: Genzyme, Fovea and Merial

One of Sanofi's main objectives in 2011 was to assess with the new affiliates whether Sanofi's animal welfare policies cover all in vivo activities. The Group plans to develop an agreement in 2012 among all affiliates for the implementation of a global animal welfare policy.

#### Working with third parties

For studies conducted by contract research organizations (CROs) on behalf of Sanofi, the Purchasing Department carries out an assessment of the provider's commitment to comply with the Group's ethics principles. Sanofi experts conduct on-site assessments of in vivo activities in compliance with Sanofi guidance. Providers must meet the Group's standards in order to be selected.

#### Accreditation of research laboratories

In addition to controls performed by national, federal, international and local authorities, and in order to guarantee that the Group's laboratories and animal facilities comply with high quality standards, Sanofi seeks accreditation by an independent, internationally recognized agency, the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). This association is responsible for assessing and certifying laboratory animal care and use programs. Assessment is based on the animal's environment, housing conditions and veterinary care, as well as policies and procedures for animal welfare (and also for occupational health and safety).

#### 3R's principles: Replacement, Reduction, Refinement

The goal of the 3R's is the optimization of animal health and welfare before, during and after *in vivo* experimentation. We are working on an internal Sanofi Group 3R's internal award to encourage and promote ethical animal experimentation. Sanofi, Sanofi Pasteur, Merial and Genzyme all adhere to the 3R's principles.

- **Replacement** measures consist of obtaining the same level of scientifically relevant information using lower-order species (invertebrates) and substitute methods (without the need to use animals).

- **Reduction** measures consist of obtaining the same level of scientifically relevant information while decreasing the number of animals used or obtaining more information using the same number of animals.
- **Refinement** measures address welfare for each individual animal and aim to minimize distress, discomfort and pain before, during and after research procedures. They are also designed to improve housing conditions.

For more information:

- *Use of laboratory animals / Indicators*

## Actions

- ▼ [Sanofi's key 2011 initiatives](#)
- ▼ [Accreditation status of Sanofi sites](#)
- ▼ [Animal welfare audits of new sites](#)
- ▼ [Actions to implement the 3R's](#)

### Sanofi's key 2011 initiatives

- Supporting transport companies worldwide that are committed to implementing best practices regarding animal welfare
- Working with external stakeholders at EFPIA to reach an agreement on a European charter on animal welfare
- Seeking to create a global steering committee for animal care and use, including all affiliates, in order to promote a Sanofi global animal welfare charter

### Accreditation status of Sanofi sites

#### Sanofi Pharma R&D

Sites in the United States, Germany, Italy and Hungary have maintained continued accreditation.

In France, the Vitry and Alfortville sites have also maintained their accreditation status. Two new sites applied for accreditation:

- The Toulouse site visit outcome was positive and the site received full accreditation in early 2012.
- The Chilly site applied for accreditation at the end of 2011 and will be visited in the first months of 2012.

#### Sanofi Pasteur

In France, the site at Marcy l'Etoile was accredited in 2011 and the Alba site is expecting accreditation in early 2012.

In the US, the Acambis site will submit an application in 2012.

## Genzyme

The U.S. site has already obtained accreditation.

## Animal welfare audits of new sites

All new sites acquired by Sanofi are automatically subject to an internal audit devoted to animal welfare. In 2011, Genzyme was audited; Fovea and Merial will be audited in 2012. The objective of audits is to assess the sites' compliance with the Sanofi Group's standards. Any issues that arise during audits are expected to lead to an action plan to ensure all standards are met.

## Actions to implement the 3R's

### Replacement

The MIMIC® (the Modular IMMune In-vitro Construct) technology developed by VaxDesign and acquired in 2010 by Sanofi Pasteur is intended to capture in vitro genetic and environmental diversity and is based on data generated in a surrogate human immune system. Initial results with a vaccine candidate showed that the MIMIC system was concordant with the phase 1 clinical trial while assessment of efficacy in animal models was not conclusive. In the future, we believe that the use of this novel model for our vaccines pipeline may provide earlier selection of the optimal product candidate, complemented by the use of animal models prior to studies in human clinical trials. The ultimate goal remains unchanged: to develop an in vitro predictive and robust model to evaluate the human immune response.

### Refinement

PRIT: Positive reinforcement training in large animals used in repeated studies

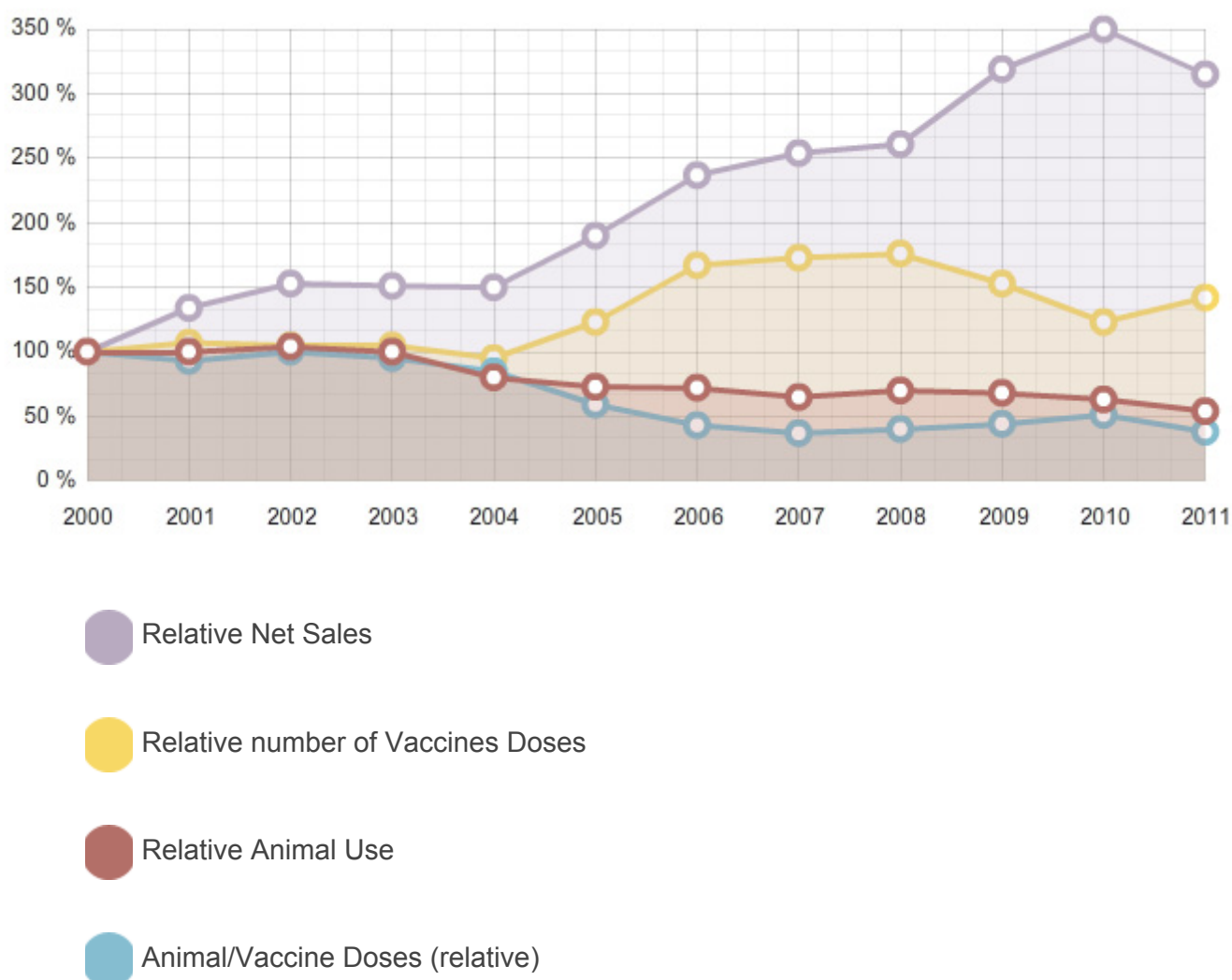
Positive reinforcement training uses praise and / or treats to reward animals for doing something researchers want them to do. Because the reward makes the animal more likely to repeat the behavior, positive reinforcement is one of the most powerful tools for shaping behavior. With positive reinforcement, the animals look forward to a research procedure (i.e., when researchers perform an exam, draw a blood sample, etc.) as a good experience. Just as importantly, data that are obtained when the animals are relaxed and not stressed are much more consistent and relevant. In Sanofi, several pharmacology and safety evaluation studies may use large animals (such as pigs, goats and dogs) that may be used over a period of time. Caretakers and technical staff have developed various positive reinforcement training techniques. This is yet another example of Sanofi's "Culture of Care" program to create conditions that improve animals' welfare in the context of the collection of data, while also enhancing the scientific validity of such data.



## Indicators

### 3R's indicators: Reduction

#### Reduction



The implementation of the 3R's program complementing the Animal Care and Use program enables Sanofi Pasteur to considerably reduce the number of animals used. We have observed a 45% reduction in animal use over the last 10 years. If we take into account the increase in vaccine doses produced, also over the last 10 years (approximately 50%), the adjusted decrease in animals used per dose of vaccine reaches 60%.

## Other indicators

Protocols reviewed by an internal ethics committee

In 2011, 100% of Sanofi Pharma R&D, Genzyme, Merial and Pasteur protocols were reviewed.

## Breakdown of animals used

In 2011, in preclinical development studies performed by Sanofi, more than 95% of the animals used were rodents and 5% were non-rodents (fish, dogs, etc.).

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For Sanofi R&D: Worldwide, 8 of 42 animal supplier sites were audited in 2011, which represents 19% of suppliers currently providing animals to Sanofi R&D.

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For Sanofi R&D: 4 of 38 CRO sites were audited in 2011, which represents 10.5% of CRO sites. Every year an audit plan is developed to meet business needs.

## Nanotechnology

### Background and Policy

Nanotechnology is a new approach that is based on limited practical experience due to the number of marketed products that is, for the time being, relatively small. Nanoscience and nanotechnology refer to the understanding and control of matter at the atomic, molecular or macromolecular levels, at the length scale of approximately 1 - 100 nanometers (nm). The objective is to encourage the study of basic biological phenomena and engineer nanotechnology-based solutions that may enable biomedical breakthroughs in the diagnosis, treatment and management of disease.

Research projects may include the development, modification or integration of advanced nanotechnologies and nanoscience-based tools, methods, concepts and devices. In addition, engineering nanoscale structures and systems provides a way to study and understand biological processes in health and disease. They may contribute to developing novel diagnostics and drug delivery approaches for treating disease. For this reason, nanotechnology may be an innovative approach for several therapeutic areas such as Cancer and Alzheimer's diseases.

The risks associated with nano-particles should be investigated from a fundamental understanding of the physico-chemical and biopharmaceutical features of nano-objects in safety studies designed specifically for this purpose, prior to first in man studies.

### Cancer

For solid tumors, the basic principle is that, due to nano-particles' small size (one nm corresponds to one billionth of a meter), they may be able to carry a drug into the vicinity of cancer cells or directly into the cells themselves. A key property to promote drug delivery in the tumor is the nano-objects' ability to avoid being captured by the immune system's macrophages, and the fact that they remain for an extended time in the circulating blood. In collaboration with the team of Professor Patrick Couvreur (School of Pharmacy of Châtenay Malabry), Sanofi researchers have been pioneers in the investigation of key attributes of nano-objects leading to long circulating properties.

Encapsulation of drugs in nano-objects to promote crossing the intestinal barrier is another potential nanotechnology-based drug delivery approach aimed at giving access to orally delivered biomolecules. The key principle is that, while being protected from degradation in the gastro-intestinal fluids, the drug may be transported to the near vicinity of the intestinal epithelium cells thanks to the specific diffusion properties of nano-objects. The objective of the

Trans-Int European consortium led by Professor Maria-José Alonso (University of Santiago de Compostella) is to identify the key attributes of the biomolecule/nano-object assemblies promoting oral bioavailability and, at the same time, to explore the particular safety aspects of this route.

The development of nanotechnologies lies at the crossroads of medical research and material science and technology, including synthetic chemical and biotechnology approaches. It is necessary for research to be coordinated so that science-based benefit / risk evaluation can be addressed in this particular context and the development of the potential new treatment can proceed expeditiously. Some nanotechnology preparations using cytostatics conveyed in liposome or nano-particles are already commonly used today.

The potential development of truly targeted treatment that destroys cancer cells through docking of the nano-objects by a homing device is still a few years away, if it can be accomplished. Another innovative approach still in its early stages is the potential encapsulating or linking engineered nucleic acids with nano-particles for delivery to cancer cells.

### Alzheimer's disease

In Alzheimer's disease, an early diagnosis combined with a new nanotechnology-based drug delivery approach aimed at crossing the blood-brain barrier potentially could provide new tools to design improved treatments. Central nervous system drug delivery constitutes a real challenge owing to the tight junctions sealing the endothelial cells at the blood-brain barrier. In addition to fine tuning the intrinsic brain tropism of some nano-particles, research efforts are currently focusing on appending to the nanonized systems molecules targeting receptors at the brain endothelium and allowing for internalization via transcytosis or trans-endocytosis. Here again, long circulating properties are a pre-requisite to modulating the biodistribution of the drug carried by the nano-object.

It is important in particular to demonstrate that these supramolecular assemblies are biodegradable and to understand the key attributes conditioning their biodistribution and elimination. In addition, the potential occupational health aspects related to nano-particles need to be considered, for laboratory and subsequent manufacturing activities. Their potential environmental impact must also be taken into account.

## Actions

### Developing knowledge and collaborations in Nanotechnology

Sanofi is working with public research institutions (e.g., Caltech, MIT, Universities of Paris and Toulouse) to explore and understand the behavior of nano-structures, anticipate the associated risks and develop mitigation plans, while aiming to explore their potential therapeutic use. Sanofi is also working with scientific consortia: Medicen in the Paris region (a cluster for innovative therapies and advanced technologies in healthcare) and Trans-Int (European Framework Program 7) to anticipate future regulatory policies for the use of nano-objects, and to address the necessary investments for this specific type of research.

### Defining group position

Before formally moving into nanotechnology research, Sanofi intends to express the Group's position and determine the precise scope of research-based risk assessment in collaboration with academic institutions and health authorities working in this field.

Once the direction of such research has been clearly defined, Sanofi will set up an expert committee to review and approve development on animal models. The Group will establish a charter to define the context in which these technologies may be used, in compliance with health authorities' standards and regulations.

## Business ethics

Ethical business conduct is a key issue for Sanofi, which establishes codes and charters to manage its business activity. The Group believes that economic performance cannot be dissociated from responsibility.

## Governance

### Background

The Group's goal is to be in line with the highest standards for good corporate governance. As a company governed by French law, Sanofi's practices comply with recommendations contained in the NRE (Nouvelles Régulations Economiques) and in the AFEP-MEDEF Code de gouvernement d'entreprise (Corporate Governance Code of the Association Française des Entreprises Privées and the Mouvement des Entreprises de France).

### Policy

- ▼ Governance structure
- ▼ Independence of directors
- ▼ Functioning of the Board and its committees
- ▼ Complying with corporate governance standards

### Governance structure

The offices of Chairman and Chief Executive Officer have been separated since January 1, 2007. While this decision was initially adopted out of a desire to ensure an orderly succession in light of the scheduled departure of Jean-François Dehecq, who was nearing the mandatory age limit set in the Company's Articles of Association, the annual evaluations conducted since have indicated that this governance structure is suitable to the Group's current configuration. This arrangement was thus continued with the appointment of Serge Weinberg to the office of Chairman. The Board of Directors considers that this governance structure is appropriate in the Group's current context.

The Board is attentive to the interests of shareholders and other stakeholders.

Non-voting employee representatives attend and participate at Board meetings, contributing their point of view to questions debated by the Board. Employee input and questions on key corporate issues is also solicited through such internal tools as the corporate intranet, the establishment of non-mandatory consultative bodies such as the European Works Council, and alert mechanisms such as those required under the U.S. Sarbanes-Oxley law.

*Regular contacts with large or small investors are ensured by the Board or company employees acting on its behalf on questions of corporate governance through various channels and events*

*such as Salon Actionaria organized in France, the establishment of a minority shareholder committee, the maintenance of an award winning Investor Relations and Individual Shareholder department, interactions with Proxy Agencies and Social Rating Agencies, and individual outreaches* \*.

## Independence of directors

The corporate governance standards used by Sanofi primarily come from the AFEP-MEDEF Corporate Governance Code.

Under the terms of the AFEP-MEDEF corporate governance code, a director is deemed to be independent when the director has no relationship of any nature whatsoever with the Company, the group it belongs to or its senior management which could compromise the exercise of the director's freedom of decision. More specifically, independent directors are required:

- not to be an employee, nor a corporate officer of the Company, nor a corporate officer of a related company,
- not to be a customer, supplier nor a banker with respect to the business or financing of the Company,
- not to have close family ties with any corporate officer of the Company,
- not to have acted as auditor for the Company over the course of the last five years,
- not to have been a director of Sanofi for more than 12 years,
- not to be representative of a significant shareholder or control person of the Company.

In conformity with the Board Charter and pursuant to the AFEP-MEDEF Corporate Governance Code, a discussion as to the independence of the current directors took place during the meeting of the Board of Directors of December 13, 2011.

Of the 15 directors, eight were deemed to be independent directors having regard to the independence criteria set forth in the AFEP-MEDEF Corporate Governance Code: Uwe Bicker, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Suet-Fern Lee, Carole Piwnica, Klaus Pohle, and Gérard Van Kemmel.

Not only is a majority of Sanofi's Board composed of independent directors, but each of the Board's committees are made up a majority of independent directors and are presided either by the Chairman of the Board or by an independent director.

In its examination of the independence of each Director, the Board of Directors took into account the various relationships that could exist between Directors and the Group and



concluded that no such relationships were of a nature that could put into question their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the last three years, sold products and provided services with, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent or members of their close family were senior managers or employees during the financial year 2011. Each time, the amounts paid or received from such companies over the past three years were determined in accordance with the normal course of business and did not represent amounts that the Board considered to be of such nature as to bring into question the independence of the directors in question. In the same manner, the Board of Directors did not find the office of trustee held by Uwe Bicker and Klaus Pohle with the Aventis Foundation (Germany) was of such nature as to bring into question their independence with respect to the Sanofi Board of Directors.

## Functioning of the Board and its committees

The Board Charter provides that once a year, the Board of Directors dedicates one item of its agenda to a debate concerning its functioning and that every three years a formalized assessment is made.

An overall positive appreciation of the functioning of the Board and its committees resulted from the annual debate on the Board and its committees' functioning in 2011. Directors recognized progress on several areas such as openness of discussion, the clarity of the strategy and the balance of powers between President and CEO.

The assessment revealed that the Board appreciated the different presentations of Group activities made during meetings of the Board or its Strategy Committee, in particular the Executive Vice President Chief Financial Officer, the Senior Vice President Legal Affairs and General Counsel, the Senior Vice President and Chief Medical Officer, the President Global Operations, the Vice President of Industrial Affairs, the Vice President of Mergers and Acquisitions the Senior Vice President Animal Health, the Senior Vice President Latin America Region, and the Chairman and Chief Executive Officer of Sanofi Pasteur.

Aside from their informational value, these presentations provide an opportunity for directors to better know the senior leadership of the Group. Directors have expressed a strong interest in continuing such initiatives. In this period of intense changes, Directors renewed their commitment for a regular review of the performance of growth platforms and a control of required assets.

In connection with their appointments, Carole Piwnica and Suet-Fern Lee were each provided a several days of training during which they were familiarized with the Company, its occupations and the highly specialized sector of health care, and in particular, of the pharmaceutical

industry. The triennial formal evaluation on the functioning of the Board and its committees will be held in 2012.

Additionally, the Group has organized its internal control system through the distribution of Group codes and charters. Their degree of implementation is monitored on a regular basis through audits and self-assessments.

**For more information** on corporate governance:

 [Directors, Senior Management and Employees, beginning](#) (abstract from 2011 Form 20-F)

 [Gouvernement d'entreprise of the 2011](#) (abstract from Document de Référence in French)

 [Rapport du Président du Conseil d'administration](#) (extract from Document de Référence in French)

- [Corporate governance organization on the Sanofi website](#)

## Complying with corporate governance standards

| GOOD GOVERNANCE STANDARDS                                     |  | SANOFI   |   |                         |                        |                                       |                            |
|---|--|--|---|-------------------------|------------------------|---------------------------------------|----------------------------|
| INDEPENDENCE  | DIRECTORS <sup>(1)</sup>                               |  | Board of Directors  | Audit Committee         | Compensation Committee | Appointments & Governance Committee   | Strategic Review Committee |
|   |  | At least <b>50% of Board</b> and Compensation Committee directors are independent                                      |   |                         |                        |                                       |                            |
|   |  | Board of Directors <b>chose to follow independence criteria</b> provided in the AFEP/MEDEF's Corporate Governance Code | 8 out of 14 independent   | 3 out of 4 independent  | 3 out of 5 independent | 4 out of 7 independent                | 3 out of 7 independent     |
|   |  | No cross check   | No cross check  |                         |                        |                                       |                            |
|   |  | Length of director's term  | 4 years<br>Staggered terms of office in order to ensure that directors are progressively re-elected   |                         |                        |                                       |                            |
|   | Number of terms held simultaneously by Group directors | Link to the 2011 Form 20F (p 143)  |   |                         |                        |                                       |                            |
|   | AUDITORS <sup>(2)</sup>                                | Statutory auditors may not provide consulting services with the exception of audit services                            | See details in the 2011 Form 20F (p F-117)  |                         |                        |                                       |                            |
|   |  | Auditor and Audit Committee meetings without management in attendance  | During Audit Committee meetings, which take place prior to Board meetings approving semi-annual and annual financial statements   |                         |                        |                                       |                            |
|   | INVOLVEMENT IN DECISION MAKING                         | DIRECTORS  | Number of meetings of the Board of Directors in 2011<br>Average attendance rate at Board meetings in 2011   | 10 meetings<br>Over 91% |                        |                                       |                            |
|   |  |  | Accounting, Compensation, Appointments and Strategic Review Committees  | Audit Committee         | Compensation Committee | Appointments and Governance Committee | Strategic Review Committee |
| Number of meetings in 2011                                    |  |  | 7   | 4                       | 2                      | 2                                     |                            |
| Attendance rate   |  |  | 100 %   | 90 %                    | 75 %                   | 90 %                                  |                            |
| Assessment of Board operations every 3 years                  |  |  | The second formal assessment was carried out in 2009, conducted by the Board secretary. On December 13, 2011, the Board performed its annual review of its operations and its committees' operations. |                         |                        |                                       |                            |
| SHAREHOLDERS  |  | Proportion of votes expressed in a General Meeting by shareholders present, represented or by absentee vote            | At the General Meeting of May 6, 2011, the total number of votes represented 64% of existing voting rights. Resolutions were adopted by between 78.2% and 99.88% on average.                          |                         |                        |                                       |                            |
| <sup>(1)</sup> among themselves and in relation to management |  | <sup>(2)</sup> in relation to management   |   |                         |                        |                                       |                            |

## Actions

Several examples illustrate the Group's corporate governance practices:

- ▼ Board Charter
- ▼ CSR-related issues addressed by the Board and its committees
- ▼ Diversity within management bodies
- ▼ Compensation of senior executives
- ▼ Preventing conflicts of interest
- ▼ No anti-takeover statutes

### Board Charter

The Board Charter establishes the responsibilities of the directors, the composition, duties and working procedures of the Board and its committees, and the roles and powers of the Chairman and the Chief Executive Officer.

On December 13, 2011, the Board Charter was updated in particular to increase the minimum number of shares that each Director is required to hold from 500 to 1,000 shares. This is in line with the AFEP-MEDEF Corporate Governance Code which requires that a director should be a shareholder personally and hold a fairly significant number of shares. If he or she does not hold them when assuming office, he or she should apply his or her directors' fees to acquiring them.

For more information:



[Directors, Senior Management and Employees \(extract from 2011 Form 20-F\)](#) (PDF, 173Kb)

### CSR-related issues addressed by the Board and its committees

*A part of the Board's time is dedicated to issues of Corporate Social Responsibility related to Group's strategy, including sustainable development and workforce diversity.* \* The presence of five employee representatives at all Board meetings ensures that the Board is informed of the potential social impact of Board Decisions by a source distinct from Company management. *The Board has established a special committee for strategic reflection, to ensure that a long term perspective is developed.* \* The Board's audit committee actively follows major risks, and on a regular basis holds information sessions about CSR-related topics such as pharmacovigilance, environmental issues, litigation, and insurance.

## Diversity within management bodies

Diversity prevails in the different management bodies of the Company and is reflected in gender balance, internationalization of the Board and Comex, as well as qualifications and expertise of the Board members.

### **Gender balance**

Sanofi believes that gender balance within the boardroom helps improve corporate governance. Since 2008, the Group has also been involved in the Boardwomen Partners program that includes CAC 40 companies that want to promote greater gender balance on their boards of directors.

Under new legislation in France, within the next three years, 20% of board members must be women, and within the next six years, the percentage must reach 40% (French Law No. 2011-103 of January 27, 2011 on the balanced representation of women and men on boards of directors and supervisory boards, and on professional equality).

In 2011, the percentage of women on the Board of Directors increased with the appointment of Suet Fern Lee, bringing the percentage of women to 20%. On the Group's Executive Committee, one out of nine members is a woman.

### **Internationalization of the Board and Comex**

The Board of Directors is composed of seven members out of fifteen who have a different nationality than French. The Comex is composed of three members out of nine who have a different nationality than French.

### **Qualifications and expertise of Board members**

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and the composition of its committees, in particular, the Board seeks to ensure a balanced representation of men and women, and diversity of background and country of origin, since the business of the Group is both diversified and global. The Board also investigates and evaluates the potential candidates each time individual directors are up for election. Above all, the Board seeks talented directors, who show independence of mind and who are competent, present and involved.

For more information:



[\*Directors, Senior Management and Employees \(extract from 2011 Form 20-F\)\*](#) (PDF, 173Kb)



[\*Form 20-F 2011\*](#) (PDF, 1289Kb)

## Compensation of senior executives

The compensation and pension arrangements of the Chief Executive Officer, Christopher A. Viehbacher, is fully disclosed, including performance shares and options.

The compensation of the other Executive Committee members is established upon the recommendation of the Compensation Committee taking into consideration the practices of major global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation, which is determined as a function of the trends in the business areas for which the senior managers in question are responsible. Variable compensation generally represents 60% to 110% of their fixed compensation.

In addition to cash compensation, Executive Committee members may be awarded share subscription or purchase options and/or performance shares.

With respect to 2011, the total gross compensation paid and provisioned with respect to members of the Executive Committee (including the Chief Executive Officer) amounted to 13.9 million euros, including 5.7 million euros in fixed compensation.

For more information:



[\*Compensation \(extract from 2011 Form 20-F\)\*](#)

## Preventing conflicts of interest (related-party agreements and no cross-holdings)

Sanofi has introduced measures to prevent risks pertaining to conflicts of interest.

- Shareholdings: The Group does not have any shareholdings in its major shareholders. As such, there are no cross-holdings.
- Related-party agreements: In order to protect shareholders and ensure that senior executives and directors do not take advantage of their duties by entering into, for their benefit, agreements that are unfavorable for Sanofi, the commitments made by the Group in favor of a senior executive or a major shareholder are subject to authorization by the Board of Directors and approved by the shareholders at a general meeting. Agreements with corporate officers, directors and the Group's main shareholders are thus presented to

- shareholders transparently. Related-party agreements are addressed in a Special Report of the Statutory Auditors that is presented in the 2011 Document de Référence.

For more information:



*Rapport spécial des commissaires aux comptes sur les conventions (extrait du Document de Référence 2011)* (PDF, 57Kb)

## No anti-takeover statutes

Sanofi has not adopted any anti-takeover measures. The Group's Document de référence specifies that the Group's bylaws do not contain any provisions to delay, postpone or prevent a change in control for the Group. Furthermore, the bylaws stipulate that any measures to be adopted to counter a takeover bid must be voted on by the Group's shareholders.

For more information:



*Document de Référence 2011 - Éléments susceptibles d'avoir une incidence en cas d'offre publique (Extrait)* (PDF, 55Kb)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Vision / CSR performance / Statutory auditors' review report*

## Prevention of conflicts of interest

### ▼ Background

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### ▼ Policy

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### ▼ Actions

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## Background

Conflicts of interest arise in situations where there is a risk that Sanofi employees' personal interests will interfere with, or give the appearance of interfering with, Sanofi's legitimate business interests. A conflict of interest can create the appearance of impropriety, which may undermine confidence in the individual or Sanofi and harm both their reputations.

## Policy

### ▼ Employees' personal interest and Sanofi's interest

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### ▼ External commitments

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### ▼ Personal relationships

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### ▼ Items of value other than purely token gifts\*

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In order to give guidance to Group employees, Sanofi has devoted a chapter of its new Code of Ethics to the prevention of conflicts of interest.

In addition, a Group Conflict of interest Directive for employees has been issued in 2011. Its purpose is to implement a proactive mechanism to enable the early detection of conflict of interest situations for Sanofi employees across the Group, and to provide a methodology to follow in such situations.

## Employees' personal interests and Sanofi's interests

- Employees may find themselves in situations where there is a risk that their personal interests will come into conflict with those of their employer. Any real or apparent conflict of interest may lead to problems and harm Sanofi's reputation.
- "Personal interests" should be taken in the broad sense, covering not only the interests of individual employees but also those of their close associates (whether people or organizations). To prevent conflicts of interest, employees must safeguard against situations



- in which the objectivity of their business decisions may be impaired, in particular as concerns:

### External commitments

Employees must inform their superior in advance of any investment in a competitor, supplier or customer, whether by acquiring an equity interest (other than by buying shares in a listed company) or a business activity. Situations of this kind may impair the objectivity incumbent on a Group employees when acting on behalf of the Group.

While employees are entitled to participate in not-for-profit activities in a personal capacity, they should ensure that this does not create a conflict of interest with the Group.

We respect the political opinions and personal commitments of our employees, but any expression of such beliefs or commitments must remain personal (i.e., outside working hours and at the employee's own expense). Consequently, Sanofi employees are formally prohibited from committing the Group to any political activism or demonstration by mentioning Sanofi's name or by using Sanofi's letterhead, funds, or resources. Similarly, Sanofi premises may not be used for personal political activities.

### Personal relationships

Employees may have someone close to them whose personal interests are linked to the Group's activities. In situations where such a connection is identified and the objectivity of decisions made by the Group might be challenged, employees must inform their superior of the connection before any decision is taken and play no part in the decision-making process.

### Items of value other than purely token gifts\*

When such gifts concern people who work with the Group or who wish to do so, they can generate conflicts of interest. Accepting a gift may create a sense of obligation for recipients, potentially undermining the objectivity of their decisions.

For more information:

- [Policies and management systems](#)

## Actions

### Training and awareness

To raise employees' awareness on conflicts of interest, an ethical moment is available on the Global Compliance intranet. A training based on the Group Conflict of Interest Directive for employees will be launched in 2012.

For more information:

- [Sanofi Code of Ethics](#)

\*What is regarded as a “token” gift varies from country to country depending on local legislation, culture and economic environment.

## Responsible Lobbying

### ▼ Background

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### ▼ Policy

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## Background

Lobbying practices are often the focus of debate in today's business and political world, with ever-increasing demands from the public for greater transparency.

Lobbying may be a useful part of the legislative process provided it is conducted in compliance with legal requirements. Through lobbying, industries can help shape policies by providing valuable information and insights about potential legislation that impacts business activity.

Yet it is essential that a clear framework for the regulation of lobbying activities be provided to protect the public's interest and avoid corrupt or unfair practices. In 2010, the OECD issued "Ten Principles for Transparency and Integrity in Lobbying" to provide decision makers with guidance and meet expectations of transparency and accountability in public policy making.

**For more information:** The OECD's ten principles

- [www.oecd.org / Transparency and integrity in lobbying](http://www.oecd.org/Transparency%20and%20integrity%20in%20lobbying)

Responsible lobbying is closely tied to the fight against corruption in all its forms, addressed by Principle 10 of the UN Global Compact, to which Sanofi subscribes.

**For more information:** The UN Global Compact

- [www.unglobalcompact.org / About the GC / The ten principles](http://www.unglobalcompact.org/About%20the%20GC/The%20ten%20principles)

## Policy

Because our business model is highly dependent on regulatory frameworks and decisions by administrative and government authorities, Sanofi wishes to be involved in public policy debate and the drafting of legislation that will affect our business, to the extent appropriate and consistent with applicable law. Changes to the regulatory landscape in certain areas may have substantial consequences for pharmaceutical companies such as ours: rules governing research, procedures to obtain marketing authorization, intellectual property protection, reimbursement policies, access to treatment, etc.

The Group aims to establish sustainable interactions with legislators and other stakeholders, where appropriate and lawful, who share its objective of seeking to increase access for the largest number of patients and consumers to the best medicines and healthcare products while preserving incentives for research and innovation.

Through the Group's regional and affiliate public affairs networks, we develop and maintain appropriate and lawful relationships with the institutions that create and enforce the industry's regulations. For the sake of transparency and clarity, we try to provide these institutions with the information they may need and communicate the Group's positions on many key issues.

For more information:

▼ [Ethics / Business Ethics / Responsible lobbying / Actions / Sanofi's key positions](#)

Sanofi's lobbying activities are conducted in compliance with the Sanofi Code of Ethics (insert link) and applicable lobbying and advocacy laws and regulations where the Group does business. To meet our stakeholders' expectations, we are also committed to complying with the "Ten Principles for Transparency and Integrity in Lobbying" published by the OECD. We believe that it is in our best interest to advocate for regulations that encourage ethical business conduct, which will contribute to building a climate of trust. As defined here, Sanofi is committed to publishing the Group's financial contributions to official organizations. In addition, the Group decided to voluntarily publish the amounts of support we provide to European-based patient associations for activities undertaken in 2010 onwards.

For more information:

- [Supporting patients](#)

## Actions

The year 2011 was marked by two major events that reflect the Group's progress in this field: the creation of the Sanofi International Public Affairs Coordination (IPAC) and the drafting of a Responsible Lobbying Directive. At the same time, we continued to publish the Group's major financial contributions as well as our positions on key business topics, and to uphold the European Commission Transparency rules.

- ▼ International Public Affairs Coordination (IPAC)
- ▼ Responsible Lobbying Policy
- ▼ EU Transparency Register
- ▼ Publication of major Group financial contributions to official organizations
- ▼ Sanofi's key positions

### International Public Affairs Coordination (IPAC)

One of the highlights of 2011 was the development of the Sanofi International Public Affairs Coordination (IPAC). The role of this team is to build a strong, pro-active network to provide clear messages in today's turbulent international business environment, helping the Group to speak with one voice. IPAC facilitates communication between Sanofi's various offices and divisions, ensures alignment between local messaging and global activities, and helps to promote good practices. Its work also supports decision-making by senior management.

Through our efforts to ensure that Sanofi complies with responsible lobbying practices, we preserve our reputation and the interests of our shareholders. In 2012 we expect to build on the significant strides made in 2011 and achieve even greater progress.

### Responsible Lobbying Policy

We are well aware that lobbying practices can give rise to controversy and at times may challenge public trust. We wished to go beyond compliance with international codes and standards governing this activity, and in 2011 IPAC members drafted the Sanofi Responsible Lobbying Policy, under which the standards we set for ourselves can be clearly stated. Moreover, the Group's transformation has broadened the scope of entities potentially involved in

lobbying, and it is essential to ensure that everyone in the Group who may be involved in this issue will have a sound understanding of the conduct they must adopt.

The Responsible Lobbying Policy became effective in early 2012. The purpose of the Responsible Lobbying Policy is to define a global frame for all lobbying activities carried out by Sanofi at international, regional, federal, national and local levels. The policy is related to Sanofi's Code of Ethics and Sanofi Anti-Bribery Policy. Additionally, the OECD Principles for Transparency and Integrity in Lobbying are used as a reference in developing the policy. The policy indicates that Sanofi performs lobbying with the highest ethical standards and commitment to the patient. In addition to compliance with Sanofi's code of ethics and applicable lobbying and advocacy laws and regulations where Sanofi does business, the key principles of the policy include, but are not limited to: quality of information circulated by Sanofi, support of initiatives that aim to increase transparency in public and business life, and that only personnel who are registered lobbyist or having prior approval from Sanofi management can engage in lobbying on behalf of Sanofi.

## EU Transparency Register

In 2009, Sanofi joined the European Commission's Transparency Register, which provides European citizens residents with direct access to information about which organizations are engaged in activities aimed at influencing the EU decision-making process, as well as the resources invested in these activities. Registrants are required to provide information about their lobbying and advocacy activities and sign the Transparency Register Code of Conduct.

**For more information:** The transparency register

- [webgate.ec.europa.eu / European Commission's Register of Interest Representatives](http://webgate.ec.europa.eu / European Commission's Register of Interest Representatives)

## Publication of major Group financial contributions to official organizations

In line with our commitment to transparency, the Group publishes the following information about our financial contributions (all contributions and expenditures are rounded to the nearest 10,000 euros or dollars).

### In the area of human health

| Organization  | Group contribution in 2011                    |
|---|---|
| Federal Lobbying Expenditures in the United States* | Sanofi: \$ 4,060,000<br>Genzyme: \$ 1,610,000 |
| Contributions to PhRMA <sup>(1)</sup>               | Sanofi & Genzyme: 11,376,000                  |

| Organization  | Group contribution in 2011                                      |
|---|---|
| Contributions to BIO <sup>(2)</sup>   | Sanofi: \$ 590,000<br>Genzyme & Sanofi Pasteur: 650,000         |
| Contributions to LEEM <sup>(3)</sup>  | € 3 770 000   |
| Contributions to IFPMA <sup>(4)</sup>   | \$ 240 000<br>+ € 40 000 (vaccines related activities)          |
| Estimated costs related to direct interest representation activities with European institutions | Sanofi: € 500 000 - € 600 000<br>Genzyme: € 500 000 - € 600 000 |
| Contributions to EFPIA <sup>**</sup> (5)  | Sanofi: € 340 000<br>Genzyme: € 120 000                         |
| Contributions to EFPIA/EVM <sup>**</sup> (6)  | Sanofi: € 340 000<br>Genzyme: € 120 000                         |
| Contributions to IEBE <sup>**</sup> (7)   | Sanofi: € 20 000<br>Genzyme: € 20 000                           |
| Contributions to AESGP <sup>**</sup> (8)  | Sanofi : € 40 000   |
| Contributions to EuropaBio <sup>**</sup>  | Genzyme: € 60 000   |

- *\*In accordance with the Lobbying Disclosure Act of 1995 and the Honest Leadership and Open Government Act of 2007, Sanofi reported \$ 4,060,000 in federal lobbying expenditures and Genzyme reported \$ 1,610,000 in federal lobbying expenditures in 2011. This covers compensation for all employees engaged in lobbying activity, including research, planning, preparation and strategizing for lobbying,, payments to lobbying consultants, travel and expenses related to lobbying activity, and dues to associations or coalitions that are allocated to lobbying*
- *\*\* In accordance with the Transparency Register Compliance Guidelines, published June 23rd, 2011, full membership fees, contributions and participation costs in trade or professional associations, think tanks, special events organized by third parties should not be taken into account for those organizations that have voluntarily registered. Despite the fact these organizations voluntarily registered, we agreed, for the sake of transparency, to disclose our contributions.*
- (1) *Pharmaceutical Research and Manufacturers of America*
- (2) *Biotechnology Industry Organization*

- (3) *The French Pharmaceutical Companies Association*
- (4) *International Federation of Pharmaceutical Manufacturers and Associations*
- (5) *European Federation of Pharmaceutical Industries and Associations*
- (6) *European Federation of Pharmaceutical Industries and Associations / European Vaccine Manufacturers*
- (7) *European Biopharmaceutical Enterprises*
- (8) *Association of the European Self-Medication Industry*

In the area of animal health

In Europe, Merial's Public Affairs strategy was only implemented through organizations that have voluntarily registered. In the U.S., no Merial employees meet the federal threshold of being registered lobbyists. Merial's main contributions to Animal Health Professional organizations are :

| Organization   | Group contribution in 2011 |
|--|----------------------------|
| International Federation for Animal Health - IFAH Global | € 130,000                  |
| International Federation for Animal Health - IFAH Europe | € 100,000                  |
| Animal Health Institute (AHI)                            | \$ 710,000                 |

### Sanofi's key positions

As part of any responsible lobbying approach, it is important for companies to clearly state their position on key issues affecting their business. Sanofi communicates the Group's positions on a range of CSR topics:

- ▼ Access to healthcare
- ▼ Supporting Innovation
- ▼ Intellectual Property Rights
- ▼ Efforts to ensure the quality of medicines and fighting counterfeit drugs
- ▼ Price Setting
- ▼ Compulsory Licensing
- ▼ Patent Pool: A pooling of patents to facilitate voluntary licenses
- ▼ Orphan Drugs
- ▼ Biosimilars
- ▼ Technology and knowledge transfer



- ▼ Use of post-approval real-world data
- ▼ Good Promotional Practices
- ▼ Patients' Rights
- ▼ Clinical Trials
- ▼ Parallel trade
- ▼ Pediatric drugs
- ▼ Human Rights
- ▼ Using animals in Research and Quality Control
- ▼ Biodiversity
- ▼ Climate Change & Health

## Access to healthcare

Access to healthcare should be a right. Access to medicines and to vaccines is an essential element of access to healthcare. The impact of intellectual property on access to medicines and vaccines is at the heart of ongoing debate and, at times, controversy.

Sanofi, as a global and diversified healthcare group, assumes our role as a contributor to public health through a diversified offering of medicines, both innovative and generic, to help meet the needs of patients throughout the world. However, we believe that the primacy often accorded to IP in the context of access to medicines and vaccines does not properly reflect the most significant barriers to access to healthcare, which in most cases are poverty and under-investment in healthcare infrastructure.

Sanofi considers that the goal of meeting the real needs of patients must be the first criterion to assess the validity and pertinence of healthcare policies. Sanofi's belief is that patients should have access to innovations that can improve their health as quickly as possible, and not encounter unjustified administrative obstacles.

Sanofi values the right to health for everyone, as defined in the International Covenant on Economic, Social and Cultural Rights. Furthermore, since 2003, Sanofi has adhered to the Ten Principles of the Global Compact. One symbol of this commitment is our yearly Communication On Progress (COP) to the Secretary of the United Nations, given by Christopher A. Viehbacher, Sanofi CEO, which describes the Group's progress in this area.

For more information:

- [Ethics / Human rights / Policy](#)

For an in-depth explanation of our position and actions on Access to Healthcare, see:

- [\*Position Paper: Innovation, IP rights, access to healthcare and the sustainability of healthcare systems\*](#)
- [\*Access to Healthcare\*](#)

## Supporting Innovation

Sanofi considers that medical innovation can enable medical advances that may lengthen life, reduce disability and improve productivity, and as such must be seen as a valued part of healthcare and economic solutions. Innovation is also critical to helping to address social and health challenges and vital to help answer unmet medical needs. It can also be seen as a driver for economic growth and competition.

Innovation in pharmaceuticals most often occurs as a series of incremental improvements in the safety, efficacy, and utility of drugs that together can have a significant impact on patient care. As a diversified healthcare company, Sanofi also considers that innovation in Animal Health is critically important for society as a whole, because it can impact food production, pet health and control of zoonotic diseases.

Understanding, connecting and communicating with external collaborators are key competencies for innovation, and for this reason a collaborative approach is essential. Sanofi takes an Open Innovation approach, dedicating a substantial amount of resources to identifying third-party innovation that, when combined with Sanofi's own innovation and development expertise, may lead to a new drug or a better drug.

For an in-depth explanation of our position and actions on Supporting Innovation, see:

- [\*Supporting Innovation Position Paper\*](#)
- [\*Patient / Innovation For Patients\*](#)

## Intellectual Property (IP) Rights

A patent is an essential tool for sharing information because new inventions must be shared with both the scientific community and manufacturers as part of the patent process. The World Trade Organization's (WTO's) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of January 1, 1995 is the most complete intellectual property agreement to date. All member countries have to comply with TRIPS as of January 1, 1996 and for those countries on the United Nations list of least-developed countries, the transitional period is eleven years. The

Agreement allows for an extension of the transitional period upon request and for legitimate reasons.

We believe that intellectual property is an important tool to promote innovation by guaranteeing innovators' exclusivity for the time accorded by applicable law and providing security to share information about the innovation. For this reason, Sanofi is fully committed to studying the use of additional mechanisms to support innovation and increase access to medicines.

In reference to compliance with TRIPS (defined above), we support extending the deadline for the eligible least developed countries to comply with the agreement, where appropriate.

Further, in the event of an emergency or a serious public health crisis, and providing the defined procedure is respected, Sanofi considers that intellectual property rights should not become an obstacle to access to medicines or vaccines.

For an in-depth explanation of our position and actions on Intellectual Property and Innovation, see:

- [\*Position Paper: Innovation, IP rights, access to healthcare and the sustainability of healthcare systems\*](#)

## Efforts to ensure the quality of medicines and fighting counterfeit drugs

Sanofi strives to ensure product quality for patients and medical personnel in all countries in which it does business throughout the world.

The Group actively supports public authorities' efforts to guarantee high standards of drug quality and safety and fight counterfeit drugs through the following actions:

- Working closely with local authorities and professional organizations to deliver information and educational program to create awareness and fight against counterfeiting drugs and their potentially serious risk to patients' health.
- Centralizing all suspect drugs and samples from market in our specialized Laboratory.
- Endeavoring to ensure the quality of its medicines, secure the supply chain and pro-actively protect its drugs with innovative solutions to help prevent falsification and fight against counterfeiting
- Reinforcing cooperation with official bodies (international agencies, customs, police...) to support their work in the fight against counterfeiting

- Fostering a dedicated and structured organization involving experts from Security, Legal, Industrial Affairs, Cybercriminality, Communication, Medical and Regulatory departments to coordinate at corporate and local level all activities regarding the fight against Counterfeit medicines

In accordance with this position, it alerts health authorities of the risks of falsified medicines.

For more information:

- [Position Paper: The Group's position](#)

## Price Setting

In countries where price setting is practiced by administrative authorities, the Group would like prices to take into account the need to pursue today's research efforts for the potential benefit of tomorrow's health.

In Europe, where prices are set by authorities in the different countries but products circulate freely, the Group has stated its preference for pharmaceutical companies' freedom to set a single "factory exit" price for Europe with variable national compensation (from one country to another) applied to locally consumed products.

For drugs that are not reimbursed by a public health insurance system, the Group does not have a uniform global strategy. In general, price is largely driven by the nature of each local market. In addition, the Group is implementing the "Next Billion Consumers" program in order to tailor prices and drugs to better suit local income levels and needs consistent with applicable law.

## Compulsory Licensing

Investing in the long-term discovery and development of innovative new medicines is unpredictable and risky, in addition to being expensive. As a general rule, Sanofi opposes governments waiving Intellectual Property (IP) rights because this can undermine the expectation that these rights will help support the scope of investment that drug development requires.

However, Sanofi recognizes that there are legitimate but limited circumstances where a nation may rightfully order a compulsory license. Those circumstances may arise when the IP Right holder is not commercializing the drug and there is a compelling national interest to preserve the

safety and well-being of the nation's citizens. Under such circumstances, the IP Right holder is nevertheless entitled to just compensation in exchange for the taking.

Sanofi strongly opposes the tactics from nations that have recently imposed unilateral concessions from the IP Right holder.

For an in-depth explanation of our position and actions on Intellectual Property and Innovation, see:

- [Position Paper: Innovation, IP rights, access to healthcare and the sustainability of healthcare systems](#)

### Patent Pool: A pooling of patents to facilitate voluntary licenses

The Patent Pool is an initiative launched by UNITAID, a non-governmental organization that works to pool together different antiretroviral patents. The Patent Pool negotiates voluntary licenses so that interested manufacturers can use the patents in exchange for paying royalties. For the moment, this initiative is limited to antiretrovirals.

As Sanofi does not manufacture any medicines to treat HIV / AIDS, it is not active in the UNITAID Patent Pool. Nevertheless, Sanofi follows initiatives that facilitate access to medicines for HIV / AIDS with great interest, as they have often led to improvements in access to healthcare in general.

For an in-depth explanation of our position and actions on Intellectual Property and Innovation, see:

- [Position Paper: Innovation, IP rights, access to healthcare and the sustainability of healthcare systems](#)

### Orphan Drugs

Orphan drug legislation has radically increased the number of innovative therapies in development and positively impacted the lives of patients with life-threatening and serious rare diseases. In addition, the economic and regulatory incentives provided by orphan drug legislation are directly correlated to the exponential growth of the biotechnology industry. Many governments view the biotechnology industry as a priority sector in a knowledge-driven economy.

Sanofi considers that policies in countries should promote product- or system-level innovation and facilitate patient access to treatments for rare diseases, including orphan drugs. The Group

considers that decisions about orphan drugs should be made at the highest level, with appropriate economic and regulatory incentives to promote global access to treatments.

Sanofi believes that the evaluation and review process for orphan drugs must take into consideration the unique attributes of rare diseases and orphan drugs. Dialogue among key stakeholders is also needed to identify Healthcare Technology Assessment (HTA) methods that adequately acknowledge the unique characteristics of rare diseases and orphan drugs. Consensus is needed among stakeholders on overall orphan drug policy objectives and outcomes. A wide range of benefits from orphan policies should be considered. When contemplating developing specific orphan drug legislation, countries should consider the following elements as part of a comprehensive national orphan drug policy:

- **Critical Elements:** Early Screening & Diagnosis; Centers of Excellence (i.e. Mechanism for Patient Access and Treatment); Multi-Stakeholder / Expert Advisory Committee (i.e. Mechanism for Disease Management); Full / Conditional Reimbursement (i.e. Mechanism for Pricing & Reimbursement); Funding / National Centralized Funding
- **Desired Elements:** Definition / Designation; Public Awareness Initiatives; Patient Registries; Expedited Registration; Market Exclusivity; Tax Relief; Development Grants; Clinical Trial Designs Advice; Fee Waivers.

## Biosimilars

- Sanofi supports the establishment and implementation of pathways for the regulation of biosimilars.
- Patient safety must remain the priority in biosimilars regulation. Therefore, approval pathways for biosimilars must include rigorous safety and efficacy standards.
- Legal/regulatory frameworks should take into account the differences between biosimilars and generic drugs.
- Similarity between a biosimilar and the originator product is essential. But approval of a biosimilar must be based on clinical proof of safety and efficacy as well.
- Because all biological substances are unique, biosimilars cannot be identical to their reference product. Therefore, Sanofi believes that biosimilars may not be automatically interchangeable with the reference product.

- To ensure patient safety, a modified naming convention should be used to ensure physicians, patients, and pharmacists can make informed decisions on whether to substitute products. The use of distinctive International Naming Nomenclature (INN) for each product may be necessary to support accurate pharmacovigilance monitoring.
- Biosimilar products should be appropriately labeled to fully inform healthcare providers and patients that the product is a biosimilar, how the biosimilar was compared with the reference product, what clinical data was obtained for the biosimilar, and what the regulatory decision is, if any, regarding substitution of the biosimilar for the reference innovator product.
- While Sanofi supports the establishment and implementation of pathways for the regulation of biosimilars, such policies should not negatively impact existing branded products or current legislation/regulation that rewards innovation.

## Technology and knowledge transfer

According to the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), the protection and enforcement of intellectual property should contribute to the promotion and diffusion of the transfer of technology (TOT). However, TOT is not yet fully implemented by international companies, and thus may create high expectations on the part of developing and emerging countries.

- Sanofi is committed to actively contribute to the transfer of knowledge and technology in developing and emerging countries by encouraging harmonization of practices and quality standards in these countries.
- Sanofi considers that the sharing of expertise through training and employment of local staff contributes to technology transfer, while fostering improvement in patients' health. Sanofi also works with local regulatory authorities and carries out clinical trials in many countries.

For an in-depth explanation of our position and actions on Technology and knowledge transfer, see:

- [Position Paper: Innovation, IP rights, access to healthcare and the sustainability of healthcare systems](#)

## Use of post-approval real-world data

Use of post-approval real-world data to continuously assess drugs is becoming more and more important in the effort to help ensure that the benefit-risk profile of a product is maintained once it is marketed and used in routine practice. Indeed, regulators and payers increasingly ask for data coming from real-world studies to assess drug utilization, real-life safety and effectiveness. Sanofi, a company committed to patients to offer safe and effective drugs, believes that the use of real-world data can bring additional value for the patients.

Internal experts within the company are able to perform real-world studies and answer specific requests from health authorities. They furthermore anticipate these needs.

A board of external international experts in the field of real-world investigations has also been convened and meets on a regular basis to provide guidance and recommendations to the company.

## Good Promotional Practices

In all activities that serve to promote or advertise our products, we are committed to applying high ethical standards. The materials used are intended to provide information that is up-to-date, accurate, objective and is not misleading. Materials also are intended to be sufficiently comprehensive to allow for a proper assessment of the quality of the product and for its proper use, which helps to ensure that all promotional materials and product information are based on scientifically proven results.

We are committed to addressing expectations regarding the transparency of financial support be Sanofi to healthcare professionals and patient groups. In 2011, Sanofi decided to publish the amounts of support provided by the Group in 2010 for patient associations based in Europe, exceeding EFPIA (European federation of Pharmaceutical Industries and Associations) mandatory requirements, and Medical Education Grants in 2010 to patient associations in the US.

In our relationships with healthcare professionals, we are committed to complying with applicable law in both the home country of the healthcare professionals and the host country of the event, conference, congresses and scientific events. We follow rules relating to the distribution, tracking and control of requests for and returns of pharmaceutical product samples.

We also comply with the code of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and with regional and national codes applicable in countries where we promote our products to healthcare professionals.



For more information:

- [Sanofi Code of Ethics](#)

## Patients' Rights

Sanofi considers that meeting patients' needs must be the first criterion to assess the validity and relevance of health policies.

Patients should be able to benefit from innovations that can improve their health as quickly as possible without obstruction by unjustified administrative barriers.

## Clinical Trials

Sanofi supports efforts to improve clinical trial transparency so that potential patients and / or healthy volunteers will be well informed about the trials in which they participate and their rights will be protected. The Group publishes information about our own clinical trials via specialized Internet sites.

Regardless of the country where the Group carries out clinical trials, Sanofi ensures compliance with ethical standards designed to protect those enrolled in the trials.

For more information:

- [en.sanofi.com / RD/ Clinical trials / Our commitments](#)

## Parallel trade

Experience has clearly shown that parallel trade brings very little benefit to patients.

In addition, increasing the number of commercial intermediaries can make it more difficult, and sometimes impossible, to ensure product traceability. This may create patient risk, especially in connection with counterfeit products introduced into commercial channels.

For all these reasons, Sanofi has always expressed very strong reservations about the parallel trade of medicine.

## Pediatric drugs

Sanofi routinely studies the opportunity to develop new pediatric medicines and meets registration agencies' requirements. The Group also applies this approach to drugs for the treatment of diseases in developing countries: for example, we produce a pediatric version of the drug combination artesunate + amodiaquine (ASAQ), launched recently by the Group for the treatment of malaria, a disease that especially affects children.

## Human Rights

By complying with international human rights standards and principles, Sanofi has made a formal commitment to incorporate human rights principles in the Group's operating activities. The Group's Code of Ethics takes as its references the Universal Declaration of Human Rights, the United Nations Global Compact, the Organization for Economic Cooperation and Development directives and the International Labor Organization principles, as well as national laws and regulations. The Group is also committed to the right to health for all, as defined in the International Covenant on Economic, Social and Cultural Rights.

Furthermore, since 2003 Sanofi has complied with the 10 Principles of the United Nations Global Compact. Within the scope of this commitment, each year the Group issues a Communication On Progress (COP), which is signed by Christopher A. Viehbacher, Sanofi CEO, to report on the Group's progress in human rights to the Secretary-General of the United Nations.

For more information:

- [\*Human Rights\*](#)

## Using animals for Research and Quality Control

Sanofi is committed to ensuring that animal studies are only undertaken when alternatives validated by the scientific community and the health authorities do not exist.

When animals are needed for R&D purposes, Sanofi is committed to using the smallest number required and ensuring that each and every animal in our care is treated with due care and respect.

The use of animals in research and for quality control is strictly governed by internal Group procedures compliant with the most stringent regulatory requirements. Sanofi has also implemented internal control systems, such as audits, to ensure the application of these rules. Sanofi endorses research and other activities to reduce, refine or replace animal testing.

Sanofi's objective is to obtain AAALAC international accreditation designed to ensure that the best practices are effective at all Group sites.

For more information:

- [\*Position Paper: Using animals for Research and Quality Control\*](#)

## Biodiversity

In accordance with international standards, Sanofi has established principles aimed at preserving the biodiversity of natural plant and wild animal species for use in research projects to discover new drugs, and ensuring fair distribution and sharing of benefits resulting from the use of this type of resource with the countries where these species are found. These principles also emphasize that the Group endeavors to preserve biodiversity surrounding our sites, particularly those located in sensitive natural areas.

For more information:

- [Biodiversity](#)
- [Position paper On Biodiversity & Biopiracy](#)

## Climate Change & Health

Sanofi is committed to global sustainability and already has taken numerous steps to help reduce its greenhouse gas emissions that could impact climate change.

Potential climate change impacts include acute emergency situations where human lives may be in immediate danger: Sanofi is committed to efforts to engage in emergency provision of drug and vaccines for populations exposed to acute emergency situations.

In addition, the Group has inventoried the diseases that are likely to be impacted by climate change and is preparing, in our fields of expertise, to anticipate their potential health consequences. These include mainly diseases related to increased urbanization (pollution, stress, unbalanced diet, food and water-borne diseases, etc.), and possibly the spread of vector-borne diseases such as malaria and dengue that could expand beyond the areas where they are found currently. Sanofi has a broad portfolio of drugs and vaccines, as well as R&D programs in a variety of fields (infectious diseases, cardiovascular illnesses, mental health diseases, diabetes, cancer, etc.) that could help address some of the potential health problems that may be related to climate change.

For more information:

- [Climate Change and Health Position Paper](#)

## Fighting corruption

### Background

Today organizations are aware of the harmful consequences of corruption on international business transactions and the world economy. Corruption is a deterrent to economic development in general, particularly in emerging countries because it undermines fair competition among economic players and destroys public trust.

Over the past few years, authorities in the United States and in Europe have increased their scrutiny of the healthcare sector. As a consequence, healthcare companies may find themselves particularly vulnerable with regard to specific practices in the industry.

For several years now, Sanofi has implemented appropriate measures and tools to prevent and fight corruption in all countries where the Group does business.

### Solid guidelines

Fighting corruption requires international rules adhered to by as many countries as possible, as well as effective anti-corruption legislation enforced nationally. The adoption of the Organization for Economic Cooperation and Development (OECD) and United Nations (UN) conventions against corruption and national laws with very broad coverage, such as the U.S. Foreign Corrupt Practices Act (FCPA) and the U.K. Bribery Act, contributes to achieving this goal. Fighting corruption also requires multinational companies to play an active role by helping ensure a level playing field.

To ensure ethical conduct, Sanofi adheres to:

#### **The external reference principles of the United Nations Global Compact (Principle 10)**

- [www.unglobalcompact.org / Anticorruption](http://www.unglobalcompact.org/Anticorruption)

#### **The United Nations Convention against Corruption - adopted on 31 October 2003**

- [www.unodc.org / United Nations convention against corruption](http://www.unodc.org/United_Nations_convention_against_corruption)

**The Organization for Economic Cooperation and Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions**

- [www.oecd.org / Convention on Combating Bribery of Foreign Public Officials in International Business Transactions](http://www.oecd.org/Convention%20on%20Combating%20Bribery%20of%20Foreign%20Public%20Officials%20in%20International%20Business%20Transactions)

**Measures adopted in application of the U.S. Sarbanes-Oxley Act (Section 301)**

## Policy

- ▼ Strengthening governance: the Executive Compliance Committee
- ▼ Code of Ethics
- ▼ Anti-corruption Policy
- ▼ Suppliers Code of Conduct

Sanofi is committed to preventing corruption in all countries where we operate. All Group employees have a responsibility to uphold this mission. To help them, the Global Compliance Department provides training and guidance including training on anti-bribery laws, such as the Foreign Corrupt Practices Act and the U.K. Bribery Act, and international conventions such as the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. Furthermore, the Group has launched a process to screen third parties against corruption risks. Third parties now engaged by Sanofi are required to adhere to applicable laws and to the Group's policies when it comes to preventing corruption.

As part of Sanofi's transformation, the Group created an even stronger Compliance function at the corporate, region, country and functional levels and, among other things, by recruiting additional compliance experts.

### Strengthening governance: the Executive Compliance Committee

An Executive Compliance Committee, which is chaired by the CEO, has been created to facilitate and ensure the effectiveness of all aspects of Sanofi's compliance program. The committee plays an executive role to recommend and review the implemented actions to sustain the effectiveness of compliance programs within Group, and to foster a continued commitment to Group values.

Furthermore, Sanofi affiliates are encouraged to establish local compliance committees to oversee compliance with the Group's Code of Ethics, policies and procedures, applicable legal and regulatory requirements, and industry standards. Best practices as well as recommendations for the Model Compliance Committee Charter have been communicated to Group affiliates in all countries.

### Code of Ethics

Fighting corruption is one of the main focuses of the Sanofi Code of Ethics. The Code reaffirms the Group's commitment to fight all forms of corruption – active, passive, direct as well as indirect corruption. Under the Code, the Group must comply with all international and national

anti-corruption laws and regulations such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act. It is paying particular attention to relationships with third parties.

For more informations:

#### **U.S. Foreign Corrupt Practices Act:**

- [www.justice.gov / Anti-Bribery and Books & Records Provisions of The Foreign Corrupt Practices Act](http://www.justice.gov / Anti-Bribery and Books & Records Provisions of The Foreign Corrupt Practices Act)

#### **U.K. Bribery Act:**

- [www.legislation.gov.uk / Bribery Act 2010](http://www.legislation.gov.uk / Bribery Act 2010)

#### **Code of Ethics**

- [Sanofi Code of Ethics](#)

#### **Anti-corruption Policy**

In 2011, Sanofi finalized an anti-corruption policy and made it available to all employees via the Group intranet and the Global Compliance intranet. The policy was also distributed by Compliance Officers worldwide.

In addition, in 2011 a Group policy was developed, in the frame of the transparency initiative, to address financial and non financial interactions between any entity of the Sanofi Group and HealthCare Organizations and Medical or Scientific Associations, in the domain of medical, scientific or educational areas.

Among tools put in place to prevent corruption the Group has also a strong delegation of authority process and group wide procedures on expenditure authorization.

For more information:

 [Sanofi-aventis anti-bribery policy](#) (PDF, 1457Kb)

- [Sanofi Code of Ethics](#)

## Suppliers Code of Conduct

Service providers must adhere to the Suppliers Code of Conduct, which is distributed by the Group's buyers.

 [Sanofi suppliers code of conduct](#) (PDF, 407Kb)

- [Responsible Procurement](#)

 [Code of Ethics "Security in dealing with contractors"](#)

- [Sanofi Code of Ethics](#)



« Ethical values belong to our culture. Acting with integrity is fundamental to our business and it is on this basis that we build our reputation and the public's trust. »

**Dante Beccaria**

Vice-President, Global Compliance Officer



## Actions

- ▼ Developing awareness in-house and implementing training tools
- ▼ Fraud prevention and incident monitoring
- ▼ Due Diligence of Third parties
- ▼ Contributing to cross-industry initiatives
- ▼ Introducing an effective alert system

### Developing awareness in-house and implementing training tools

Having policies, processes and monitoring in place is an important part of any effective compliance program. However, ensuring that people understand the challenges and the issues behind such policies and processes is also essential. Awareness and training not only help people understand what is expected of them; they contribute to making people accountable. As a result, everyone understands their roles and responsibilities.

Prevention of corruption is one of the items of the e-learning module on the Code of Ethics that was rolled out in 2011. In addition, various presentations anti-corruption matters have been made available to all employees via the Global Compliance intranet.

*As from the end of 2010, a worldwide anti-corruption training program with a primary focus on R&D and Medical Affairs employees was launched throughout the Group. This program was based on a “train the trainers” concept with champions who were to be identified primarily in the R&D and Medical Affairs functions in the countries and globally. To date, more than 60 champions from the R&D and Medical Affairs functions but also from other functions at the global level and in the countries have been selected and trained. Champions are asked to cascade what they have learned throughout their own organizations and/or countries, and to adapt and develop processes and controls for preventing corruption risks.*

*Most of the training has been done through face to face meetings but in some countries, like in the US, the program was also rolled out through e-learning platforms. By late 2011, more than 3.600 employees, mostly in the R&D and Medical Affairs functions at global level and in the countries, were trained by the Champions and are expected to carry the anti-corruption message within the Group. Moreover more than 400 employees from Group corporate functions such as Internal Audit, Legal, Industrial Affairs, Security but also from Oncology and Diabetes divisions have been trained on anti-corruption since end of 2010. \**

Ever mindful of the need to expand initiatives to prevent and combat corruption, the Group provided specific presentations in 2010 and 2011 for management committees, regional

operational managers and business sector operational managers. Special presentations were organized in countries such as Ukraine, Greece, Mexico, Brazil, India, China and the Czech Republic.

At Sanofi Pasteur SA, the Sanofi Vaccine division, specific awareness on anti-corruption risks to vaccines commercial operations employees started in 2005, Compliance presentations are regularly made during regional seminars with the Country Managers, Country Regulatory heads, Sales & Marketing representatives and Country Financial Directors.

For more information:

- [Our Vision / Policies & systems / Code of Ethics /training section](#)

In 2010 and 2011, the Group introduced special e-learning training for all affiliate managers, their employees and compliance officers. This e-learning tool is also available via the Global Compliance intranet.

The Global Compliance intranet also features other tools, including short videos covering issues such as fighting corruption, conflicts of interest, and antitrust & competition law. The Global Compliance team and a network of compliance officers in affiliates around the world convey the messages contained in the training tools.

### Fraud prevention and incident monitoring

To increase awareness among Group directors, managers and employees, Sanofi communicates the Group's fraud prevention and incident monitoring program to all affiliate general managers worldwide. Pursuant to section 302 of the Sarbanes-Oxley Act, the Chief Executive Officer, the Executive Vice-President and the Chief Financial Officer are required to perform an evaluation of the adequacy and effectiveness of the Group's control over published financial information and over fraud. To this end, senior management relies on representation letters signed twice a year by local chief executive officers and chief financial officers to demonstrate their commitment to the process and to report fraudulent cases, if any that occurred during that time period. There is no minimum value included in the definition of fraud, and appropriate sanctions are levied in all cases.

### Due Diligence of Third parties

In order to avoid fines, reputational damages and criminal penalties it is crucial to conduct appropriate due diligence review of third parties prior engaging them. In that perspective, Sanofi has decided to put in place a due diligence process on third parties taking into account many factors such as the nature of the business, the local environment, the type of relationship, the

nature and extent of the activities to be performed by the third party for Sanofi. A Group wide process, developed by key functions and business representatives is being implemented in order to conduct appropriate due diligence on third parties.

Moreover, a Sanofi Pasteur International Compliance initiative at the Vaccine headquarters was launched in 2003 with the aim of controlling all relations and payments with third parties with regard to sales and marketing of vaccines to third-parties (e.g. distributors, agents, clients and service providers). This initiative continues through regular monitoring of such relations.

### Contributing to cross-industry initiatives

To make progress in the fight against corruption, an anti-corruption working group was set up by the G20 after the Toronto Summit in June 2010. The group was created to identify priority actions and ensure concerted monitoring of their implementation. Within the framework of the G20 Summit that took place in Cannes (France) in November 2011, the French government, with the support of the OECD and the United Nations Office on Drugs and Crime, organized a conference on good private-sector practices. Held in Paris on 27 and 28 April 2011, the conference encouraged the drafting of an anti-corruption report by the B20 (business organizations of the G20 countries). As a member of the B20, Sanofi was involved in the conference and in drafting the B20 anti-corruption report.

**For more information** about the B20 anti-corruption report:

- [www.b20.fr / Final report with appendices](http://www.b20.fr/Final_report_with_appendices)

Furthermore, Sanofi is willing to contribute to leveling the playing field by supporting international anti-corruption initiatives originating in the private sector, such as those developed by the International Chamber of Commerce (ICC). Among the practical tools proposed by ICC, Sanofi is an active supporter of a training tool known as RESIST (Resisting Extortions and Solicitations in International Transactions). The ICC has contributed to develop this tool in cooperation with the World Economic Forum, the UN Global Compact and Transparency International. It is used to train company employees how to prevent bribes and how to respond in a safe, ethical and efficient way in the event of a bribery attempt. RESIST is based on 21 real-life scenarios of solicitation and extortion demands. Sanofi was involved in the translation of this tool into French and is actively participating in the creation of an e-learning version of RESIST.

**For more information** about RESIST:

- [www.transparency.org / Global priorities / Private sector](http://www.transparency.org/Global_priorities/Private_sector)

## Introducing an effective alert system

If an employee believes in good faith that a rule or one of the principles laid down in the Code of Ethics has been or is about to be violated, they may inform their superior or the Global Compliance Department of any concerns regarding possible illegal practices or ethical violations, while respecting the rules applicable in the country where they live and work.

The Group has a secure alert system to facilitate reporting any failure to comply with laws, regulations or any of the principles established in the Code of Ethics, particularly in terms of financial and accounting standards, internal control, antitrust or competition regulations and fighting corruption.

For more information:

- [\*Our vision / Policies and management systems / management systems / Compliance / Warning system\*](#)

In order for all Sanofi employees to better understand the new Code of Ethics, if possible in their native language, it was translated into many different languages. As of late 2011, the Sanofi Code of Ethics is available in 31 languages. Additional languages will be available in 2012.

For more information:

- [\*Sanofi Code of Ethics\*](#)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Respect for free competition

### Background

Violation of antitrust and competition laws is punishable by fines imposed on the company and on the implicated individuals and may result in damage claims. In certain countries, serious violations such as illegal agreements on price-fixing or on allocating markets with competitors could be punishable by prison sentences for those involved. Problems associated with competition and with antitrust activities may arise both from contacts that Sanofi maintains with our competitors and from our relationships with suppliers and customers. Over the past three years the pharmaceutical sector has been under scrutiny by European Commission. In 2009, following the release of its final report on the pharmaceutical sector enquiry, the European Commission initiated yearly monitoring of pharmaceutical patent settlement agreements between originator companies and generic companies in order to ensure that settlements are not concluded to limit or delay the market entry of generic drugs.

### Policy

**In the Group's contacts with competitors, or "horizontal agreements,"** Sanofi employees may never address the following:

- **Price-fixing:** tariffs, standards, discounts, conditions for promotions and invoicing, margins, reductions, rebates
- **Product information:** marketing projects and strategies
- **Production:** industrial capacity, logistics, product quality
- **Allocation of markets:** by geographical zone, by customer, or by therapeutic area
- **Financial information:** costs of goods and services purchased or products, profits, margins
- **Intention to submit** (or not) a bid in a call for tender
- **Existing agreements or contracts** with a supplier or a customer

**Within the scope of relationships with suppliers as well as customers, or so-called "vertical agreements,"** any practice of a discriminatory nature as well as boycotting are violations of competition rules and antitrust laws in most countries.

In practical terms, this is what Sanofi requires of Group employees:

- To respect legal and regulatory measures, both national and international, concerning the right to free competition
- When attending forums, seminars or any other meetings, to avoid informal contact with competitors in order to avoid discussing subjects that could be likely to violate antitrust laws. If one or more competitors were to raise such a topic, employees are asked to express their reluctance to continue the discussion. They must not hesitate to state their unwillingness to address a specific topic, and bring an end to the conversation.
- To contact their supervisor or the Legal Department if they have questions or doubts.

For more information:

- [Sanofi Code of Ethics](#)

## Actions

### Training and awareness

To raise employees' awareness on free competition matters an ethical moment is available on the Global Compliance intranet.

Competition and antitrust issues may arise from contacts between Sanofi and its competitors, or between Sanofi and its suppliers and customers.

Excerpt from the Sanofi Code of Ethics

## Supply Chain

### Introduction

The Sanofi CSR approach is integrated across our entire supply chain. We carefully monitor not only the quality of raw materials that go into making our products, but the practices of our suppliers. To ensure the safe manufacturing and distribution of our products we establish quality policies and comply with good manufacturing processes. As a global healthcare leader, we make an absolute priority of protecting the health of patients and consumers by contributing to the fight against counterfeit drugs.

We work closely with suppliers to make sure they are aware of the economic, social and environmental standards that are fundamental to our CSR strategy. Around the globe, we take a multi-faceted approach to addressing supplier-related challenges. On a regular basis, we audit our suppliers in all countries and develop long-term contingency plans to ensure the continuity of the Group's activities under all circumstances.

At every step, Sanofi is committed to constantly improving our processes and ensuring the quality of our products, right up to the moment they are dispensed to those who need them.

The diagram below presents an overview of three core areas in our supply chain management.

Sanofi is a member of the **Pharmaceutical Supply Chain Initiative (PSCI)**, which sets standards for suppliers in the areas of ethics, labor, health and safety, and the environment.

For more information:

- [www.pharmaceuticalsupplychain.org](http://www.pharmaceuticalsupplychain.org)
- [Ethics / Business Ethics / Responsible Procurement](#)

Sanofi welcomes the **International Conference on Harmonization (ICH)** guidance for the achievement of safe, effective, and high quality medicines.

For more information:

- [www.ich.org](http://www.ich.org)
- [Patient / Product Risk Management / Global Quality](#)





| Suppliers   | Manufacturing and Distributing   | Pharmacies, Patients and Prescribers   |
|---|--|--|
| <ul style="list-style-type: none"> <li>• Improve awareness among suppliers of the Group's CSR principles so they are compliant with fundamental social, environmental and ethical principles</li> <li>• Train Sanofi buyers about responsible procurement through our supplier relationship charter</li> <li>• Address full range of procurement risks and guarantee risk assessment and mitigation. Value of goods and services purchased in 2011: €12.8 billion</li> <li>• Evaluate suppliers' practices and identify "high-risk" categories of suppliers: 2,073 suppliers were assessed in 2011, of which 51% were high-risk</li> <li>• Select environmentally friendly goods and services through approved suppliers</li> </ul> | <ul style="list-style-type: none"> <li>• Establish quality policies and guidelines to ensure our processes comply with good manufacturing practices and applicable mandatory requirements</li> <li>• Set-up and maintain a quality system to ensure the highest quality of drugs manufacturing and distribution</li> <li>• Use Supply Chain indicators to monitor quality of service, assess performance and enhance our internal approach</li> <li>• Develop business continuity plans and back-up solutions for unexpected events; determine production priorities for life-saving drugs</li> <li>• Limit environmental impact by applying internal standards compliant with regulations as well as development of alternative sources of energy and modes of transport</li> </ul> | <ul style="list-style-type: none"> <li>• Take a coordinated and structured approach to combating counterfeit drugs</li> <li>• Safeguard the quality of our medicines and use cutting-edge technology to protect patients' safety</li> <li>• Cooperate with national and international anti-counterfeit organizations; promote investigations and legal actions</li> <li>• Develop awareness about counterfeit products and educate the public</li> <li>• Apply strict internal and external responsible marketing codes in providing fair and balanced product information</li> <li>• Actively support unused and expired medicines collection programs for proper disposal</li> </ul> |



For more information:

## Suppliers

- [Ethics / Business Ethics / Responsible procurement](#)



[Suppliers Code of Conduct](#) (PDF, 578Kb)

## Manufacturing and Distributing

- [Patient / Product risk management / Global quality](#)
- [Patient / Product risk management / Continuity of activities and supplies](#)
- [Planet / Energy and carbon footprint](#)

## Pharmacies, Patients and Consumers

- [Patient / Product risk management / The fight against counterfeit drugs](#)
- [Ethics / Business Ethics / Responsible marketing](#)
- [Planet / Pharmaceuticals in the environment](#)
- [Sanofi Code of Ethics](#)

## Responsible marketing

Sanofi is committed to promoting products in a manner that is ethical, objective, balanced and reliable when communicating information about our medicines and vaccines. Stakeholders today are increasingly focusing attention on pharmaceutical companies' marketing practices.

## General policy

We are committed to follow applicable legislation regarding the marketing of our medicines and vaccines, and to adhere to all relevant rules in all countries.

Stakeholders expect a clear commitment from pharmaceutical companies to greater transparency, ethics and standards in marketing practices. Regardless of the promotional materials used, the Group must provide all necessary information to Health Care Professionals about the proper use of a medicine so they can make an informed decision about the product's risk / benefit ratio. Similarly, the patient must receive all useful information to ensure the proper use of a non-prescription drug.

▼ Stakeholders' expectations

▼ Guidelines and procedures

▼ External and internal codes to which the Group adheres

### Stakeholders' expectations

Marketing practices in the healthcare industry are the focus of growing attention from stakeholders today, especially patient organizations and consumer advocacy groups, which have called for concerted action by pharmaceutical companies, government, institutions and consumer advocacy groups to:

- Develop guidelines and common indicators for CSR reporting on responsible pharmaceutical promotion
- Ensure that industry complies with existing CSR codes, standards and regulations
- Strengthen existing codes to provide a stricter framework for the promotion of medicines via the Internet, interactions with pharmaceutical companies and patient organizations, and disease awareness campaigns
- Suggest alternatives to self-regulation alone
- Promote greater transparency in relationships between pharmaceutical companies and healthcare professionals

## Guidelines and procedures

In order to market medicines internationally, information must be standardized, and the messages conveyed must comply with strict rules.

As a global company, Sanofi adheres to the codes governing our industry in Europe (EFPIA), the United States (PhRMA) and worldwide (IFPMA). The internal codes drawn up by the Group to oversee its promotional activities are based on these guidelines and refer to them explicitly. In some cases, however, it is important to take into account specific cultural environments as well as medical care standards and regulations that may vary from one country to another.

Procedures and directives that comply with international standards have been established by the Sanofi Global Medical Affairs Department:

- For promotional materials: the principles of Good Promotional Practices, guidelines concerning gifts and promotional items of medical use, procedures for the review of promotional materials, etc.
- For websites: the validation procedure used by the Internet Committee for all websites developed by the Group

## External and internal codes to which the Group adheres

Pharmaceutical product promotion is governed by national regulations and by codes developed collectively by pharmaceutical companies.

## EXTERNAL CODES

- WHO rules
- EFPIA Code
- IFPMA Code
- National codes ( e.g. France, United States, Germany, UK, Japan ... )

## INTERNAL CODES

### PRINCIPLES OF GOOD PROMOTIONAL PRACTICES

- Compliance with the principles of truthfulness and honesty in the promotion of medicinal products
- Compliance with the Code of Ethics on Good Commercial Practices

### PROMOTIONAL MEDIA HANDBOOK

- Primary rules to apply in order to respect the principles of Good Promotional Practices
- Covers promotional materials, congresses/seminars, medical sales calls and follow-up tests/post-marketing studies

### COMMUNICATIONS GOVERNING CLINICAL STUDIES

- Respect study protocol
- Respect statistical findings
- Primary rules depend on who will receive information

### AFFILIATES' CODES AND CHARTERS

- Framework more strict for certain subjects
- The most restrictive code takes precedence

For more information

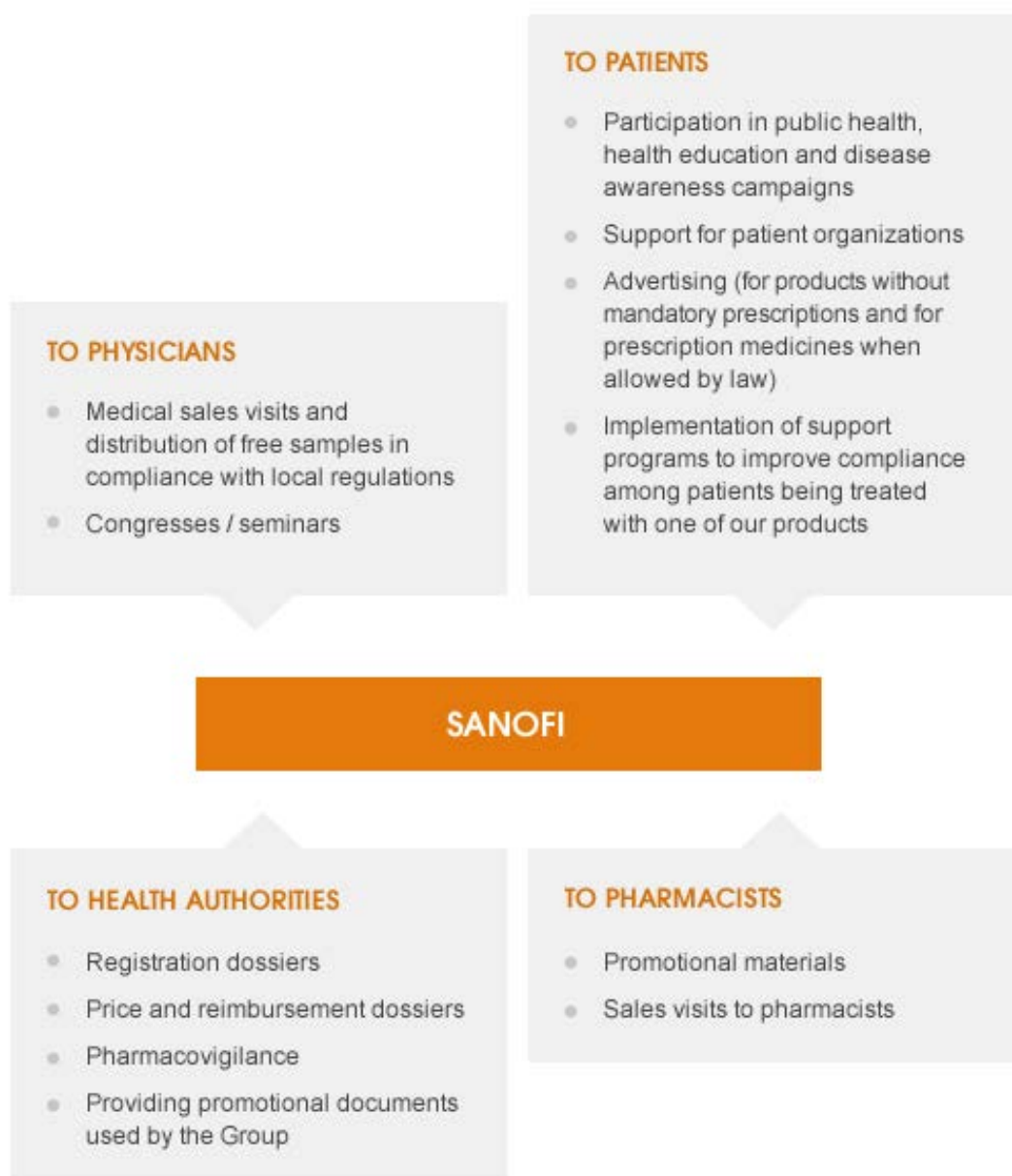
- [\*Sanofi Code of Ethics\*](#)
- [\*EFPIA Code\*](#)
- [\*IFPMA Code of Practice\*](#)
- [\*Directive 2001/83/EC of the European Parliament\*](#)

## Pharmaceutical marketing practices

### Background

Sanofi is responsible for ensuring that the message conveyed by medical sales representatives is fair, balanced, accurate, and not misleading in any way. The information provided by representatives must be fair and ethical, and it must comply with regulatory requirements and in-house conduct standards concerning the promotion of medicines. Practices during pharmaceutical sales visits and the approach taken by medical sales representatives are monitored and evaluated on a regular basis.

How Sanofi communicates about its products:



### For more information

- [Sanofi Code of Ethics](#)
- [EFPIA Code](#)
- [IFPMA Code of Practice](#)
- [Directive 2001/83/EC of the European Parliament](#)

## Policy

Sanofi adheres to the codes of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Group explicitly refers to these codes in its internal codes. Specifically,

The Group is committed to:

- Providing ongoing training for medical sales representatives
- Applying the highest ethical standards to promotional materials used by the Group
- Providing up-to-date, accurate, objective information this is not misleading
- Distributing materials that are sufficiently comprehensive to allow for a proper assessment of the quality of the product and for its proper use
- Ensuring that all promotional materials and product information are based on scientifically proven results
- Meeting stakeholders' expectations regarding the transparency of relationships between Sanofi and healthcare professionals, patient groups, suppliers and customers

A new “good practice” directive relating to scientific information and marketing

In 2011, Sanofi created an internal directive in connection with good practices when it comes to scientific information and marketing. This was the first time common requirements have been provided on investigational medicinal products, vaccines, medical devices, cosmetics and nutraceuticals, applying to scientific information (promotional and non-promotional information; inquiries about medical information; complaints, gifts & other items, patient support programs, samples and hospitality). This directive is endorsed by leadership of global functions of Sanofi including Medical Operations, Quality Systems, Quality Operations, Clinical and Medical Quality as well as Global Quality.

## Standardizing medical and scientific publications

Sanofi is committed to publishing the results of clinical studies and of scientific work on medicinal products and devices conducted by or on behalf of the company, with the highest



standards of quality and transparency, and respecting the editorial independence of external authors and institutions. All publications, whether presented at congresses or published in medical journals, must conform to internationally recognized requirements such as developed by the International Committee of Medical Journal Editors and by the International Society for Medical Publication Professionals, and must be aligned with global and local industry commitments.

Company wide procedures were developed and made available in 2012, to ensure that these standards are observed throughout the company. They set global rules on topics ranging from authorship qualifications to review and validation processes, protection of patients' privacy and of intellectual property, and sharing of clinical trial data with study investigators.

Accordingly, a new companywide medical and scientific publication review tool, named Clear, has been developed. It was rolled out internationally in late 2011 to most company entities, and will be distributed on a larger scale in 2012.

## Actions

Sanofi's Code of Ethics contains a good promotional practices section in order to ensure compliance with the highest ethical standards throughout the Group.

To access the section on good promotional practices in Sanofi's Code of Ethics:

- [Sanofi Code of Ethics](#)

Furthermore, Sanofi implements a wide range of actions to ensure compliance with good promotional practices:

- ▼ Monitoring promotional documents
- ▼ Websites for healthcare professionals and patients
- ▼ Auditing affiliates
- ▼ Using an internal warning system
- ▼ Addressing complaints
- ▼ Evaluating responsible marketing trends
- ▼ Initiatives to understand the needs of customers in a changing healthcare environment
- ▼ Harmonizing fees paid to healthcare professionals (HCPs) worldwide

### Monitoring promotional documents

Global Medical Affairs reviews a sample of promotional materials developed locally. The purpose of this review is to:

- Assess the quality and volume of promotional materials produced by affiliates
- Make recommendations for materials to be developed in the future
- Request corrective measures to be taken, if necessary
- Collaborate with the Quality Department for audits of affiliates

In 2011 a new worldwide process was established for reviewing promotional materials. Affiliates are required to complete a template every two months on the promotional material produced at the local level. Following a risk analysis performed on given criteria, Medical Information Compliance (in Global Medical Operations) identifies around 10% of the promotional material the affiliates need to submit for global review.

Following this review, precise feedback and recommendations are provided with information on key promotional principles. When a significant non-compliance case is observed, it could lead to withdrawal of a promotional material. In 2011, affiliates produced more than 30,000 promotional materials and one internal withdrawal was requested. An increase in the number of promotional materials produced is due to various acquisitions.

**For more Information:** Our innovations 2011 acquisitions and partnerships

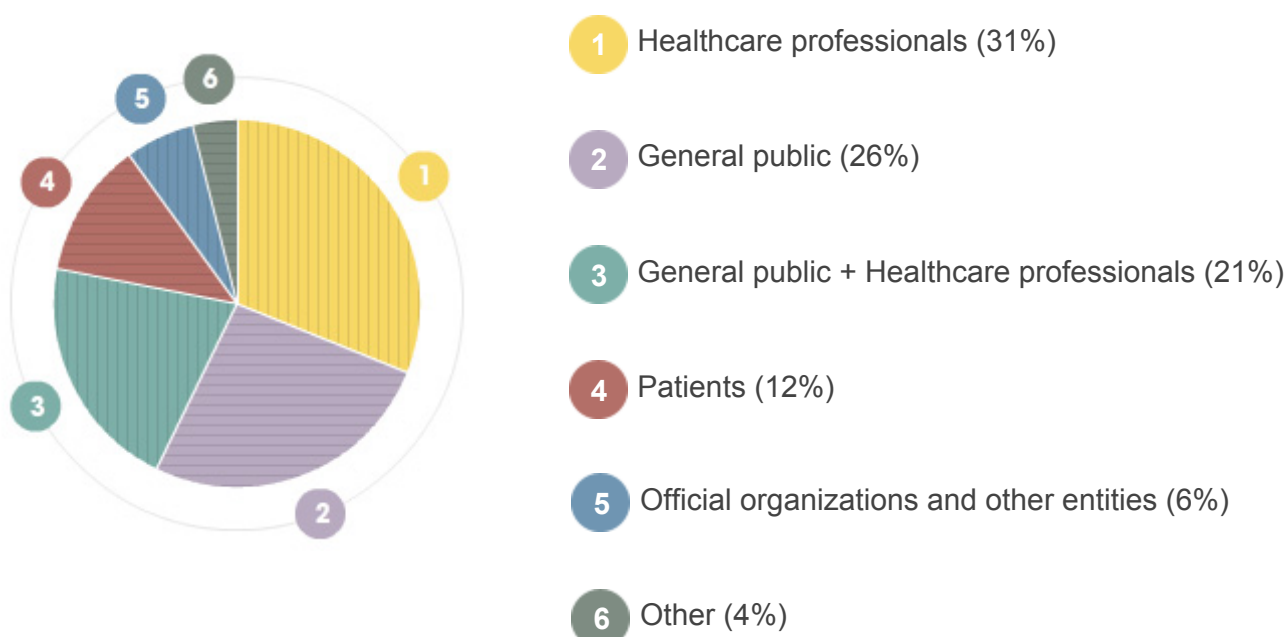
- *Innovative acquisitions partnerships and other business ventures*

#### Websites for healthcare professionals and patients

Sanofi sets up websites to provide information regarding disease prevention and information on treatments to healthcare professionals and patients. These websites are subject to internal control.

The Internet Validation Committee, which is made up of representatives from a wide range of functions (Medical Affairs, Legal Affairs, Communications, Pharmaceutical Customer Solutions, IT, etc.) validates the launch of every internet website and social media project, in order to ensure that internet rules are respected.

By late 2011, the Internet Validation Committee had reviewed 161 new websites. In addition, a total of 88 Web 2.0 projects were reviewed in 2011.



## Auditing affiliates

Within the scope of audits, the Group conducts targeted audit of the affiliates' compliance with the approval procedures for promotional materials, as well as its adherence to Sanofi codes and national regulations concerning authorized promotional material content. This type of audit may cover visual presentations and displays, brochures, websites, promotional items for medical use, etc.

In addition, as part of the global audit plan, the Internal Audit Department reviews the compliance and effectiveness of processes in connection with commercial, promotional and marketing activities in all countries where the Group operates. If any deficiencies are observed, it recommends corrective and/or preventive measures and follow-up their implementation. In 2011, 30 internal audits focused on these activities.

## Using an internal warning system

Sanofi has implemented an internal warning system so that employees may report any potential inconsistencies between practices in the field and the Group's Code of Ethics. Employees may also contact the Human Resources department directly. The Compliance Officer at the affected affiliate investigates to determine whether allegations are well founded, and then communicates this information to the Group Compliance Department. Confirmed violations give rise to disciplinary measures.

## Addressing complaints

A current project addressing handling of complaints about promotional activities (both global and local activities) will release its findings in early 2012. Complaints about promotional activities provide a critical indicator for medical information compliance. Medical Information Compliance manages and tracks complaints generated by or against Sanofi entities, and a database centralizes the information received from the affiliates. To improve the process, a standard operating procedure (SOP) is in preparation to ensure that all complaints are managed and tracked according to all applicable international principles and Sanofi standards.

## Evaluating responsible marketing trends

In 2011, integrated Pharmaceutical Customer Solutions (iPCS) organized special meetings to collect ideas from leading companies about ways to identify key marketing trends. Members of Sanofi marketing teams were involved in a think-tank with other best-in-class companies to develop key questions that help marketers evaluate of the whether their offers comply with responsible marketing practices. This initiative will be pursued in 2012.

## Initiatives to understand the needs of customers in a changing healthcare environment

In an effort to strengthen internal understanding of key healthcare systems and megatrends, a new educational initiative was introduced in 2011 by the Market Access and Pricing Strategies Department, with the aim of implementing the deliverables in 2012.

This will be accomplished through the creation of a repository capable of tracking, predictive modeling and signaling leading healthcare reform indicators and trend breaks and the implications for market access and pricing.

Moreover, Sanofi is carrying out studies in real world settings to support our local and global patient-centric strategies. Real life studies allow better understanding of the needs of patients and physicians and the way medicines are actually used. This will help Sanofi to propose more relevant patient and disease management strategies.

## Harmonizing fees paid to healthcare professionals (HCPs) worldwide

Sanofi may enter into an arrangement to compensate healthcare professionals who provide meaningful services for which Sanofi has a legitimate business need. In order to ensure consistency across the Group, and because different Sanofi entities may work with the same individual, and in order to be fully compliant with applicable laws and regulations, Sanofi adopts a common methodology for compensating all HCPs we engage. Additionally, HCPs must be compensated at the fair market value applicable in their country of practice. Sanofi has defined a single methodology to be applied each time we work with a HCP.

## Training for medical sales representatives

### Background and Policy

Medical sales representatives must have a sound understanding of the characteristics of the products they promote, as well as their environment, in the broad sense. New employee training is provided to medical sales representatives when they first join the Group. In addition, they receive ongoing training and undergo reviews to test their knowledge.

In France, the Public Health Code regulates promotional practices during pharmaceutical sales visits to physicians.

In 2004, within the framework of the reform of the national health insurance scheme, the French Pharmaceutical Companies Association (LEEM) and the Economics Committee for Health Products (CEPS) signed the Charter of Ethics for Medical Sales Visits. This Charter sets out and strengthens the role of pharmaceutical sales visits in the proper use of drugs and the quality of information provided to prescribing physicians.

In 2006, the French National Authority for Health published guidelines concerning the certification of visits by medical sales representatives. These guidelines reflect the Charter of Ethics for Medical Sales Visits' requirements and criteria, which can be audited. The scope of this document, which originally only covered the activity of pharmaceutical sales calls to physicians and specialists whose fees are reimbursed by the French healthcare system, was expanded in July 2009 to cover the pharmaceutical sales calls to hospitals. The guidelines concern all medical sales call activities, whether it involves face-to-face visits or contact by other means; it is applicable to all operating pharmaceutical companies that are signatories to a CEPS agreement.

Since February 2007, Sanofi has been certified by AFNOR, the French Standards Association for the quality approach in managing medical sales visits. The certification covers hospital sales calls since 2010. There is a certification audit conducted every year.

Certification indicates official recognition for the quality of the management of the sales representatives and the information provided during medical sales representatives' visits, which comply with standards of ethics and professional conduct. This level of quality provides an additional basis for our customers' trust.

#### For more information:

- [Consult the Charter of Ethics for Medical Sales Calls](#) (in French)
- [AFNOR's website](#)



## Actions

To support our new sales representatives in providing quality information to healthcare professionals, a wide range of actions were put in place in 2011. Additionally, ongoing training is provided to ensure that our sales representatives stay abreast of product information as well as the rules and regulations of ethical behavior in working with healthcare professionals.

- ▼ Product training for newly hired medical sales executives
- ▼ Improved continuous training
- ▼ Training about good promotional practices
- ▼ Evaluating pharmaceutical sales visit presentations

### Product training for newly hired medical sales executives

When new medical sales representatives join Sanofi, they are trained in science and in the products that they need to be familiar with for their professional activity. This training has three goals:

- To enable new medical sales representatives to acquire knowledge about our products
- To adapt medical sales representatives' knowledge to their product portfolio (e.g., for new products or changes in their workload)
- To teach medical sales representatives about new developments concerning the products they promote.

Training materials are adapted to participants' needs. Specific training is offered about traditional products, as well as consumer healthcare and generic products. Training methods vary and may involve face-to-face sessions, printed documents and remote learning.

Following training, an assessment is carried out to evaluate participants' knowledge about basic product information.

This evaluation consists of a questionnaire, made available one to two months after the end of training, to be completed on-line at any point during a three-week period of time. The questionnaire includes randomly selected questions about important basic product information



covered during each product training session. Participants must answer at least 70% of questions correctly. If their score is below 70%, the questionnaire is made available again two weeks after the first evaluation, to be completed at any time during a two-week period of time. If the minimum score is not obtained the second time, personalized support is provided.

#### Improved continuous training

All members of the sales force must remain up to date on essential medical, scientific and product information. Continuous training is essential for medical sales representatives in order to:

- Give them the necessary knowledge about basic product information, which will be the basis of evaluation
- Ensure that all promotional activities are in full compliance with all applicable rules
- Maintain quality and high standards

Various types of training are offered to reach these goals: printed documents, continuing education, classroom training and other high tech means. Many projects are underway to help further enhance training:

- Training using printed documents, already widely used, will continue to be developed.
- Continuous training may be offered via remote training methods, for example through virtual classes. Presentations by leaders and / or experts can be used to provide up-to-date information on a given disease or other aspects of their area of specialization.
- The Group also plans to continue classroom training.
- New means of information, such as podcasts, will be made available.

#### Training about good promotional practices

The quality and ethics of medical presentations are key challenges. As such, Sanofi focuses on ensuring that medical sales presentations will be fair, accurate and comprehensive, and not misleading in any way. This is accomplished by providing training for medical sales representatives with respect to products, diseases, marketing tools and pharmacovigilance. To a greater extent, affiliates are increasingly testing the knowledge level of their medical sales representatives on a regular basis.

## Evaluating pharmaceutical sales visit presentations

Presentations of medical sales representatives are evaluated on a regular basis to guarantee their quality.

Meetings for medical sales representatives are organized approximately twice a year in France to present the promotional materials for use during sales visits to healthcare professionals. At each of these meetings, evaluations are carried out to guarantee the scientific and regulatory quality of information and review the presentations delivered by medical sales representatives.

The following ratings may be assigned: "compliant as is," "compliant with revisions," or "non-compliant." Sales representatives' presentations are corrected as needed during the meeting. Adjustments may be made to ensure compliance with the information contained in the Summary of Product Characteristics (SPCs), with recommendations established by official organizations (such as the Transparency Committee and the French National Health Authority), and to verify the fairness and objectivity of the presentation. Good practices for medical sales representatives are also reviewed (for example, when providing prescribing information and recommendations from the Transparency Committee concerning products presented during the visit). Additional corrective actions, both individual and collective, may also be taken with respect to specific training for medical sales representatives, clarifications and new information for promotional materials, the creation of new documents, etc.

In 2011, these evaluations were performed during seminars for medical sales representatives and during dedicated training sessions when they were assigned new products.

In 2011 in France, a total of **1,090** oral medical sales presentations were evaluated.

The results of the evaluation were as follows:

Compliant as is: **863**, representing **79%** of the presentations evaluated

Compliant with revisions: **227**, representing **21%** of the presentations evaluated

Since the Group began validating presentations in 2006, no presentations have received a "non-compliant" rating.

## Distribution of samples

### Background and policy

The distribution of free samples is part of pharmaceutical product promotion. Samples must always be distributed in compliance with local regulations and the rules defined by the International Federation of Pharmaceutical Industries and Associations (IFPMA).

Sanofi adheres strictly to the IFPMA Code concerning the promotion of pharmaceutical products and complies with local regulations. These documents define the rules that apply to the distribution of samples. The Group's Principles of Good Promotional Practices outlines these rules.

Sanofi also applies the EFPIA Leadership Statement on Ethical Practices, which recommends that pharmaceutical companies in Europe limit the number of samples distributed to healthcare professionals in accordance with the European Directive.

### Actions

Subsidiaries are audited on a regular basis to ensure compliance with rules governing sample distribution. The Quality and Compliance Department of Regulatory Affairs is responsible for these audits. In 2011, 20 affiliate system audits including MA scope was performed.

The outcome of audits is contained in a report that may be consulted by Group departments in charge of ensuring compliance with rules concerning promotional practices and training for teams in the field.

By performing these checks, Sanofi wishes to ensure no samples are distributed without a prior request from physicians.

## Conferences and physicians' meetings

### Background

Conferences and physicians' meetings are privileged forums where pharmaceutical companies can communicate the latest scientific data about their products. These events must comply with a number of regulations to which Sanofi adheres.

As a leader in the pharmaceutical industry, Sanofi has a constant supply of new information about cutting-edge pharmaceutical products. Consequently, the Group is especially well suited to act as a collaborator with professional societies that organize international congresses. Conferences and physicians' meetings must comply with the general principles of the pharmaceutical industry and the local legislation and regulations in place. As a result, measures must be taken to ensure that local regulations are applied. This means having sound knowledge, in advance, of specific aspects of local regulations and having close ties with the senior management of the affiliate where the congress is being held.

#### For more information:

- [Code of Pharmaceutical Marketing Practices on the IFPMA website](#)

### Policy

Sanofi is committed to ensuring that all the Group's affiliates respect the rules of good conduct when it comes to the organization of physicians' meetings.

All organized events – medical conferences, international conventions, targeted meetings and medical training – must comply with numerous external rules that govern the relationship between the pharmaceutical industry and healthcare professionals: IFPMA, EFPIA and PhRMA codes, as well as local legislation in the countries where the events are held.

The comprehensive regulatory framework defines the conditions that determine, for example, whether a pharmaceutical company may cover travel expenses for healthcare professionals (travel conditions and type of hospitality, hotels, etc.) as well as congress registration fees.

The Medical Information Compliance Department ensures that all documents used during congresses and satellite symposia comply with local regulations.

Affiliates are also consistently consulted when congresses take place in their country.

## Actions

- ▼ Participating in scientific events
- ▼ Developing the Group's "Green Attitude"
- ▼ Updating hospitality guidelines

### Participating in scientific events

Scientific events organized or sponsored by Sanofi in 2011 fall into three categories:

- Conferences and international conventions that may bring together healthcare professionals, competitors in the pharmaceutical industry and a wide range of organizations. The overall objective is to promote knowledge-sharing and exchange.
- Targeted meetings organized entirely by Sanofi that are specifically designed to take stock of the Group's scientific projects – both current and future. They may also focus on new developments in a given therapeutic area. Participants at this type of meeting may include Sanofi employees, recognized scientific experts from outside the Group and healthcare professionals.
- Sanofi may engage with Healthcare Organizations and Medical/Scientific Associations in order to support independent medical educational program or activity, as well for improving the scientific knowledge. This support can be provided through a grant or a sponsorship, according to the expected tangible return. It is thus of primary importance to clearly differentiate grants from sponsorships, and to describe the related processes for providing a support in these both cases. A document is being written to serve this purpose. It will apply to all entity of the Sanofi Group; its release is planned Q1 2012.

Certain meetings may be accredited by ad hoc organizations, such as the American Academy of Continuing Medical Education (AACME) in the United States and the European Accreditation Council for Continuing Medical Education (EACCME) in Europe. In this case, training is officially recognized as continuing medical education for healthcare professionals who attend the meetings.

## Developing the Group's "Green Attitude"

Sanofi is dedicated to fostering eco-responsible behavior for the conferences and events at which the Group participates.

The Group established a Green Meeting Charter in 2010. The charter lists ten key points to be used whenever the Group organizes events, in a variety of areas including: transportation, using environmentally-friendly materials, communication tools, accommodations, etc.

For more information:

 [Sanofi-aventis Green Meeting Charter](#) (PDF, 93Kb)

To support employees in meeting the goals of this charter, a Carbon Foot Print Calculator was launched. Since its launch, improvements were made in late 2011 in four pilot countries and in the Meetings & Events Department of integrated Pharmaceutical Customer Solutions (iPCS) and Intercontinental Region (ITC). It will be rolled out across the entire Group in early 2012.

- [Planet / Climate change and energy / Green Meetings Section](#)

## Updating hospitality guidelines

Sanofi has updated in 2011 hospitality rules when interacting with healthcare professionals in the context of a scientific event and has produced a related e-learning which is available for all employees interacting with healthcare professionals.

Sanofi is committed to conducting its business in accordance with the highest ethical standards, national and international codes of practice applicable to pharmaceutical industries, as well as with all applicable laws and regulations, including but not limited to anti-corruption laws.

Beyond the compliance with those standards and rules, Sanofi does expect that, in a changing environment, this commitment will allow us to build sustainable interactions with healthcare professionals worldwide. For that purpose, Sanofi has updated the leaflet to be distributed to each HCPs we invite, and which describe Sanofi Hospitality Rules for HCPs. This leaflet is available in English, but some affiliates have already translated it in local language.

For more information:

 [Hospitality Rules for Healthcare Professionals](#) (PDF, 485Kb)

## Protection of Personal Data

### Background and policy

Personal data include information that makes it possible to identify an individual. Due to the widespread use of information technology today, protecting these data is a CSR issue.

Given the rise in the international transfer of personal data, it has become essential to take efforts to help protect these data in order to help guarantee fundamental liberties, especially the right to privacy, which is an integral part of Human Rights.

### Respecting the regulatory framework

In the countries where Sanofi operates, the Group respects local legislation and regulation governing the processing of personal data. Where no laws exist, the Group provides a strong level of protection as set out in the Sanofi Personal Data Protection Charter. Such legislation is designed to protect the right to privacy.

#### For more information:

- World map of countries that have adopted personal data protection laws:
  - [www.privacyinternational.org](http://www.privacyinternational.org) / *Global data protection map*
- European Directive of 24 October 1995:
  - [eur-lex.europa.eu](http://eur-lex.europa.eu) / *Directive 2001/83/EC of the European Parliament and of the Council*
- French national data protection authority (CNIL), which is in charge of ensuring respect for the French law on Data Processing, Data Files and Individual Liberties:
  - [www.cnil.fr](http://www.cnil.fr) / *english*

### What is at stake

Recent serious privacy incidents, such as illegal access to personal data through the Internet (data breaches), have increased public awareness and concern regarding how companies are handling personal information. As a consequence, more and more companies are finding they need to reinforce their privacy programs and security processes. Indeed, clear and well-defined

processes are key organizational elements helping to design a privacy program. Strong privacy practices contribute to a company's reputation and brand recognition.

All Sanofi employees, and all third parties with whom Sanofi has dealings (patients enrolled in clinical trials, healthcare professionals, contractors, scientists, etc.), are entitled to their privacy. Sanofi is committed to taking appropriate measures designed to help protect their personal data. In addition, the Sanofi Code of Ethics states that, personal data protection gives individuals whose data are held the right to control the collection, processing, use, disclosure and storage of their data. Sanofi makes every effort to ensure that all people whose data are collected are informed of this fact.

### **Concerning data for patients involved in clinical and pharmacovigilance trials**

These data consist of information about individuals who receive our treatments (during clinical trials, genetic studies, epidemiological and pharmacovigilance studies, etc.).

Patients' personal data include information that is necessary to conduct the studies (for example: age, gender, medical history, phenotype (set of observable characteristics such as anatomy, morphology), genotype (gene composition), etc. For processing, a distinction is made between two types of information: data used for clinical development research and data used for other types of research (fundamental research, for example).

At Sanofi, informed consent is required each time a patient participates in a clinical trial. Informed consent ensures both respect for the free participation in the study and for patients' right to privacy and data protection consistent with the requirements of applicable law. No consent is required for adverse event cases reporting (pharmacovigilance), but the person who reports the case, most often the healthcare professional, informs the patient of the transfer of non-identifiable health data relating to him or her; this transfer is restricted to pharmacovigilance purposes and to the market authorization holder and health authorities in charge of pharmacovigilance.



## About informed consent

Informed consent is required to make the processing of personal health data lawful. Thus, informed consent is mandatory in all studies sponsored by Sanofi that requires the collection or use of individual patients' health data.

### Informed consent for clinical trials

Informed consent helps make it possible:

- For individuals to decide whether or not to pursue participation in a trial, after having received all information related to the trial's purpose, procedures, benefits, risks, potential discomfort, and precautions to be taken. There is no obligation for an individual to participate in a trial and patients who are enrolled can withdraw from the study at any time. Individuals to whom the participation in a trial is offered and who decline to participate or patients who withdraw from the trial may pursue alternative treatment procedures where appropriate and in consultation with their medical professional.
- Help protect each individual's right to privacy by making sure that personal data are used for legitimate purposes consistent with applicable law and that such utilization is clearly pre-defined.
- Support the protection of personal data by protecting transparency and fairness as well as security and confidentiality during personal data processing (making sure that measures are taken to help prevent fortuitous or illicit destruction, accidental loss, modification, disclosure and unauthorized access).

For more information:

- [Clinical Trials](#)

## In the event of human biological sample collection or biobank storage

A biobank is a type of biorepository, which uses a cryogenic storage facility to archive human biological samples for use in research, particularly genomics research.

The human samples collected in the course of a trial are used to conduct the planned experiments only. They are retained only for the time necessary to conduct these experiments or to comply with retention periods imposed by applicable regulations.

Where specified by applicable law, human biological samples retained for further research purposes can only be kept if the patient has given explicit consent for this additional purpose. Genetic analysis will only be run on samples for which the patient has given explicit consent relative to this use.

## In case of research requiring human fetal tissues or human stem cells

The use of fetal tissues or stem cells extracted from humans is strictly regulated in most countries. The Sanofi Bioethics Committee determines the rules governing the use of this material and oversees such use.

In some jurisdictions, fetal tissue collection requires the prior consent of the mother and the father, when known, except when umbilical cord blood is collected, in which case the consent of the mother is sufficient.

Embryonic stem cell collection is strictly regulated regardless of the country in which research will be conducted. In France, pharmaceutical companies or public laboratories may not obtain embryonic stem cells directly: the Agence de la Biomédecine decides on a case-by-case basis to grant exemptions to the legal ban on using embryonic stem cells and to provide anonymous samples based on a request sent by the company. This request contains a scientific rationale establishing in what way the transfer of these embryonic samples is necessary for a specific research program, and why no other biological sample is usable for this kind of research. Regardless of the type of sample collected and potentially stored in Sanofi's Biorepository, the Group tracks the storage, use and disposal of samples and must submit a report to the health authorities about research performed on these samples.

The creation of a biorepository must also be registered with the health authorities.

## Actions

To promote personal data protection within the Group, Sanofi implements many different initiatives:

- ▼ Defining rules at Group level
- ▼ Developing training modules
- ▼ A data security awareness campaign for employees
- ▼ Organizing the approach

In 2011, nearly 90,000 employees were targeted by awareness-raising initiatives focused on data security

### Defining rules at Group level

Sanofi's approach is based on the Code of Ethics, the Group's Personal Data Protection Charter and the Binding Corporate Rules (BCR).

### The Code of Ethics

Sanofi's Code of Ethics contains a chapter that addresses the respect of private life and personal data protection.

In the Code of Ethics, which is available to all employees and to third parties working with the Group, Sanofi confirms our commitment to protecting personal data by guaranteeing a person's right to exercise control over the collection, processing, use, disclosure and storage of personal data relating to them.

#### For more information:

- [Sanofi Code of Ethics](#)

### The Group's Personal Data Protection Charter

Based on the European Directive of October 24, 1995, Sanofi also established the Group's Personal Data Protection Charter.

Available on the Group's web site, this charter ensures that the same policy will be applied in all countries. It also helps to ensure compliance with local legislation where laws have been enacted.

For more information:



[\*Sanofi-aventis Group Charter on personal data protection\*](#) (PDF, 66Kb)

## BCR (Binding Corporate Rules)

The transfer of certain personal data is authorized among member states of the European Union because each country has implemented the Directive of October 24, 1995, which sets out in particular the standards to guarantee the protection of applicable personal data during their transfer and subsequently.

Transfers of applicable personal data from a European Union country to a third country are regulated. To facilitate appropriate transfers of relevant data within the Group, Sanofi has issued a set of "Binding Corporate Rules," which govern the processing of applicable data transferred from a European legal entity of the Group to a non-European affiliate. These Binding Corporate Rules have been validated by the French national data protection authority (CNIL) and by each authority in charge of personal data protection within the European Economic Area in which Sanofi operates.

Outside the European Economic Area, each Sanofi affiliate concerned by these data transfer rules (BCRs) has signed a contract, whose template has been validated by the CNIL, making explicit their commitment to respect these rules. The Binding Corporate Rules, which were approved in late 2009, started to be applied within the Group in 2010.

## Developing training modules

Sanofi has developed three training modules so that all employees will be aware of the importance of data protection and data transfer matters within the group. The training modules are available on the Group's Intranet site and have been distributed in various countries through the Compliance Officers Network. Training modules are anticipated to be updated on a regular basis.

Three training modules are available:

- A general training module about personal data protection, designed for all employees; (2,721 employees participated in this training module)

- A specialized training module focusing primarily on BCR, intended especially for Group employees in charge of databases containing applicable personal data information; (1,199 employees number participated in this training module)
- A module designed for Research & Development activities focusing specifically on clinical trials and pharmacovigilance.

Initially provided in French and English, the two first training modules come with a translation kit so that affiliates may develop adapted versions in their local language. The module for Research & Development activities is available in French and English.

The purpose of these remote modules is to offer training to as many employees as possible. By late 2011, they had been distributed in Austria, Mexico, China, Romania, Morocco, Italy and France and to all the Group's support functions. They will be rolled out in other countries in 2012.

From 2010 to end of 2011, 2,721 employees received training on personal data protection and 1,199 employees received training on BCRs. Both training were in e-learning modules format.

#### A data security awareness campaign for employees



In 2011, a campaign was organized to raise awareness about the importance of protecting Sanofi's data and expertise – specifically by showing employees and service providers how to avoid information leaks.

This winning initiative is expected to bolster protection of the Group's assets and will ultimately help contribute to preserving personal data, Sanofi's competitiveness and the sustainability of our vital strategic assets.

The campaign emphasized four key concepts intended to raise awareness and prevent information leaks: precaution, vigilance, discretion and caution.

Innovative in design and scope, this campaign illustrated the Group's determination to protect our strategic information in a competitive environment where the risk of data leakage increases as communication technologies develop.

The highly effective campaign, initiated by Sanofi's Corporate Economic Security Direction, owed much of its success to valuable input received from other departments, including Information Systems Security, Compliance and Information Systems Audit.

The importance of awareness about data security was communicated using a multi-faceted approach:

- A clear commitment from the CEO and the Management Committee to motivate all employees. In addition to a video clip shown on the Group intranet, featuring an interview with the CEO, members of Senior Management sent messages to directors of all affiliates;
- The campaign targeted Group employees, interns and many service providers;
- Modern communication technologies focused attention on a security issue that is typically treated as highly confidential;
- All employees were called on to become active players in protecting the Group's interests.

In 2011, nearly 90,000 employees were targeted by awareness-raising initiatives focused on data security.

Intended as a strategic initiative to ensure the sustainability of Sanofi's personal data, projects and investments, this highly communicative and humorous campaign won three awards for the Group: in September 2011, it was hailed as the Best Corporate Security Project by Private Security Trophies in France. In late November, the information security campaign was also awarded the 2011 Grand Prize for Corporate Communications and the 2011 Prize for International Communications.

## BUSINESS CASE



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- Business case: Protection of Personal Data

### Organizing the approach

Sanofi has taken several measures to ensure compliance with procedures, including:

- A dedicated Group intranet site and a Research & Development activities devoted intranet site
- A Compliance Officers Network whose task is to ensure that all Group employees have access to the Sanofi Code of Ethics and Personal Data Protection Charter;
- A Personal Data Protection Committee, which is being set up at Group level, is composed of representatives from various departments such as Human Resources, Industrial Affairs, Information Systems, Legal, Pharmaceutical Operations, Research & Development, Scientific and Medical Operations and Vaccines. The mandate of the Personal Data Protection Committee is to guarantee that the Data Protection Charter will be enforced effectively within the Group. The Committee determines the Charter's general orientation and reviews any proposed developments;
- A Research & Development Data Privacy Office which develops R&D internal rules and procedures to ensure compliance of Research & Development activities with applicable personal data protection regulations and supports departments in solving issues related to personal data;
- A Research & Development Privacy network composed of representatives from the countries and departments that are most involved in clinical studies and pharmacovigilance activities. The network makes it possible to ensure smooth communications with the Research & Development Data Privacy Office.

## Business case

### An imaginative campaign to promote information protection

#### The challenge

To enhance information protection, it was necessary to raise awareness among Group employees and service providers about the importance of protecting Sanofi's data and expertise.

#### Our response

We devised a creative campaign to illustrate the need to protect and preserve the Group's data, information and assets in a competitive environment where the risk of information leakage increases as communication technologies develop. We designed this campaign to increase awareness and encourage employees to adopt best practices.

The campaign was initiated by the Group's Corporate Economic Security Direction with valuable input from several other divisions: IS Security, Compliance and IS Audit.

One week before the official launch, wall hangings, posters and stickers appeared in the entrance hall and other strategic locations at Group headquarters: elevators, water coolers and coffee machines, meeting rooms, the company cafeteria, etc. They showed puddles of water with the words "Small leaks can cause lots of damage," which were designed to pique the curiosity of employees and service providers. An ad along the same lines also appeared on the Group's intranet.

Following this virtual campaign, all employees received a message inviting them to view humorous video clips featuring people who talk about professional topics in places where they could be easily overheard, such as the company dining hall and building entrances.

For the campaign's official launch at the Sanofi headquarters, the key message was disclosed in full: "Four key tools for preventing leaks: precaution, vigilance, discretion and caution." Christopher A. Viehbacher, Sanofi's CEO, granted an exclusive interview in a video message viewed by all affiliates via the intranet. His participation was a clear sign that data protection is a major issue for the Group.



Another feature of the campaign was an educational module designed to test individual employees' knowledge. The Serious Game asked players to identify the correct behavior to adopt in different situations (at the office, in meetings, while taking public transportation, at home, in the lab).

### Benefits for stakeholders

This campaign helped raise awareness about the need to safeguard the Group's information and expertise by showing how to avoid leaks and adopt best practices, in addition to adopting the right attitude. It contributed to preserving Sanofi's competitiveness and the sustainability of our vital strategic assets. It created value by letting patients and healthcare professionals know that Sanofi is committed to the protection of their interests and personal data.

Since the launch of the campaign, significant improvement has been noted in alerts and incident reporting. By increasing visibility about data protection, it reinforced the Group's image and reputation.

### Opportunities for the Group

Thanks to close cooperation between economic security and communications teams, this campaign was rolled out across the entire Group. Such a global approach allowed each site to receive individual support while adapting the information to match their local culture and needs.

This highly communicative and humorous campaign won awards for the Group: in September 2011, it was hailed as the Best Corporate Security Project by the Private Security Trophies in France. In late November, the information protection campaign was also awarded the 2011 Grand Prize for Corporate Communications and the 2011 Prize for International Communications.

### The future

Related initiatives – such as training programs or presentations by government experts – will be organized in the future. They will target employees and service providers in order to maintain a strong sense of the importance of ensuring data protection and avoiding information leaks.

## Responsible procurement

### Background and policy

When it comes to procurement, Corporate Social Responsibility matters. CSR in this sector aims to select goods and services that are provided in compliance with high social, ethics and environmental standards.

### Procurement and responsibility

Until recently, the role of the procurement function within a business was to guarantee that suppliers deliver goods and services of high quality, on time, and at the best price available. But this role has changed: in an ever more global world, which evolves at an ever more rapid pace, with disparate social, environmental and ethics regulations at the local level, buyers can no longer ignore the ecological impact of the goods and services they purchase. Similarly, they must take into account the social, ethics and environmental context in which goods and services are produced or provided.

### Sanofi's commitment

In 2011, Sanofi purchased goods and services for a value of € 12.8 billion, excluding newly acquired businesses.

Since 2007, Sanofi has developed a robust methodology and program for the large-scale and targeted evaluation of our suppliers worldwide. As part of this program, the Group has committed to:

- Share the fundamental principles of the United Nations Global Compact as well as the Group's values with all suppliers,
- Require compliance with these principles and values in the production of goods and provision of services to Sanofi,
- Incorporate respect for the environment into the general conditions of goods and services purchased by the Group.

**For more information:** the United Nations Global Compact website

- [www.unglobalcompact.org](http://www.unglobalcompact.org) / [United Nations Global Compact](#)

## A new approach to responsible procurement

2011 was a year of transition for Sanofi's Procurement function, marked by a far-reaching strategic and organizational transformation.

To provide a framework and consistent support for this new business model, the Group selected four strategic objectives:

- Develop a reliable, sustainable and efficient suppliers' base, fully aligned with the Group's strategic and operational objectives,
- Design and continually improve a set of responsible procurement processes aimed at delivering the best added value for the Group in terms of quality, continuity of operations, competitiveness, and innovation,
- Set up and continually improve an effective organization fully aligned with the businesses and Corporate functions,
- Promote full compliance of the suppliers' base and in relations with suppliers.

In addition, the Procurement function adopted a matrix organization based on a global category management and a regional execution principle.

As a consequence, the Group has entered into a second development phase for the responsible procurement approach with a two-fold objective:

- To make the approach more efficient for both Sanofi and our suppliers,
- To strengthen integration of the approach into the company's risk-management and compliance processes.

Today the responsible procurement process is part and parcel of a global procurement risk management model initiated in 2011.

To develop this new approach and better meet risk management challenges, the Group created a new structure and position to deliver a risk management strategy (methodology, processes and systems) adapted to procurement needs and challenges, including those related to CSR. This procurement risk management model was initiated in coordination with the Group's Enterprise Risk Management Program, in order to avoid considering CSR risks in a stand-alone mode.

For more information: Risk evaluation

- *Actions / Risk evaluation*

Sanofi is developing and implementing this new approach in coordination with the procurement community and our business partners.

As the Group launched the transformation process in 2011, we focused on reshaping the responsible procurement methodology and processes to support the procurement community and suppliers, and to become an even stronger ally in the CSR approach.

We plan to cascade this new approach across the entire Procurement organization in 2012 as we continue to adapt our policies, develop new tools and provide training for the members of the procurement community.



By subscribing to the United Nations Global Compact, Sanofi has pledged to support and apply fundamental principles in the areas of human rights, labor and working conditions, environmental protection and anti-corruption. The procurement function integrates into its activities this Group' commitment by developing procurement policies, by training buyers and by establishing an appropriate relation with suppliers. Procurement has set up and communicated on its objectives.

**Jean-Philippe Collin,**  
Vice President Chief Procurement Officer

## Actions

Sanofi translates the Group's commitment into actions when it comes to training, evaluation, awareness and selecting products and services:

- ▼ Rolling out the approach and training procurement employees
- ▼ Risk evaluation
- ▼ Creating awareness among suppliers
- ▼ Supplier evaluations
- ▼ Selecting more environmentally friendly goods and services

### Rolling out the approach and training procurement employees

To ensure that Group buyers have a sound grasp of the issues and of the responsible procurement approach, Sanofi has implemented a training program worldwide.

This training program helps to integrate a deep understanding of the principles contained in the United Nations Global Compact, Conventions of the ILO (International Labor Organization) and other specific standards (in particular, SA 8000 and ISO 14000).

The training program has greatly enriched our procurement community, contributing to the implementation of our responsible procurement approach throughout the Group's affiliates. In addition, this topic is addressed in procurement seminars and steering committee meetings on a regular basis.

The new Supplier Relationships Charter was distributed to the entire Sanofi organization in September 2011. The Charter sets out the rules of conduct that must be respected by all Group employees in their relations with suppliers and governs issues relating to invitations, gifts, meetings and correspondence.

For more information:

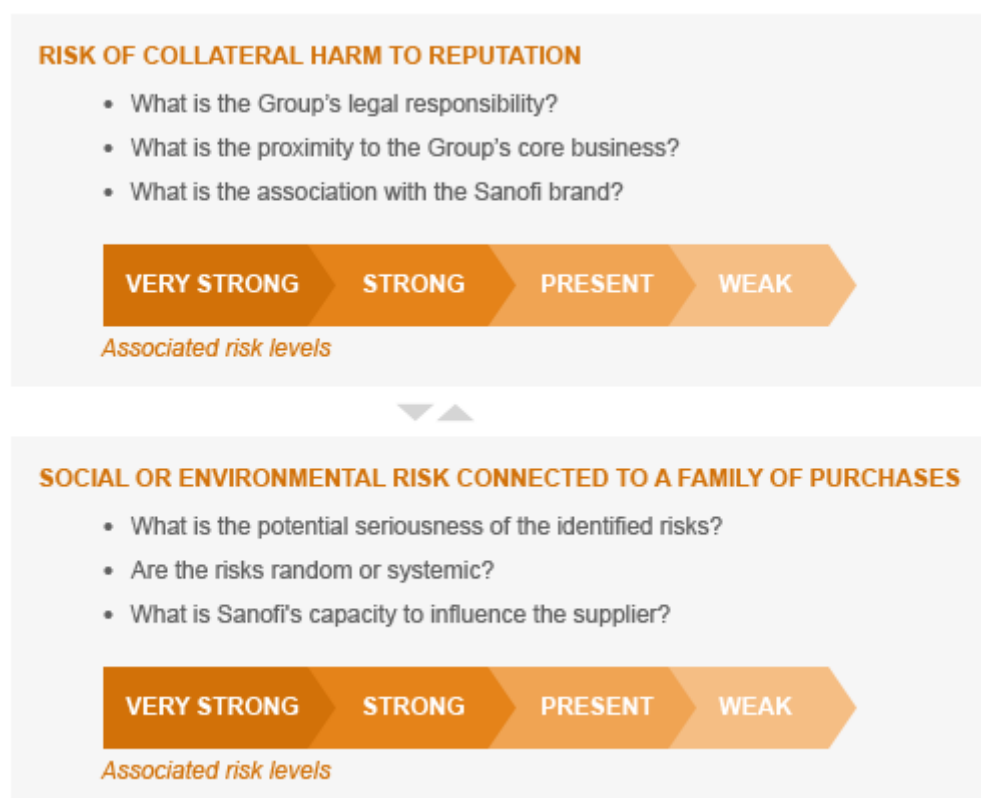
 [Supplier Relationships Charter](#) (PDF, 673Kb)

## Risk evaluation

A specific risk methodology was set up to identify and assess suppliers that should receive priority attention in terms of evaluation and monitoring. The risk matrix takes into account three dimensions:

- Labor/social and environmental risks (type, frequency, scope),
- Collateral damage to reputation risks,
- Buyers' degree of control and influence over suppliers based on specifications, knowledge of the market and other information.

The following diagram presents the criteria for analysis and the questions asked at each step:



In 2011, we initiated a new approach to address the full range of procurement risks and guarantee appropriate risk assessment and mitigation. Plans are underway to deploy and integrate this approach into the procurement category strategy in 2012 by addressing and formalizing the following risks by procurement category (if relevant):

- Globally: natural, geo-political, technological shortcomings, etc.
- Operationally: single source, dependency, innovation, etc.
- Compliance: governance, procedures and policies, the fight against corruption and bribery, etc.
- Corporate Social Responsibility (social / labor, environmental, supply chain, etc.)

This approach helps ensure that responsible procurement risks are not addressed as isolated or stand-alone issues, but are instead considered part of comprehensive risk coverage.

In addition, in 2011, specific measures linked to the fight against corruption and bribery were strengthened further by adapting our procurement policies, procedures and CSR supplier questionnaires in order to confirm our strict compliance with current applicable anti-corruption laws and regulations (OECD convention, US Foreign Corrupt Practices Act, UK Bribery Act).

At the end of December 2011, 51% of suppliers belonging to what are considered “high-risk” categories had been assessed (out of a total of 2,073).

In certain countries, where risks are considered to be more significant, the Group decided to routinely evaluate all chemical product suppliers. In line with the Group’s commitment, it should be noted that 100% of chemical product suppliers in India and China were evaluated.

## Creating awareness among suppliers

### **Sustainable Sourcing**

The Sanofi Suppliers’ Code of Conduct, which is distributed to all suppliers, was developed to ensure that all suppliers are aware of the Group’s CSR principles. This code of conduct is part and parcel of the Group’s CSR approach and the Group thereby intends to require our suppliers to comply with fundamental social, environmental and ethics principles.

The Supplier Code of Conduct is based on the Global Compact principles and the ILO conventions and defines Sanofi’s requirements concerning:

- Human rights and labor practices (child and forced labor, inhumane treatment, working hours, wages and social benefits, freedom of expression, equal opportunity)

- Health and Safety (protection of workers' safety and health, safety information about hazardous substances used, training, operations and maintenance, emergencies)
- The environment (compliance with legal and regulatory requirements, effluents and emissions, waste management, pollution prevention, etc.)
- Ethics (the fight against corruption, fraud and bribery).

Suppliers' compliance with this code may be decisive in their commercial relationships with Sanofi.

For more information:

 [Sanofi suppliers code of conduct](#) (PDF, 407Kb)

In France, Sanofi ratified the “Charter of Good Practices with French SMEs,” which sets out ten commitments aimed at building mutual trust between suppliers and customers. Environmental issues are part of these commitments. The Group needs to anticipate the challenges of CSR – including the potential environmental impact of our procurement policy, sourcing and specifications – and to be prepared for potentially evolving regulatory requirements (concerning recycling, waste treatment, pollution, energy consumption, carbon footprint). The Group appointed an internal ombudsman, independent of the Procurement function, who is in charge of facilitating the resolution of work-related differences between the Group and our suppliers with neutrality, impartiality, and confidentiality.

For more information:

 [Charte de la médiation du crédit et de la CDAF](#) (PDF, 1660Kb)

## Suppliers' diversity initiatives

Supplier diversity represents a clear statement of respect for the resourcefulness of individuals, regardless of their background or their companies' size. It also represents a key means to support the local economies where our major sites are located.

In the United States, Sanofi has been dedicated to ensuring that opportunities are available to small, minority-owned, women-owned, HubZone, disabled business enterprises, veteran and service-disabled veteran-owned businesses. This initiative advises suppliers they have opportunities to participate in Sanofi US total purchases:

- It may bring value to our business as well as to communities in which we live and serve,



- It reinforces our dedication to a diverse supplier base and it can drive innovation,
- It promotes continued innovation and an entrepreneurial spirit and can create value for our business.

### **Pharmaceutical Supply Chain Initiative**

Sanofi is a member of the Pharmaceutical Supply Chain Initiative (PSCI) and endorses the PSCI principles, which set standards for suppliers in the areas of ethics, labor, health and safety and the environment. Members include major pharmaceutical companies committed to upholding standards of responsible procurement and to sharing a vision of better social, economic and environmental outcomes for all suppliers involved in the pharmaceutical supply chain.

For more information:

- [www.pharmaceuticalsupplychain.org / Pharmaceutical Supply Chain Initiative](http://www.pharmaceuticalsupplychain.org / Pharmaceutical Supply Chain Initiative)

### **Supplier evaluations**

Since 2007, the Group has developed a robust methodology and process for the large-scale and targeted evaluation of our suppliers worldwide.

The suppliers' assessment process primarily relies on:

- The use of CSR questionnaires,
- The use of additional questionnaires, when relevant, depending on the procurement category (i.e. low-skilled workers, IT purchases, waste, etc.),
- Audits conducted on site.

Suppliers are assessed during two- to three-hours interviews. A general questionnaire containing 30 questions about social, environmental and ethics issues provides a basis for discussion. Depending on the type of supplier, more specific additional questionnaires may be used.

Potential deviation, if any, relating to labor / social and environmental rules may drive the Group's decision regarding business continuity or the request for an action plan. In face-to-face meetings, our buyers go over suppliers' responses to confirm implementation actually takes place, or to define a corrective action plan when necessary. The implementation of corrective

action plans has to be formally followed-up by the buyer in charge according to a timeframe agreed upon with the supplier.

**For more information:** Suppliers evaluation results

- [Indicators Section](#)

## **Responsible procurement collaborative platform**

*In addition, the Procurement function launched a project pilot in 2011 with 50 suppliers in order to leverage the new responsible procurement approach. In this new platform suppliers, must address specific questions about the environment, labor practices and human rights, fair business practices and sustainable procurement.*

*Launched with the support of an external CSR provider, this project consisted of using a web-based responsible procurement platform, processed by an external provider, in order to:*

- *Standardize and improve efficiency of the process by creating a single, harmonized and realistic process,*
- *Optimize our actions by avoiding time-consuming questionnaires and administrative burden,*
- *Facilitate and support exchange and analysis of environmental, social and ethics criteria (administrative processes, data collection, analysis and results),*
- *Focus on action plans and suppliers' performance,*
- *Comply with new regulations and policies,*
- *Deliver relevant KPI's to the procurement community, our business partners and external stakeholders.*

*By the end of 2011, the responsible procurement collaborative platform was up and running, providing the procurement community and Sanofi's business partners with relevant indicators (e.g., scorecards, reliable CSR indicators, etc.). \**

Based on the results and the buyers' feedback, the project is expected to be deployed on a larger scale in 2012.

**For more information:** Suppliers evaluation

- [Indicators Section](#)

## BUSINESS CASE



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- Business case: Responsible Procurement

### Direct sustainable sourcing for promotional materials

The Group has developed a specific sourcing program for promotional items (MedDirect program), which are directly mainly sourced from Chinese factories. This helps avoid the use of “in between” suppliers (producers, re-sellers, wholesalers) and thereby helps to safeguard our supply chain management.

This program aims to guarantee that sourcing origins are in accordance with Sanofi’s CSR standards and allows the Group to trace production and preserve quality and product safety.

Located in Shanghai, a dedicated in-house team is in charge of day-to-day business relationships with internal customers and Chinese factories. It is also responsible for testing each sales order before delivering promotional materials.

On-site audits are carried out in the local language with the support of a specialized and independent third party on behalf of Sanofi. Audits are designed to monitor our suppliers’ compliance with labor, social and environmental requirements. They include a visit to factories, workshops, dormitory buildings and other facilities, as well as face-to-face interviews with employees.

Audit results are subject to a formal review by the Procurement function, which decides on approval, rejection, or request for action plans. If potential issues give rise to a corrective action plan, the Procurement function is in charge of monitoring proper implementation with the supplier and requesting a follow-up audit.

In 2011, 58 suppliers were assessed, including 40 in China, 14 in Turkey and four in Taiwan.

### Selecting more environmentally friendly goods and services

Sanofi is committed to taking responsibility for the environmental and social impacts of our products and to promoting responsible procurement throughout the supply chain process. As a result, the Group encourages our sites to promote fair trade by using work garments manufactured with fair trade cotton and developing programs to share unused equipment.

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For this project, a comprehensive approach was established in 2008 and managed by the Industrial Affairs Procurement Department, covering each step from harvesting the cotton to delivering the work garments at the sites.

Using fair-trade cotton to create work clothing required re-thinking the design of the uniforms themselves, thus creating a new opportunity: the standardization of work garments for all Industrial Affairs employees at French sites, by activity (chemical manufacturing, pharmaceuticals and distribution).

The project, which involved many different stakeholders, involved teams at the participating sites including HR, HSE, Quality, Procurement and service providers to manufacture and clean the garments.

The teams involved in the project faced a major challenge: each garment had to meet specific standards, requirements and characteristics in connection with each plant's workstations and safety concerns. As a result, several different garment collections had to be redesigned. Taking into account that each site is free to select the service provider of their choice for managing the garments was an additional factor making this a complex project.

In response to this challenge, the Group adopted a very clear methodology:

- Convince the sites that this is a worthwhile project,
- Standardize the garment collections,
- Remove intermediaries in the choice of collection,
- Better control the garment production chain.

Garments are made from fair-trade cotton grown in Mali or Senegal by producers whose identification, certification and traceability are established. Spinning and weaving take place in France and the garments are made in Tunisia and Morocco.

The responsible procurement approach implemented by Sanofi is anticipated to have a positive impact at many levels for cotton-producing countries and local populations:

- From a socio-economic viewpoint, the people who produce and process the cotton have enhanced stability in income stream because the cotton is sold at a guaranteed minimum price. Moreover, cotton-producing countries may commit to investing in local development projects as the selling price is slightly above market price,
- From an environmental viewpoint, fair-trade agricultural practices respect the planet. They support traditional growing by family farms and village cooperatives, rather than large

- landowners. They give priority to rain-fed farming (bearing in mind that irrigation-based farming requires an estimated 29,000 liters of water per kilogram of fiber produced), manual harvesting and limited chemical inputs. Growers can continue mixed-crop farming and crop rotation, alternating cotton and cereal crops.

Nearly four years after the launching of this project, 100% of chemical, pharmaceutical solids and distribution sites in France use work garments made from fair-trade cotton.

Moreover, uniforms have been standardized, with a total of three collections in France. As a result of standardization, it is now easier to manage supplies at the sites and cleaning and upkeep of garments has been simplified. Thanks to close cooperation with HSE teams, the most recent garments offer improved safety protections (for example, flame-retardant fabric).

Contrary to expectations, using fair-trade cotton to make these work garments has not turned out to be more expensive than using traditional cotton. Actually, the opposite has occurred: by reducing the number of models, standardization has made it possible to increase procurement volumes, which controls costs.

### **Bringing unused assets back to life**

In September 2010, the Group launched an initiative so that all Sanofi communities could have an opportunity to share unused laboratory, manufacturing, packaging, handling, bulk / compounding and utilities equipment.

The program aims to build a single, shared system to encourage optimal use of unused assets by posting availability on the Group's intranet site so that other sites can make use of this equipment.

Listings are available via the Groups' intranet; members do not need any specific training or an account to take part in the program. Equipment is available for at least one month before it may be donated or discarded.

Initially launched at European R&D sites, this program was quickly adopted by Industrial Affairs and is available today for all Group activities (including newly-acquired businesses). By the end of 2011, 76 sites were involved in this initiative and 370 types of equipment (laboratory equipment, chromatography, cold storage equipment, etc.) were recorded in the database.

From a cost savings perspective, taking a "re-use" approach rather than a "buy" approach may translate into less need for storage and preventive maintenance.

From an environmental and economic perspective, this initiative allows the sites to recycle equipment or extend its period of use, which may reduce consumption of natural resources as well as unnecessary disposal.

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Vision / CSR performance / Statutory auditors' review report*

## Indicators

In 2011, Sanofi continued to implement the responsible procurement approach initiated by the Group several years ago and made use of dedicated collaboration-based tools.

The Group also continued supplier evaluations. In 2011, 190 new suppliers were evaluated (including 58 on site-audits) to reach a total of 2,073 suppliers who have been or are being evaluated in 29 countries.

The evaluations may be broken down as follows:

| Supplier evaluations YTD 2011 (*) | Approved     | Action plan | Refused   | Ongoing    | Total        |
|-----------------------------------|--------------|-------------|-----------|------------|--------------|
| COGS & Distribution               | 837          | 37          | 13        | 140        | <b>1,027</b> |
| CAPEX Manufacturing               | 205          | 1           | 2         | 24         | <b>232</b>   |
| Common Spends                     | 303          | 3           | 4         | 51         | <b>361</b>   |
| Sales & Marketing                 | 162          | 79          | 18        | 19         | <b>278</b>   |
| Scientific & Clinical             | 153          | 5           | 1         | 16         | <b>175</b>   |
| <b>Total</b>                      | <b>1,660</b> | <b>125</b>  | <b>38</b> | <b>250</b> | <b>2,073</b> |

(\*): excluding new acquired businesses

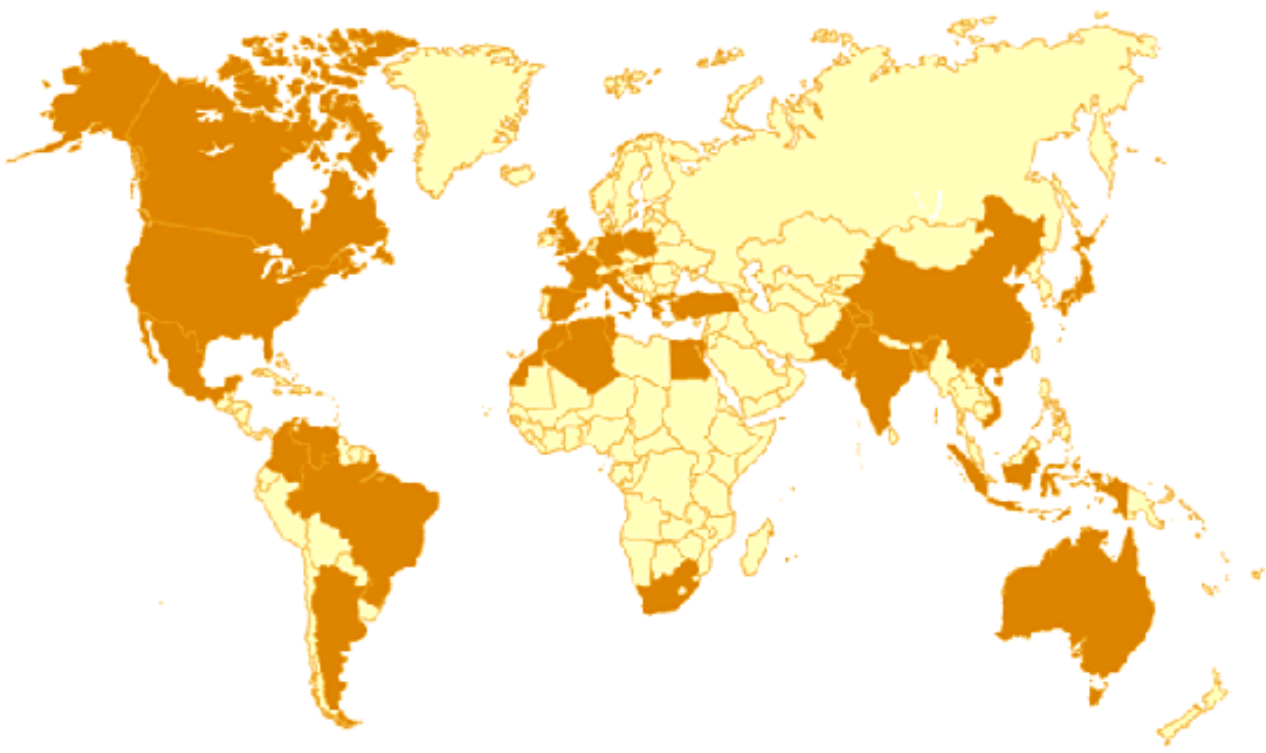
- Approved: the supplier complies with Sanofi values and principles
- Action Plan: Improvement is needed on one or more major points and the supplier agrees to implement an action plan
- Refused: Improvement is needed on one or more major points but the supplier refused to implement an action plan
- On going: the evaluation process is in process

At end of December 2011, 51% of suppliers belonging to what are considered “high-risk” categories had been assessed (out of a total of 2,073).

In certain countries, where risks are considered to be more significant, the Group decided to routinely evaluate all chemical product suppliers. In line with the Group’s commitment, it should be noted that 100% of chemical product suppliers in India and China were evaluated.

**29 countries adopted the “Responsible Procurement” program**

|           | Africa /<br>Middle East                                | America   | Asia / Oceania   | Europe   |
|-----------|--|---|--|--|
| Countries | Algeria<br>Egypt<br>Morocco<br>South Africa<br>Tunisia | Argentina<br>Brazil<br>Canada<br>Colombia<br>Mexico<br>United States<br>Venezuela | Australia<br>Bangladesh<br>China<br>India<br>Indonesia<br>Japan<br>Pakistan<br>Turkey<br>Vietnam | France<br>Germany<br>Greece<br>Hungary<br>Italy<br>Poland<br>Spain<br>United Kingdom |





## Business Case

### Responsible Purchasing

#### The challenge

At Sanofi Australia, we needed to develop a more structured, systemic approach to sustainability to build on the momentum our affiliate had already achieved with ad hoc sustainability initiatives. We wished to focus on our carbon footprint, resource usage and relationships with the community.

#### Our response

The Australian affiliate joined the “Sustainability Advantage Program” (SAP), which is a business support service offered by the Department of Environment and Climate Change in New South Wales. This program aims to help companies limit their environmental impact while boosting environmental performance and creating business value.

SAP provides a series of modules so that companies can implement the methodology at their own pace, in line with the commercial business and resource availability. The consulting costs of SAP were supported by the government in partnership with the commercial business for improved ROI and expertise.

To date, we have completed three SAP modules, which consist of:

- Vision, Commitment & Planning: formalizing our sustainability approach and setting targets
- Carbon Management: determining where we were producing the most carbon emissions
- Resource Efficiency: identifying ways to be smarter with our resources

Currently, plans are underway to complete two additional modules:

- Staff engagement: adopting a formalized approach to engaging our staff as ambassadors
- Supply Chain Management: challenging our supply chain approach and finding ways to be more efficient

We may also consider completing additional modules in the future.

SAP has five levels of recognition for participants. We have reached the second level (Bronze status), which distinguishes organizations that can demonstrate commitment to business sustainability.

Already our procurement organization has felt the impact. We have incorporated sustainability into the purchasing process so that our socially responsible purchasing is in line with procurement global directives. We audit all contracted suppliers regularly and work with suppliers that take an approach similar to our own when it comes to environmental issues.

Other examples of progress thanks to the SAP program include:

- Developing a local vision for environmental sustainability as part of Sanofi's commitment to our community in Australia
- Setting clear targets over the next five years and taking steps to use resources more efficiently and reduce our carbon output
- Partnering with suppliers with similar responses to environmental issues.

## Benefits for stakeholders

For employees:

Our sustainability efforts clearly contribute to employees' commitment and motivation. We regularly communicate to the staff about our environmental performance through a quarterly dashboard (CO2 reduction, electricity consumption, waste, water usage, etc.).

For customers:

Our Bronze SAP Partner status is proudly communicated on our website and in customer tendering proposals.

For the community:

The Australian population has an appetite for sustainability initiatives and increasingly expects companies to "do the right thing" for the environment.

## Opportunities for the Group

With the attainment of Bronze status in SAP, Sanofi enjoys a stronger position when it comes to commercial opportunities. This is primarily with customers like us, i.e., those that are seeking to partner with environmentally aware organizations, especially government healthcare. Moreover, in the eyes of the national community, Sanofi is developing a reputation as a responsible corporate citizen.

## The future

In 2012, we plan to:

- Achieve targets as set out in our Sustainability Plan
- Undertake the “Staff Engagement” module and other modules
- Make proposals for further actions to improve resource efficiency
- Implement similar sustainability success in all the affiliate’s office locations
- Achieve the next level of recognition in the SAP program (Silver status)

# PEOPLE

## Employees and communities

As a global healthcare leader, we believe that the men and women of Sanofi are key assets for the Group's development, and we are committed to meeting the challenge of supporting them during the Group's transformation process.

## People Indicators

## Diversity

### Diversity: a commitment

As a multinational company that strives to respect different cultures, Sanofi depends on the diversity and wide-ranging talents of our employees to make the Group more innovative, effective and competitive.

The Group focuses on promoting equal opportunity and reasonable working conditions for all, regardless of gender, ethnic origin, sexual orientation, religion, age and disability. Managing diversity means:

- Taking into account individual differences that are unseen as well as those that can be observed in the Group
- Preventing all forms of discrimination
- Promoting balance between professional and private life

The Group's Diversity policy is part of a forward-looking approach and aims to promote diversity in the broadest possible sense. The Group carries out proactive initiatives that address diversity-related issues in all countries.



We must all be vigilant in our actions and decision-making to prevent discrimination and act in favor of diversity, with a view to performance and inclusion of all.

**Delphine Valtier,**  
Group Diversity Director, Sanofi



Employee diversity reflects the first level of an organization's openness to the world.

**Professor Gregory Katz**  
Chaired Professor, ESSEC-Sanofi Chair Co-Director, ESSEC Institute of Health Economics & Management



## Preventing discrimination / Promoting Diversity

■ Step one of our Diversity policy is identifying and combating discrimination.

Promoting equal opportunity and reasonable working conditions for all, regardless of gender, ethnic origin, religion, disability, age and sexual orientation (or other characteristics protected by applicable local law) represents a means to develop the global economy and to guarantee personal dignity and opportunity for all.

Promoting diversity among employees begins with initiatives to increase awareness, an integral component of the Sanofi Diversity Policy.

Sanofi's objective is for all Group employees to embrace this principle and apply it on a daily basis, especially in light of today's rapidly changing business environment and transformation within our organization.

For more information about equality in the workplace, see the International Labor Organization (ILO) website:

- ILO report: [www.ilo.org / Equality at work](http://www.ilo.org/Equalityatwork)
- Read the article: "*La crise a ouvert un nouvel espace pour les discriminations au travail*": [www.ilo.org / La crise \(in French\)](http://www.ilo.org/La crise (in French))
- Read the article: "*Egalité et discrimination*": [www.defenseurdesdroits.fr / Perception des discriminations au travail \(in French\)](http://www.defenseurdesdroits.fr/Perception des discriminations au travail (in French))



[La crise a ouvert un nouvel espace pour les discriminations au travail](#) (PDF, 125Kb)



[Charter on the Human Care and Use of Laboratory Animals](#) (PDF, 38Kb)



[Baromètre du défenseur des droits et de l'OIT](#) (PDF, 1271Kb)

## Background

Discrimination in employment is universally condemned. Yet according to the International Labor Organization (ILO), workplace discrimination is on the rise. It may manifest itself in one of many different ways: from more traditional forms – based on sex, race and religion – to newer forms of discrimination based on age, sexual orientation, health and disability. In 2012, 169 ILO



member states ratified conventions concerning equal compensation and discrimination. Certain countries recently made changes to their labor codes to include new measures.

Because Sanofi operates in more than 100 countries, the Group is determined to make the fight against all forms of unlawful discrimination a major focus. This social commitment necessarily includes respect for local cultures and regulations.

## Policy

Sanofi prohibits all forms of unlawful discrimination for whatever cause or reason, as well as any behavior that infringes on personal dignity. In addition to offering equal opportunities to employees based on their aptitudes and skills, the Group sees that these principles are respected by our partners and suppliers.

True open-mindedness and the absence of prejudices concerning other people's views or attitudes are vital prerequisites for performing our jobs effectively.

Diversity, non-discrimination and equal opportunity are integral parts of our Code of Ethics.

“Sanofi is dedicated to promoting diversity, convinced that the distinctive identities of our employees and commercial partners are a source of strength and a key ingredient in the success of a global business.”

## The Sanofi Code of Ethics

- [Code of Ethics - Respect for the Individual \(page 8\)](#)

## Actions

Sanofi communicates to all employees about the Group's commitments and actions to prevent discrimination.

- ▼ Developing non-discriminatory management practices
- ▼ Organizing awareness programs
- ▼ Communicating with employees

### Developing non-discriminatory management practices

To ensure more effective implementation of applicable local anti-discrimination regulations, the Group provided support and advice to managers and the Diversity Delegate network thanks to the expertise of our corporate Diversity Department.

The Group relies on Diversity representatives in all our countries of operation to drive change and ensure that the policy is implemented locally. Our intranet, CSR blog and in-house newsletters showcase initiatives carried out by our affiliates.

Merial and Genzyme, which joined the Group recently, are also fully integrated into our Diversity network. In addition, a full-time Diversity and Inclusion position was created for the launch and coordination of actions in the United States.

Sanofi in France and Germany have signed their country Diversity Charter:

For more information:

- [\*Diversity charters\*](#)
- Diversity Charter signed in France: [www.charte-diversite.com](http://www.charte-diversite.com)
- Diversity Charter signed in Germany: [www.charta-der-vielfalt.de](http://www.charta-der-vielfalt.de)

### Organizing awareness programs

Awareness-raising initiatives are organized for newly recruited international managers during Discover integration seminars, which involve approximately 60 managers representing 24 nationalities each year.

During a one-day program designed for Human Resources (HR) managers in France, eight managers received training in 2011. Since the program was launched in 2007, more than 170 HR managers have been trained.

A similar program was offered to French Trade Union members. A total of 23 members representing five different unions took part in a day of Diversity training, which addressed issues such as identifying stereotypes, legal provisions, and the Sanofi Diversity policy.

A half-day devoted to Diversity awareness was organized for managers at industrial sites in France. Since 2009, 42 sessions have been held, with 120 managers trained in 2011.

Also in 2011, Diversity and Inclusion awareness training was organized in the U.S. and 93% of participating employees completed the program. Conferences regarding unconscious bias in our judgment and actions took place in the United States, addressing the issue of stereotypes. Dr. Mahzarin Banaji of Harvard University spoke at two such events.

In India, our affiliate took part in a pilot self-assessment of local Corporate Social Responsibility practices, including non-discrimination and respect for diversity – in particular their inclusion in Human Resources policies and practices. A meeting with the management committee representing plant and R&D sites provided an opportunity for discussion and exchange on a wide variety of topics, including women in the workplace, education, diversity, etc.

### Communicating with employees

Sanofi sets up forums for information and action for all employees. A Diversity page was added to the Group's intranet site, as were Diversity and Managing Disability contact e-mail addresses.

Communicating openly about diversity is an important part of the Sanofi Diversity Policy. In 2011, the Group took part in several internal and external events highlighting the importance of diversity, such as International Women's Day and the Women's Forum for the Economy and Society.

In 2011, the "Our countries have talent" soccer and golf tournaments embraced the diversity of Sanofi's industrial workforce, featuring:

**3** continents

**22** countries

**1,007** total participants

**115** volunteers

In France, our Industrial Affairs organization launched a soccer and golf tournament called "Our countries have talent." Turn-out was excellent, with employees from three continents and 22 countries taking part. In total, the tournament involved 1,007 participants and 115 volunteers. The three-day event brought together men and women from many functions to play soccer – with 18 women's teams and 32 men's teams – as well as golf.

In Japan, Sanofi organized various actions to promote diversity in the company. Diversity Week was held at the affiliate's head office from October 11 to 14, focusing on improving work-life balance and career development for women, supporting employees with disability, etc.

Diversity, non-discrimination and equal opportunity are integral parts of our Code of Ethics.

***“Sanofi is dedicated to promoting diversity, convinced that the distinctive identities of our employees and commercial partners are a source of strength and a key ingredient in the success of a global business.”***

## Gender balance

Gender balance is a priority issue in the Sanofi Diversity policy. In 2011, 45.7% of Group employees are women (compared to 46.3% in 2010). The percentage of women managers has remained unchanged since 2010 (45%). Across the Group, 39 % of the key positions with high responsibility are occupied by women in 2011 (compared to 37% in 2010).

## Women in the workplace

**45.7 %** of the  
Group's  
employees are  
women

■ [All statistics](#)

Women account for half of the world's population. To meet the challenges of tomorrow's economy, businesses cannot afford to ignore the talents offered by this population.

Women have made significant strides on the labor market throughout the world. The employment rate for women is increasing faster than that of men, especially in countries where they have traditionally had a lower rate of employment. Out of three billion salaried workers in the world in 2008, 1.2 billion were women (40.4%). However, the gap in compensation and responsibility between men and women remains high (it is estimated to be 15% in the European Union and nearly 20% in the United States), despite the marked rise in women's education levels.

Even more so than other sectors, the pharmaceutical industry must take advantage of the enormous pool of talent women represent, in particular women with medical and pharmacy degrees across the globe.

In Europe, Sanofi participated in the Women Matter 2011 Survey with an excellent response rate of 62%. Among the survey's key findings: Sanofi's Chief Executive Officer, Christopher A. Viehbacher, has demonstrated visible commitment to gender balance, and Sanofi has implemented more actions than the average number among companies in our sector (EU Pharma consumer goods); Sanofi's score was higher in terms of women's development

programs but lower when it comes to gender diversity indicators and dedicated HR processes and policies.

Sanofi is among the 28% of companies that designate Diversity as a top priority.

Efforts to promote equal employment opportunities for all people must continue, by combating both direct and indirect discrimination and by helping all employees achieve a balance between their professional and private lives.

**For more information:** The Global Gender Gap Report 2011, World Economic Forum for the Economy and Society

- [www.weforum.org](http://www.weforum.org)

## Policy

Eager to make the most of employee talent, Sanofi has made gender balance one of our priorities. In terms of the workforce, recruitment and management, today the Group strives to achieve equal opportunity regardless of gender, worldwide.

*The Women's Leadership Council (WLC) was created in early 2011 by Sanofi's CEO. The council is composed of nine senior managers. Their role is to promote practical work undertaken by the Group on the way to meeting our aspirations regarding Gender balance. The WLC is in charge of:*

- *Setting up working groups to propose initiatives*
- *Taking on board ideas and needs expressed by women's networks and working groups*
- *Evaluating proposals; advocating and driving support for new programs*
- *Bringing the subject of gender diversity to the attention of the Sanofi Executive Committee at least once a year*

*In addition, the Women's Leadership Council has validated the Group's ambitions when it comes to gender diversity, including:*

- *Promoting the advancement of women's interests and participation*
- *Developing diversity among the next generation of leaders*
- *Embedding a work-life balance into our corporate culture*
- *Developing role models*
- *Encouraging women's networks*

*Following the General Meeting of Shareholders that took place on May 6, 2011, the new Board of Directors is made up of 15 members, including three women (20%). \**



\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Our Vision / CSR performance / Statutory auditors' review report*

## Actions

Sanofi carries out gender balance initiatives promoting equal employment opportunities around the world.

These include:

- ▼ Professional Gender balance agreements
- ▼ Identifying women's talents
- ▼ Development programs for management
- ▼ Promotion of work-life integration and practices for all
- ▼ Initiatives promoting women's interests and participation around the world

### Professional Gender balance agreements

The Group is carrying out new gender balance negotiations for all employees based in France.

The agreement reflects the determination to promote gender balance throughout the Group, in particular with respect to access to jobs and training, and career development (mobility, promotions and compensation). The objective monitoring of the agreement is based on 30 or so specific indicators for jobs, training, mobility, absenteeism, compensation and work scheduling.

Finally, in 2011, for the fifth consecutive year, Sanofi continued to narrow the gender wage gap among men and women Group employees in France.

### Identifying women's talents

To ensure transparency when filling key positions, female candidates with the appropriate profile are systematically identified within the Group's talent pool along with male candidates. Since 2008, each Group succession plan for key positions has included a gender indicator. This year, despite Sanofi's enlarged scope of activity following the integration of Merial and Genzyme, the percentage of women in key positions reached 39%.

### Development programs for management

Initiatives to raise awareness about gender balance among members of Sanofi's management are organized on a regular basis. Below are a few examples.

## Internationally

Since 2008, Sanofi has been involved in the Board Women Partners Program, which includes half the CAC 40 companies among its members. This program targets executives interested in facilitating the representation of women on corporate boards with a view to improving governance. The program uses cross-mentoring initiatives to prepare women who will eventually become board members.

During Sanofi's Leadership conference, some 200 senior leaders welcomed Veronique Morali, President of the Women's Forum, who spoke about the importance of women's representation in corporations.

Mentoring is a powerful tool that enables senior women in a company help junior women gain confidence and a clearer vision of their potential. Sanofi's mentoring programs continued to make headway this year in the U.S., the U.K., Australia and Germany. New programs were introduced in France, Korea and Vietnam. At the Women's Forum, participants from the U.S. mentoring program offered their perspective to Sanofi delegates and to all those attending the Forum.

Women's networks are another important means for women and men to help other women. Such networks have been developed within our affiliates in the U.S., Central and East African countries, Hong Kong and Korea.

Employees at Sanofi Pasteur in Lyon (France) created a new network called "WoMen in SP." By late 2011, it had over 650 members, 52% of whom are based in France.

"WoMen in SP" includes employees in 41 countries, and 13% of the members are men. The network aims to suggest actions that will enhance gender balance at all management levels, provide opportunities for brainstorming, and promote the exchange of ideas.

Additional networks will be created in other countries in the near future.

As our indicators show, all Sanofi leadership development programs demonstrate a genuine commitment to gender balance.

For more information:

- [Statistics](#)

## In France

For the fifth consecutive year, Sanofi sponsored the "Trajectoires HEC au féminin" Prize (HEC Business School Women Excelling in their Career) in 2011. This prize was created to highlight the growing role of women as a factor of enrichment and success in corporations, and to raise awareness among leaders about the "glass ceiling" phenomenon, in which it is perceived that

certain categories of employees may not have access to positions of greater responsibility in a hierarchical structure.

## Promotion of work-life integration and practices for all

At our Gulf affiliate, over 30 female employees participated in training about the work-life balance for professional women. In addition, several Sanofi affiliates organized events for children and organized “open house” days when employees’ families were able to visit Group sites and facilities. Such initiatives were held in Israel, Pakistan, India, Taiwan, Brazil, Mexico, China, Lithuania and other countries.

For more information:

- [Compensation and benefits / Work-life balance](#)

## Initiatives promoting women’s interests and participation around the world

In 2011, Sanofi took part in many initiatives that focused specifically on women, upholding the Group's commitment to gender balance among our teams.

### International Women's Day

For International Women's Day, Sanofi’s Chief Executive Officer sent a letter to the Group's 100,000 employees reminding them of his commitment to gender balance as a source of success and open-mindedness. In the letter, Christopher A. Viehbacher officially announced the creation of the Women’s Leadership Council (WLC).

## Sanofi celebrates women's talent and insights

The CSR / Diversity Direction published a book featuring 21 portraits of women role models within the Group from a variety of functions and countries

In March 2011, the Sanofi CSR / Diversity Direction published a book of 21 portraits of women role models who work in various functions in different countries where the Group operates. As part of her portrait, each woman employee expresses her thoughts about her work and personal life.

[\*Women's insight - Regards de Femmes\*](#) (PDF, 4773Kb)

The Women's Forum for the Economy and Society, Deauville (France)

For the second year in a row, Sanofi was a premium sponsor of the Women's Forum for the Economy and Society, held in October 2011 in Deauville, France. Thirty Sanofi employees from all over the world attended. They were able to exchange ideas with one another and with women from other countries and companies. Christopher A. Viehbacher, Sanofi's CEO, who also attended the conference, clearly expressed his gender balance ambitions for the Group. Sanofi attendees had an opportunity to brainstorm with Women's Leadership Council members to enrich gender diversity actions plan.

During the "CEO Champions" session, Olivier Charmeil, Senior VP of Sanofi Pasteur, the Group's vaccines business, confirmed specific aspirations regarding progress for women employees at Sanofi.

For more information: the Women's Forum

- [www.womens-forum.com](http://www.womens-forum.com)

## 2011 Highlights

For International Women's Day, Group affiliates organized events in more than 45 countries. Conferences and debates focused on women's role in society and empowering all employees equally. The CEO's letter, the role model book, and a film made at the 2010 Women's Forum were featured during events.

Sanofi has been recognized for promoting women's interests in the work place: the French magazine Challenges rated Sanofi number four among CAC40 companies.

Sanofi Turkey supported the program “Future Women Leaders” in partnership with the association KAGIDER. This program is designed to help women jobseekers and to strengthen their position in business and social life. In preparation for professional life, the program provided training to 61 young women who recently graduated from university.

Sanofi Italy joined a women’s association called “Valore D,” which works directly with the management of companies to promote and organize initiatives designed to increase the number of women in high-level management.

In the U.S., Sanofi is a sponsor of the National Association for Female Executives. Several of our employees participated in leadership summits in 2011.

At the World Economic Forum in Malaysia, Leah Goodman, Sanofi’s General Manager, participated in a panel discussion about the perspective of women CEOs in a global company.

#### Recognition for Sanofi women

Linda Richardson received the HBA Rising Star Award in 2011. This award recognizes women in the healthcare industry who contribute significantly to their organizations. Criteria include leadership ability, helping those in subordinate or peer positions, and dedication to the industry.

Sanofi South Africa was recognized as one of the country’s best employers. This affiliate has received the Top Women’s Award for several year in a row.

## Statistics

▼ Percentage of women at various levels of the organization in 2011

▼ Proportion of women by geographic area in 2011

▼ Proportion of women in career development and training programs

**45%** of Group managers are women

**45.7%** of Group employees are women

In 2011, 45.7% of Group employees were women.

The percentage of women managers remained stable compared to 2010 (45%).

In 2011, the Group Management Committee became the Global Leadership Team. It has 46 members, including five women.

One woman is a member of the Executive Committee, which has eight members.

Two new women directors joined the Board of Directors after approval by shareholders at the General Meeting, which took place on May 6, 2011.

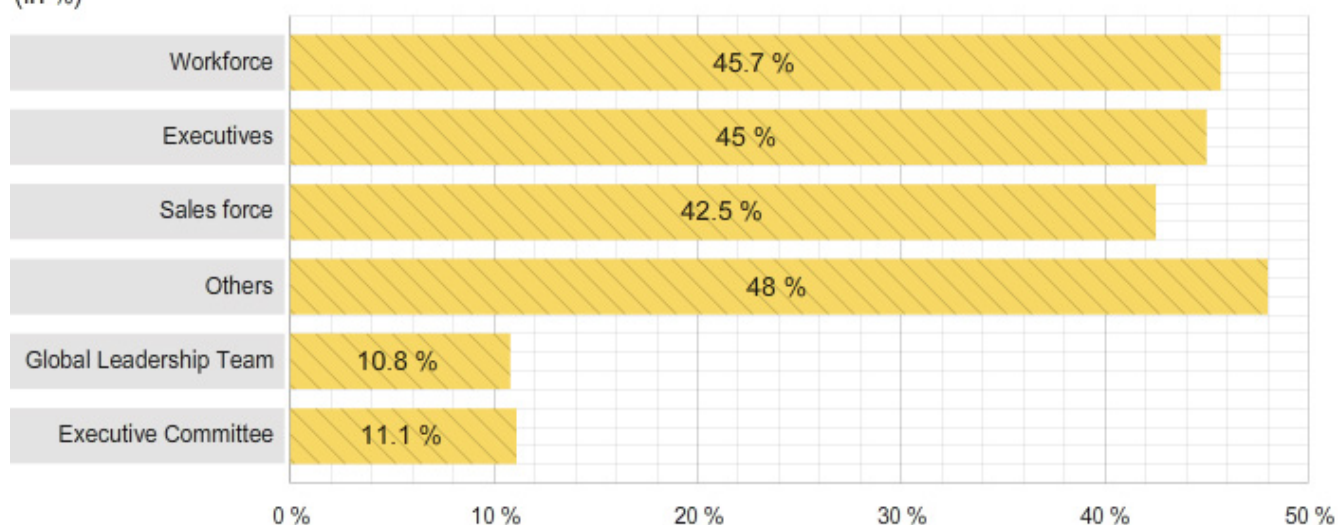
Three of the 15 members of the new Board of Directors are women (20%).

The percentage of women holding key positions with operational responsibility reached 39% in 2011.

Forty-one of the top 250 positions in the Group are held by women (16%).

## Percentage of women at various levels of the organization in 2011

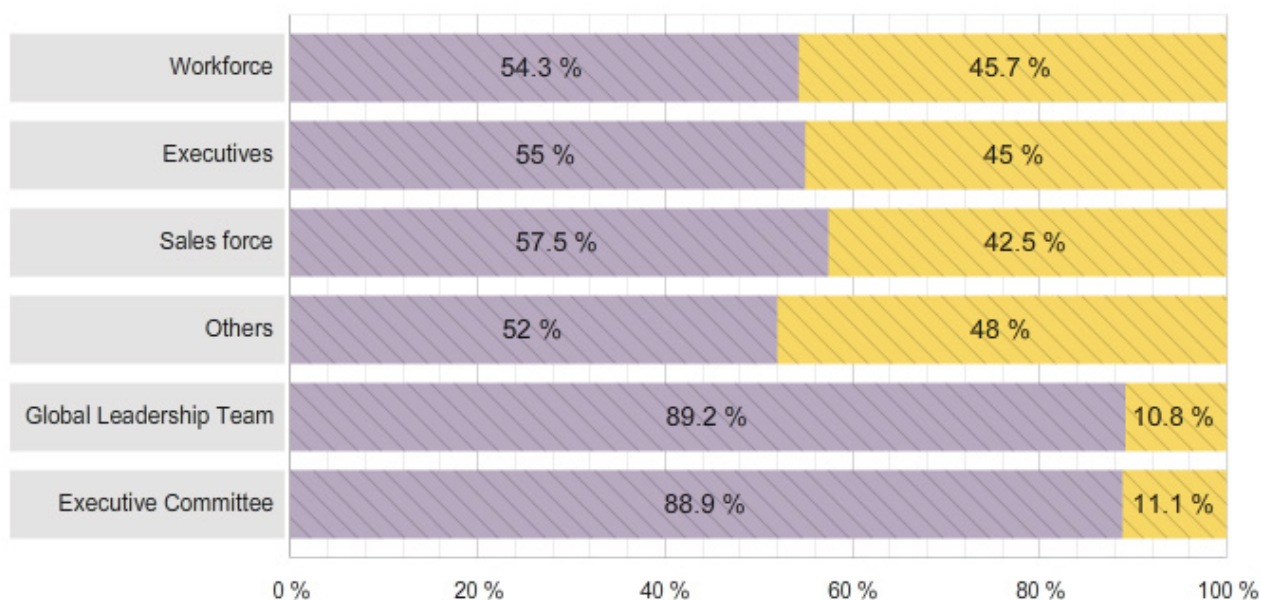
(in %)



Women

## Proportion of women by geographic area in 2011

(in %)



% Women Managers (Total: 45%)

% Women Employees (Total: 45.7%)



## Proportion of women in career development and training programs

Several women have been appointed to general manager positions – for example, in Malaysia, Egypt, Russia, Slovakia and Korea.

In 2011, 357 women took part in international career development programs, such as Discover, Explore, Evolve, Pilot, Perspectives, Accelerate and Innovate. Women represented 37% of all participants.

### For more information:

- [Workforce development / Actions / General training](#)

## Disability

### Background

Sanofi's policy on Disability is based on four key commitments:

- Retaining employees who have become disabled
- Integrating disabled employees
- Encouraging sub-contracting activities to specialized centers
- Offering training and raising employee awareness about disability in the workplace

Employment remains the best means of social integration, yet a person with disability encounters more difficulties in finding a job than do other people. It is essential to change the way people look at disability, disabled individuals and the work they can potentially do.

As a company working in the healthcare field, Sanofi must be even more concerned than other businesses about health issues and have an even clearer understanding of the difficulties created by a health problem or disability.

### Worldwide

According to the International Labor Organization (ILO), 386 million people of working age are disabled. An estimated one billion people (roughly 15% of the global population) live with some form of disability, according to the most recent survey from the World Bank and the World Health Organization (WHO).

For more information:

- [www.un.org / disabilities](http://www.un.org/disabilities)

The United Nations has adopted a convention on the rights of persons with disabilities.

For more information: the rights of persons with disabilities

- [UN Convention on the rights of persons with disabilities](#) (in French)
- [European Commission website on Disability issues](#)
- [www.who.int / disabilities](http://www.who.int/disabilities)

## In the United States

According to the National Council on Disability, 13% of the population has a disability. In addition, the number of disabled individuals appears to be rising.

## In France

Disabled individuals represent approximately 15% of the population, and this percentage is set to increase with the aging of the population. Equal opportunity, a concept that is fully accepted today, also applies to the disabled. Since the February 2005 law went into effect, more and more organizations have improved their compliance with the requirement to hire the disabled.

The unemployment rate among the disabled in France is 20% higher than the rate for the general population.

According to the AGEFIPH (a French organization to promote the employment of the disabled), one person out of two will be affected by a health problem during his or her working years.

**For more information:** employment of persons living with disability (in French)

- [www.agefiph.fr](http://www.agefiph.fr)

Guide regarding stereotypes toward disabled person:

- [www.agefiph.fr / Actualites / Stereotypes-handicapées](http://www.agefiph.fr/Actualites/Stereotypes-handicapées)

## Policy



As with any other employee, disabled individuals contribute to the Group's performance.

The Group is committed to ensuring equal opportunity and promoting diversity as a source of talent and a means to optimize performance. In every country where Sanofi operates, a dedicated “Managing Disability” team oversees implementation of the Group’s policy on disability.

They focus on four commitments:

- Retaining employees, regardless of the cause of their disability. Job retention applies to any situation where an employee’s aptitude for his or her job is altered due to disability issues. This entails preventing job exclusion and finding the best possible compromise between an employee's abilities and skills and the requirements of a specific job.
- Integrating disabled employees into the company (with a permanent contract, fixed-term contract, internship, temporary employment, etc.). As with all employees, the hiring of a disabled individual is based on that person’s skills, aptitude for the position to be filled and motivation. There are no positions that are necessarily unsuited to the employment of a disabled individual. However, adjustments are sometimes necessary. In some countries, the only measure applicable is whether a person can perform the essential functions of the job with or without a work accommodation.
- In some countries, working with specialized centers employing more severely disabled individuals who cannot be present on Sanofi sites. Outsourcing is a means to indirectly contribute to the employment of individuals who cannot be integrated into an ordinary working environment. Specialized centers can be found in numerous countries. The choice

- to outsource may consist of the temporary assignment of individuals from specialized centers to a site, or contracting out all or part of an activity.
- Increasing employee awareness about disability and work. Disability is like a foreign language: One must learn it in order to understand. A program to raise awareness about disability has been developed for all employees. Information and education are provided through brochures, posters, films and a dedicated intranet site. Special activities, such as role-playing games, lectures and testimonials, are organized for all employees to help change perceptions of disability in society. More specific training is designed for different functions: for HR teams and recruiters, social-medical teams, managers, HSE, communication, etc. Thanks to a network of Diversity-Disability delegates in various countries where Sanofi operates, the policy is put into action where consistent with applicable local law, and experiences are shared in coordination with the Managing Disability team. The Group is gradually implementing this policy and these initiatives worldwide where consistent with and pursuant to applicable local law.

## Actions

In keeping with our commitments, Sanofi organizes many different disability-related initiatives in the countries where we operate. The Group is also making efforts to implement our Disability policy worldwide, where consistent with and pursuant to applicable local law.

There was a  
**19.4%**  
increase in the  
number of  
disabled  
employees in  
the Group  
between 2006  
and 2011.

## Company-wide initiatives

### Disabled workers across the globe

The definition of a “disabled worker” varies according to local laws. When legislation does not address the issue, the Group takes into account visible disability (bearing in mind the World Health Organization definition).

WHO Definition of Disabilities: [www.who.int / topics / disabilities](http://www.who.int/topics/disabilities)

Disabilities is an umbrella term, covering impairments, activity limitations, and participation restrictions. An impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual in executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations.

Thus disability is a complex phenomenon, reflecting an interaction between features of a person’s body and features of the society in which he or she lives.

In 2011, for the entire Group, more than 25 countries reported that there were 1,758 disabled individuals in their workforce, primarily in Europe and in the industrial sector. Five years earlier, in 2006, this figure stood at 1,472.

Since 2006, a communication network coordinated by the Group's Managing Disability team has been in place to ensure that efforts are concerted and company initiatives are monitored.

#### Workplace accessibility

Using tools developed by Managing Disability and the HSE Department, the Group has undertaken studies to investigate and assess workplace accessibility.

Sanofi's new headquarters in La Boetie (Paris, France) has been carefully designed to ensure that persons with a disability have access to all facilities.

#### Access to information

Sanofi focuses considerable efforts on improving access to information for our employees and our professional stakeholders. This calls for a global approach that includes translating information into sign language, ensuring accessibility of websites, providing computer versions of printed documents, etc.

The Group continues to improve the compatibility of our websites and received the W3C AA rating for the new corporate websites. Our affiliate website have all received certification as well.

The Access to Information Charter, drawn up by the Senior Vice President of Corporate Social Responsibility and the Senior Vice President of Information Systems, was widely distributed throughout the company and demonstrates the Group's commitment to this issue. An awareness module and tutorial are now featured on the intranet Information Services and Disability web page.

In France, a new system allows employees with a hearing impairment to communicate by phone and take part in meetings – with the interface of a sign language speaker or conversation typing. By late 2011, eight employees had been equipped with such systems.

## Raising awareness

Increasing employee awareness is one of the pillars of our Disability policy. A number of countries have begun organizing their own initiatives.

In France, during the national week devoted to the employment of the disabled, activities were organized at different sites. An illustrated narrative – based on true stories showing a person with disability in different workplace situations – was distributed to all employees. This initiative aimed to combat stereotypes, improve awareness and encourage communication.



[Recognizing disabled worker status \(RQTH\)](#) (PDF, 2350Kb)

The French Pharmaceutical Companies Association (LEEM) has a new entity devoted to disability, HandiEM, and Sanofi is a member of its Board of Directors. Created in May 2010, HandiEM aims to provide disabled workers in the pharmaceutical sector, and others who would like to join them, with training, integration and job retention solutions specifically adapted to this sector. Sanofi has participated in the creation of specific brochures. In 2011, the first HandiEM seminar brought together approximately 80 different pharmaceutical companies.

For more information:

- [www.handiem.org](http://www.handiem.org) (in french)



Sanofi is an active member of HandiEM, the new LEEM entity focusing on disability

- [www.handiem.org](http://www.handiem.org)

## Raising awareness about disability: local examples

### Brazil

Various partnerships were formed between our Brazilian affiliate and different organizations, in particular organizations for the deaf and hearing-impaired, to facilitate the integration of disabled individuals. Training seminars on sign language communication (Libras) are provided for managers.

### Egypt

In Cairo, Sanofi has upheld a policy of employing individuals with disability for many years. A protocol has signed with Wayana association, focusing on education and integration of people with disabilities in the community and providing employment opportunities. The Group's "Managing Disability" policy has been in effect for some time, in addition to recruitment, training and promotion policies.

### Japan

Sanofi Japan was recognized for creating a positive working environment for persons with disabilities. The award, which was organized by the Japanese Organization for Employment of the Elderly and Persons with Disabilities (JEED), is supported by the Ministry of health, Labor and Welfare. It was presented to organizations that demonstrate best practices to improve working environments for persons with disabilities. Sanofi Japan received the Chairman's Prize at a ceremony in Tokyo in September 2011.

### France

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Sanofi entered into a company-wide agreement to promote integration and job retention of disabled persons for the period 2009-2012.

This follows the 2006-2008 agreement, during which time the Group exceeded our objectives. Sanofi recruited 165 disabled employees and increased investments in working with specialized firms. As a result of continuous awareness-raising efforts, numerous disabled employees (300

over three years) have made their disabilities known to the Group, so that specific measures could be taken to accommodate their needs.

The current agreement emphasizes the importance of retaining employees with disability and enabling them to keep their jobs. Members of the Hygiene, Safety and Working Conditions Committee (CHSCT) are major players in this process. Sixteen employees from six sites have received awareness training on disability in the workplace.

Managing Disability: Call for projects

In accordance with the new agreement, Sanofi presented awards to ten project originators for the third consecutive year. Designed to benefit disabled communities, these projects, where employees are fully involved, received funding from Sanofi. In addition to financial support, the Group wishes to highlight employee commitment to disability issues, raise awareness among all employees and pursue an active Disability policy.

For more information:



[\*The 10 completed projects from the 2010 Call for projects\*](#) (PDF, 6546Kb)

## Supporting all generations

Sanofi considers that age diversity is both a valuable resource and a factor in performance and the Group organizes initiatives designed specifically for young employees as well as older employees.

### Actions

- ▼ Supporting young people through apprenticeships
- ▼ V.I.E. around the world
- ▼ Supporting employees during the second half of their career

### Supporting young people through apprenticeships

In many countries, unemployment is extremely high among young working age people, including recent graduates. Sanofi focuses on four areas:

1. Helping junior people complement their initial training by acquiring knowledge, know-how and experience, with an emphasis on employability
2. Helping junior people land their first job, with an emphasis on entry into the workforce
3. Giving junior people the tools they need to find a job, with an emphasis on equal opportunity
4. Welcoming students and job seekers for site visits and providing a glimpse of the work we do.

The number of apprentices at our French sites increased from 500 in 2010 to approximately 1,000 in 2011. The Group also accepts apprentices in Spain, Brazil, Germany, Russia, Lebanon, Pakistan, Thailand, Columbia, and other countries.

In France, Sanofi has signed a charter to promote education through apprenticeships in companies, a project developed by the French Ministry of Labor. In addition, many of our French sites have formed partnerships with schools and universities (such as Le Trait, Bordeaux, and others) to participate in apprenticeship programs.

The Group feels it is important to participate in programs to identify and support promising junior scientists who wish to set up research laboratories in France. Within the scope of a research partnership with AVIESAN (the French Life Sciences and Healthcare Alliance), we renewed our support for the CNRS ATIP program and the Inserm AVENIR program. As of 2011, Sanofi is providing support to 15 students.

In Egypt, “Future Access” is a project run in coordination with the Faculty of Pharmacy, enabling students to receive training under the supervision of 90 Sanofi employees.



### *Sanofi*

#### V.I.E. around the world

In the healthcare field, Sanofi is the leading recruiter for International Corporate Volunteers (V.I.E.). This program is an excellent way for Sanofi to discover and recruit talented young people who may become the Group’s future leaders. In 2011, 142 young people participated in the program. Some 70% were from outside Europe, coming from the Asia-Pacific zone (25%), Africa (10%), the Middle East (4%), and Latin America (13%).

#### Supporting employees during the second half of their career

Where permitted by law, the Human Resources Department offers a “second half” career interview to interested employees over age 45. The interview is intended to touch base with employees on the subject of their career path, skills and ambitions regarding professional development and career orientation.

In Germany and other countries, specific initiatives are being carried out, primarily to help employees prepare for retirement.

An action plan to support seniors was introduced in late 2010 and implemented in 2011 in France.

## Other diversity topics

- ▼ [Supporting young people from disadvantaged backgrounds](#)
- ▼ [Ensuring supplier diversity through the purchasing activity](#)
- ▼ [Sexual orientation](#)

### Supporting young people from disadvantaged backgrounds

In France, the Group participates in programs to help young people from disadvantaged backgrounds. In addition to Group support, currently more than 69 employees volunteer their time to such initiatives.

- Since 2007, the Group has been sponsoring young university graduates from “sensitive” urban areas through a program developed by an association called Our Neighborhoods Have Talent. Over 25 mentors from the various functions help graduates in their job search by fine-tuning their CVs and coaching them on interview techniques. This year, a meeting was organized at our Vitry R&D site with professional organizations to discuss career paths and professional orientation.
- Since September 2007, together with the French Ministry of National Education and the HEC Business School Foundation, the Group has been part of a project to create and support preparatory classes for prestigious business schools (Grandes écoles de commerce). This program targets young technology graduates from high schools in priority education zones. In 2011, eight employees volunteered to coach these students. The opening ceremony was organized at our Paris headquarters, with the participation of other sponsors’ companies and 50 students and school representatives.
- The Sanofi Pasteur recruitment team takes part on a regular basis in the “Jobs and Cité Stadium” organized by Nes&Cité in Lyon. The idea is to invite companies and job seekers from so-called sensitive neighborhoods to meet inside the Gerland Stadium for “job dating” opportunities.
- Sanofi Pasteur also participates in professional orientation initiatives for young people from disadvantaged neighborhoods and supports the “Sports in the City association” as well as

- “Job in the city” for the Rhône-Alpes area. Four more Group employees have joined the program, for a total of 13 since its launch.
- In 2011, a new collaboration began with TELEMAQUE, a program that works with over 80 high schools to help bright and motivated students succeed in their studies. Currently six Group employees are tutoring young people through the program.

In Brazil, the Group’s Suzano site entered into a partnership with Government of Suzano City for young people to receive training in computer and administrative skills. Over 40 boys and girls are taking part in this program.

In South Africa, an anti-discrimination program introduced in 2000 was pursued in 2011 with an added focus on cultural diversity. The Industrial plant takes on students for one year, during which time they acquire workplace experience to complete their qualifications. This program is run in cooperation with universities.

In the United States, for the third year, Sanofi participated in an education program providing high school students internships at our office in Bridgewater, New Jersey. Ten students work one day per week, for one year. Students are assigned a supervisor and are entrusted with specific tasks. This program is beneficial for all involved, and in June 2011, 100% of the interns graduated and went on to college. “Many of these interns are the first in their family to work in a corporate setting, and hopefully we are planting seeds that can lead to fulfilling careers in science or business,” said John Spinnato, CSR Vice President for North America.

## Ensuring supplier diversity through the purchasing activity

Several Group affiliates pay particular attention to ensuring that suppliers belong to various ethnic, minority and religious groups.

In South Africa, The Group has entered into supplier agreements that comply with Black Economic Empowerment legislation. Affiliates in other countries including Israel, Iran, France and Africa have worked with identified suppliers having specific characteristics (small businesses, managed by minorities, disabilities, etc.)

In the U.S., the Purchasing Department has put in place two mentoring programs for women, minority, disabled and veteran business owners. These are the New Jersey Association of Women Business Owners and the Diversity Alliance for Science.

## Sexual orientation

In France, Sanofi participated in a study on Human Resources diversity and non-discrimination practices with regard to the LGBT (Lesbian, Gay, Bisexual, Transgender) employee population.

The study, called “Quick-scan,” was an unprecedented survey based on self-assessments among 26 French and international organizations from the public and private sectors (including, IBM, Casino, Sodexo, EDF, Vinci Autoroutes, the city of Lyon, Accenture, Monoprix, Health regional agency Ile-de-France, Sanofi, PSA, SFR, Veolia Eau, and more). It included 1.7 million employees and contractors, of which 800,000 were in France. The report also proposes a set of good practices for companies to implement, as well as practices to avoid (available in French).

For more information:

 [Quick-scan - L'autre Cercle](#) (in french)

Sanofi's Diversity Department, working with a group of volunteers and the help of the “L'autre cercle” organization, produced a leaflet distributed to company doctors. Entitled, “Sexual orientation: How can I be concerned?” This document is now available to any employee in France in the company doctors' waiting rooms.

A Sanofi affiliate provided support to an employee who was undergoing a gender reassignment operation and process. This employee, now a female, has been well accepted by other employees and customers. The local Human Resources Department implemented a non-discrimination policy, which includes access to benefits for partners of gay and lesbian employees as well as protection for partners in the event of illness.

## Supporting change

### Background and Sanofi's commitment

Since 2009, Sanofi has implemented a wide-ranging transformation program to become a diversified global healthcare company focused on patient needs. All Group entities have been involved in this transformation process: Research & Development, Industrial Affairs, Commercial Operations, Vaccines and the support functions.

The Group must adapt and progress to remain competitive internationally. We are migrating research and industrial facilities toward biotechnologies. We are also adjusting our sales forces in response to growing regulatory constraints (e.g. drugs being excluded from reimbursement or subject to price regulation) and generic competition for some of the Group's flagship products.

In certain regions of the globe, and particularly in emerging markets, we must strengthen Sanofi's presence in response to countries' development and their populations' access to care.

In each country, employee representative bodies and employees are regularly informed about the Group's strategy and the need for organizational transformations to meet the challenge of an increasingly competitive environment. Based on transparency, negotiations take place to implement necessary and appropriate support measures while taking into account local regulations.

Our transformation program has been implemented progressively in all affected countries, and Sanofi is committed to supporting impacted employees as they change functions or organizations.

The challenge facing the Group is to offer each employee a solution adapted to his or her needs. This requires anticipating change (training needs, site conversions, investments, etc.) and negotiating with employee representative organizations about support measures, where appropriate. It also entails keeping employees informed and taking the time required to fine-tune adjustments.

Two types of actions are essential to supporting change:

- Assisting employees during the Group's transformation
- Strengthening and integrating teams in areas with high growth potential, in particular following the acquisition of Genzyme and Merial



"Sanofi's socially responsible approach entails anticipation and the ability to react quickly, including being able to adapt to technological developments and broader change."

Excerpt from the Sanofi Social Charter



[Sanofi Social Charter](#)

"Sanofi aims to combine economic and social performance and recognizes these are inseparable."

Excerpt from the Sanofi Social Charter



[Sanofi Social Charter](#)



While strengthening our high expertise in the traditional chemistry, we are moving towards biotechnologies and building synergies with vaccines.



**Francis Carré,**  
Industrial Affairs Chemistry and Biotechnology

## Actions

In each country affected by organizational changes, Sanofi implements the optimal means for providing support to employees while respecting local regulations. In particular, the Group's actions involve negotiating with employee representative organizations, where appropriate, and providing internal and external training as well as career development assistance for employees.

- ▼ Assisting employees during the Group's transformation
- ▼ Assisting employees who wish to start a business
- ▼ Strengthening teams in areas of high growth potential: the acquisition of Genzyme and the integration of Merial

### Assisting employees during the Group's transformation

For all the reorganization projects, Sanofi is making every effort to provide career support to Group employees, particularly when it comes to internal and external mobility. Support measures vary from one country to the next.

#### Supporting internal career mobility in France

With our history of social engagement in this country, Sanofi is committed to maintaining an active role in France's economy. An essential part of accomplishing this goal entails providing training for Group employees. This assists them in acquiring new skills based on the Group's strategic needs in order to remain competitive, specifically migrating toward biotechnology.

Internal career mobility support includes:

- Providing training programs for employees whose jobs are impacted by the transformation from chemical industrial activities to new biotechnology activities
- Supporting mobility within the various Sanofi sites

## Training programs : Biotechnology training for employees in France

Some of the changes within Sanofi involve converting certain chemical industrial sites into biotechnology sites to keep pace with changes in the pharmaceutical sector, which increasingly relies on new technologies for research, development and the production of tomorrow's medicines. This is also necessary to maintain our sites' activities, remain competitive and enable Group employees to acquire the skills required for these new strategic directions.

Within the scope of the industrial network's increasing focus on biotechnology, it is our responsibility to provide training for all affected employees so that they can acquire new technical skills. Sanofi has created various programs to facilitate the transition to biotechnologies.

Chemistry and Biotech face a common future by playing complementary roles in rich synergy with the entire Sanofi family.

There can be no industrial strategy without a skills training strategy.

### Campus Biotech

Since 2010, 165 employees have taken part in 321 training sessions.

As this conversion got underway, a major training program, Campus Biotech, was developed in 2010 so that employees who were impacted by the conversion from chemical industrial sites to biotechnology sites could acquire new skills.

Campus Biotech is a Group initiative that aims to develop tailored training programs in bioproduction and bioanalysis for employees. Organized in partnership with renowned universities and schools in France and Germany, it helps build bridges among functions and divisions, including Industrial Affairs, R&D, Sanofi Pasteur, Merial and Genzyme. It may ultimately help our staff develop new skills in an innovative area.

In addition to providing employee training, Campus Biotech has become a reference within the Group as an in-house university of sorts that capitalizes on the Group's technical achievements

as well as experts' networks inside the Group and with outside partners. A catalogue and on-line database of Biotech training modules are currently being developed.

- In 2010, 84 people were trained.
- In 2011, 81 people were trained.

Biolaunch Passport in Vitry-sur-Seine

Following the conversion of Sanofi's Vitry-sur-Seine site for the production of monoclonal antibodies, it will become one of Europe's largest production units dedicated to biotechnology. The Biolaunch project includes training employees for new jobs in biotechnology thanks to two programs – called Biolaunch Passport (for production) and Biotech Certificate (for analysis) – which offer both theory and hands-on courses. To date, 221 people have received training.

For more information:

- [\*People / Workforce Development / Action\*](#)

Switching to vaccine production in Neuville

To prepare employees for the switch to vaccine production at the Group's chemical site in Neuville, specific training programs are offered in biotechnology and biology for employees working in Quality Control, Bulk Production and other functions. Since late 2010, approximately 70 people have been trained.

For more information:

- [\*People / Workforce Development / Action\*](#)

## Supporting mobility in France

In France in 2011, Sanofi continued to implement the necessary changes for the Group's transformation, in particular with investment and conversion plans for chemical and biotechnology facilities over the next four years, as well as the organizational plan for Sanofi's commercial activities in France, which was presented at the end of 2010 and implemented in 2011.

For all reorganization projects, Sanofi is striving to provide high quality career support to Group employees by offering a variety of transition measures that have been negotiated with employee representative organizations.

The purpose of these measures is to anticipate changes related to the Group's business and economic model so that employees can deal with career changes in the future and develop skills.

These measures are also intended to avoid lay-offs by favoring internal mobility or external solutions:

- Voluntary departure plan: retirement, early retirement and assistance for employees who have another business project (i.e., starting a business)
- Career development assistance: training program, GPEC workforce planning agreement (in particular for changes pertaining to functions such as medical sales representative) and a training program for employees whose jobs are impacted by the transition to biotechnology
- Geographic mobility assistance

All measures are financed entirely by Sanofi. Prior to implementation, they are presented to and negotiated with employee representative bodies.

**For more information:**

- [\*People / Compensation\*](#) (see action)
- [\*People / Employee benefits\*](#) (see action)

## Assisting employees who wish to start a business

### In France

For over 30 years, Sanofi has had a dedicated entrepreneurial unit, Cellule Essaimage, devoted to helping employees who would like to start a business or purchase an existing business. This “start-up” entrepreneurial unit assists employees as they go through the various phases of business development of their project by calling on the necessary expertise inside and outside the Group and providing financial support.

In 2011, this assistance was offered to employees who started their own businesses. For example: medical sales representatives in France who opted for a voluntary departure within the scope of the GPEC workforce planning agreement for those affected by adaption plans for the transition to biotechnology.

In France, **43** businesses were created or acquired in **2011** with the support of the start-up unit.

Thanks to this program, 43 businesses were created or acquired in 2011, primarily in services (17), commerce (14), health and well-being (8), hotel and restaurant (3) and tourism (1).

| Projects completed in 2011            | Part of workforce planning(1) | Start-up for an individual project | Job protection plan |
|---------------------------------------|-------------------------------|------------------------------------|---------------------|
| Number of projects finalized          | 34 <sup>(2)</sup>             | 6 <sup>(2)</sup>                   | 3 <sup>(2)</sup>    |
| Number of projects led by women       | 23                            | 3                                  | 0                   |
| Number of projects led by men         | 11                            | 3                                  | 3                   |
| Number of businesses created          | 29                            | 6                                  | 3                   |
| Number of businesses acquired         | 5                             | 0                                  | 0                   |
| Number of jobs potentially created(3) | 40                            | 6                                  | 3                   |

- (1) The workforce planning agreement (GPEC) was implemented to offer prospects for certain functions (e.g., medical sales representatives, industrial affairs, etc.) and allow employees to acquire new skills to meet the technical and economic requirements of the ever-changing pharmaceutical sector.
- (2) Business sectors in which the 43 businesses were created or acquired: services (17), commerce (14), health and well-being (8), hotel and restaurant (3) and tourism (1).
- (3) Including entrepreneurs

## In Europe

In 2011, to keep pace with changes within the European pharmaceutical sector (reduced reimbursement rates, generic competition, etc.), Sanofi announced the implementation of a new organization for commercial activities to combine certain functions based on a multi-country approach. At the same time, the Group will continue to maintain ties with health authorities and patients at the local level to respond to each country's specific needs.

Sanofi seeks to limit the impact of this new organization on jobs and provides impacted employees with support – by enabling them to fill vacancies within the Group, or through outplacement, coaching, training to acquire skills for new positions within the Group or elsewhere, as well as assistance to start a business.

In every European country affected by organizational changes, negotiations with employee representative organizations took place throughout 2011 to communicate about changes and establish measures to support employees that are best suited to their local context. The objective is to inform employee representatives at the earliest possible stage so their viewpoints and suggestions may be taken into account.

In 2011, Sanofi also implemented all the measures needed to gradually integrate teams from Genzyme and Merial, two companies recently acquired by the Group, in order to harmonize processes and labor relations in accordance with local regulations concerning compensation, social protection, etc.

### In the United States

To address changes in the U.S. market, the anticipated patent expirations for certain major drugs, and increased generic competition, Sanofi continued to make adjustments to the Group's workforce in 2011.

The Group therefore announced in November 2011 that it would reorganize operational entities with the objective of resizing and repositioning pharmaceutical activities in order to keep up with the changes in the product portfolio.

In line with Group values, Sanofi implemented support measures for these employees, specifically in relation to the financial conditions of their departure and outplacement assistance. By December 2011, the new Sanofi U.S. Commercial Support structure was in place to be fully operational at the beginning of in 2012.

In addition, following the decision to close the R&D site in Bridgewater, NJ, the Group is offering the same generous and comprehensive employee support to what was offered during the previous restructuring.

### Strengthening teams in areas of high growth potential: the acquisition of Genzyme and the integration of Merial

Welcoming into the Sanofi family the teams of recently acquired or integrated companies is an essential part of supporting change.

In 2011, Sanofi pursued a development policy with major growth platforms such as biotechnology and animal health, and the Group finalized the acquisition of Genzyme and the integration of Merial.

Through this diversification, Sanofi is facilitating the integration of some 15,000 employees all over the world – making them part of the organization and enabling them to gradually apply the Group's standards and processes.

**At Merial**, some 5,000 employees are working in 27 countries where affiliates operate. Fifteen industrial sites are located in seven countries spanning four continents – bringing production closer to markets and making it easier to meet the regulatory requirements of government agencies. Merial also has nine R&D sites in four different countries and operates in 150 other countries through a network of distributors.

Merial is a world-leading animal health company, providing a comprehensive range of pharmaceutical products and vaccines to enhance the health, well-being and performance of a wide range of animals (cattle, swine, horses, dogs, cats, etc.).

In 2011, more than 15,000 people worldwide joined Sanofi following the acquisition of Genzyme and Merial

**At Genzyme**, over 10,000 employees worldwide contribute their biotechnology expertise with a focus on rare diseases, kidney disease, endocrinology, hematology, oncology, biosurgery and a number of products under development. Genzyme operates in over 40 countries with approximately 70 sites, including 11 production sites.

As one of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. During the integration of Genzyme, Sanofi has been committed to ensuring regular and transparent communications via a dedicated Integration Center on the Group's intranet, including newsletters, Q&As, a blog, company presentations, and top management videos, as well as townhall meetings. The creation of a dedicated workstream involving Genzyme and Sanofi helped each organization understand the other's culture, differences, and similarities. It played a key role in facilitating the successful integration of Genzyme.

In recognition of these initiatives, Sanofi won the European Excellence Award for communications about Genzyme's integration into the Group.

In 2011, more than 15,000 people worldwide joined Sanofi following the acquisition of Genzyme and Merial





In the frame of the Genzyme integration process, our Manufacturing and Quality teams are working together to provide high quality medicine for all of our patients.

**Ron Branning,**  
Senior Vice President Quality, Genzyme

## Workforce development

### Background and Policy

As a major player in the pharmaceutical industry, Sanofi's priority focus is healthcare. Our business activity, which is heavily regulated, requires employees to possess a wide range of skills and the ability to keep up with fast-advancing technologies. In addition, since 2009 Sanofi has evolved to become a more diversified global healthcare company that develops innovative solutions to meet patients' needs.

We believe that each and every one of our employees counts. Because the convergence of a broad range of talents is essential to our performance, Sanofi's people development policy strives to cultivate not only each individual's skills, but also their performance and their potential to keep pace with our ongoing business challenges. Our Human Resources policy is centered on the development of all the company's diverse talents, wherever they may be.

Our commitment to the philosophy underpinning this policy is demonstrated by:

- Maintaining and developing each person's competencies through continuous dialogue between managers and employees, in addition to training;
- Showing respect for the individual and recognition that diversity, in all its forms, is a source of strength and is critical to performance and innovation;
- Being aware of the changes in the business environment and adapting when necessary;
- Enabling each employee to understand the Group's strategy and culture, in order to best contribute to the company's performance.

Our commitment to human capital development not only ensures that the company has the appropriate skills but also enhances talent attraction and retention, employee motivation and innovation potential. The Group accomplishes this through a formalized process and through employee training and recognition.

“Professional training is an essential part of development for both the employees and Sanofi. Everyone has a duty and a right to undergo appropriate training, and to this end the Group provides the necessary resources and commitment.”

Excerpt from the Sanofi Social Charter



[Sanofi Social Charter](#)

## **Established Processes**

With regard to skills development, all employees are entitled to an interview with their manager at least once a year, during which they can discuss their strengths and potential development opportunities. At the same time, they can discuss future job prospects within the company. A new process is also used to manage talent by identifying each individual's ability, contribution and potential in alignment with our ongoing business challenges. Building on this established talent management process, our new approach is even more focused on fostering geographic diversity and developing talent in emerging markets.

## **Training is essential to professional development**

Training is one of the pillars of our People Development Policy and Process. Sanofi is committed to providing information and resources so that employees receive appropriate training to perform their jobs.

Training makes it possible to:

- Anticipate and react swiftly to support organizational changes and technological advances
- Ensure the necessary resources are in place to respond to the Group's economic needs
- Prepare and support career changes and talent development within the Group
- Provide for skill transfer and knowledge sharing

To meet challenges in the field, the various operational entities provide training at the appropriate levels.

Group-wide training is also provided, specifically to promote corporate culture and support the Group's strategy by offering managers opportunities for reflection, exchange and personal development.

Training activities are provided in a variety of formats:

- Group training: in a classroom setting
- Remote learning: e-learning
- Blended training: a combination of classroom and online training modules

### **Awarding Performance**

Our performance and recognition approach is aligned with the company's global business strategy and further supports the integration of our company by ensuring the ongoing professional development of our employees.

## Actions

- ▼ Talent attraction and retention
- ▼ General training
- ▼ Pharmaceutical sector specific training
- ▼ Awarding performance

### Talent attraction and retention

In 2011, the Group continued working with the new entities that are now part of the Sanofi family to converge talent management and other approaches designed to attract and retain employees. Below are two examples of such efforts.

#### Talent Management

The Group continued to develop a single approach to talent management in 2011 based on a “One Group, One Process, One Tool” principle that includes:

- Improved ability to anticipate and plan for the Group’s future needs in terms of professional skills and employee profiles,
- Improved cross-functional collaboration thanks to the "talent reviews" conducted jointly by the functions, as well as planned and shared development initiatives,
- Ensuring consistency of the "talent review" process by implementing common methods within the various Group entities,
- Acknowledging the significant role of managers as drivers of talent development and sharing within the Group.

One important aspect of this new talent management approach is fostering geographic diversity for employees who are candidates for promotion within Group management. This also helps develop talent in emerging markets.

All development programs implemented by the Group follow a single competencies model based on the LEAD concepts (Leadership, Empower, Act, Deliver). This model provides a reference for all Sanofi employees worldwide.

## BUSINESS CASE



### Sanofi's China Talent Center

Sanofi's China Talent Center was launched in 2010 as a global pilot program enabling the Group to match individuals with the right skills and experience to the right job. This approach furthermore helps Sanofi retain talented employees and strengthens our reputation in China as an employer that values talent and allows individuals to develop to their full potential.

- [Business Case: China Talent Center](#)

## New global employer brand

Over the course of 2011, an international Human Resources (HR) and Communications project team worked together to develop a new global employer brand in order to attract talent to meet our current and future business needs. This new global brand will be provided to affiliates and business divisions to promote our global image and reputation as a preferred employer.

The active engagement of Zentiva, Genzyme and Merial in developing our new employer brand will give us the opportunity to speak with “One Sanofi Voice” as an employer and develop our brand recognition among elite talent more globally. Branding visuals and support materials will be launched in March 2012 and affiliates and businesses will be able to customize the branding to suit their local and business needs.

The international project team is made up of HR / Communications representatives from Brazil, China, India, Mexico, Russia, South Africa, France, Germany, Spain, the United Kingdom and the United States.

### For more information:

- [People / relationships with schools and universities](#)

## General training

### The process

For training purposes, Sanofi uses a tool called the “individual development plan,” which allows each employee to identify specific training programs and other development initiatives. In addition, a large number of employees have access to the Learning Management System,

which inventories all available classroom and on-line training. It retains individual information for each employee.

Employees receive regular performance and career development reviews in all countries with a rate of 100% in several countries including: Japan, Korea, Australia, Hong Kong, New Zealand, the Philippines, Malaysia / Singapore, Spain, Ukraine, Pakistan, Columbia, South Africa, Argentina, the Netherlands, India and Turkey.

**82%** of employees participated in training programs in 2011 in France, which represents **23,288** people.

In 2011 in France, 23,288 employees participated in training initiatives, which represents 82% of French employees. The average number of hours spent on training is the equivalent of 29.5 hours per employee. The French headcount represents 25% of the total headcount of Sanofi.

In addition, in countries such as Hong Kong, New Zealand, Turkey, Ukraine, South Africa, Algeria, Columbia and Malaysia/Singapore, the average number of hours of training per employee is between 16 and 30 per year.

In other countries, the number of hours of training is even higher, in particular to respond to specific skill development needs for one or more job categories. This has been the case in Mexico, Australia (sales force), Pakistan, Spain and Russia.

### Corporate Development programs

For a number of years, Sanofi has organized a broad range of Group-wide, international programs to train our managers. To support changes in Sanofi's strategy and structure, new programs were developed in 2011. Thanks to our senior leaders, Sanofi has the means to succeed and continue our performance in growth markets.

**357** managers participated in the various international career development

In 2011, we developed new programs, including Matrix, Accelerate and Innovate, while continuing established programs such as Discover, Evolve, Explore, Pilot and Perspective. Each program brings together managers from diverse geographic horizons and from all Group functions, allowing them to adopt common managerialÁ

## programs: Accelerate, Discover, Evolve, Explore, Pilot, Innovate and Perspective.

practices both as individuals and within teams. A total of 357 managers took part in at least one of these programs in 2011.

Matrix

Introduced

Introduced in 2011, the Matrix program provides a tool set that increases a managers' ability to work effectively in a matrix environment and find solutions to real business issues through more effective cooperation. It also aims to build on and increase cross-functional cooperation within Sanofi.

Accelerate

Also new in 2011, Accelerate is a senior management program to embed the organization's new leadership skills in terms of behaviors, competencies and management principles. Designed for global senior leaders, it helps participants understand the link between the company's strategy and culture, and it teaches them to be role models for the LEAD competencies (Leadership, Empower, Act, Deliver).

Innovate

Innovate is a program targeting individuals with a "change agent" profile and mindset, who are identified through the Sanofi Talent Management process. They come from all over the world and from various functions. The program is intended to develop leaders and reinforce strategic awareness and capabilities. It enhances participants' ability to think in an innovative way and build cutting-edge strategies.

Discover

As a global orientation program for recently appointed senior leaders, Discover is designed to accelerate integration, strengthen a sense of belonging to the Group and cultivates passion. Discover is intended for managers who recently joined the Group or one of our affiliates, and who hold responsibilities with an international scope. During the program, each participant has the opportunity to gain a better vision of the Group's diversity, complexity and business environment from a global perspective. Managers learn to communicate on Sanofi's strategy and convey messages about the company's culture, values, expected competencies and behaviors.

Evolve

Evolve is an international development center for employees with three to nine years of professional experience who have exhibit the skills considered to be essential in a future leader.



Evolve is designed to contribute to retaining and motivating junior talent, develop participants' competencies as a way to impact current and future performance, and support each individual in identifying key strengths and development needs.

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The Explore program is designed for team managers, project managers and team coordinators, from all functions and countries, with ten to 15 years of professional experience. As an international development centre for individuals with high potential, it provides managers with a broader vision that goes beyond their function or region and allows them to develop international, Group-wide networks. This program is especially beneficial for managers working in an international environment or moving to one in the near future.

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Pilot

Úä] cis is designed for managers from all functions in the French-speaking countries where the Group operates who are in charge of managing others. The program helps them facilitate the transition from the role of manager to the role of leader and team developer. It enhances participants' ability to take the initiative and make decisions and empowers teams to achieve results through clear objectives.

| CORPORATE DEVELOPMENT PROGRAMS |          |        |         |       |              |            |          |            |
|--------------------------------|----------|--------|---------|-------|--------------|------------|----------|------------|
| 2011                           | Discover | Evolve | Explore | Pilot | Perspectives | Accelerate | Innovate | Total      |
| Number of participants         | 60       | 95     | 52      | 21    | 20           | 85         | 24       | <b>357</b> |
| Number of nationalities        | 24       | 22     | 18      | 1     | 5            | 14         | 15       | <b>45</b>  |
| % women                        | 25%      | 56%    | 35%     | 24%   | 25%          | 27%        | 50%      | <b>37%</b> |
| Length of training (days)      | 2.5      | 2.5    | 3.5     | 9     | 6            |            |          |            |

Six support function academies to promote learning, sharing and partnering

The transformation of the Sanofi business model prompted the Support Functions to take an in-depth look at how they will help the Group meet future challenges as a global healthcare leader. As part of this review, the six Support Functions sought to identify the new competencies needed to actively support the Group's transformation and to improve their contribution to Sanofi's business performance.

From this process emerged an ambitious project to create six academies, one for each Support Function: Procurement, Communications, Finance, HSE, Legal and Human Resources (HR).

The academies will prepare each function to fulfill its role as an essential strategic partner as well as a source of expertise and advice.

They will facilitate best practice sharing and networking; they will define a common framework of knowledge and expected competencies for each function. Additionally, they will provide the means to strengthen technical competencies as each function develops and expands its business partner role.

All Group entities are taking part in this far-reaching corporate program. The goal is for participants to develop a new approach to their function, with a stronger emphasis on acting as a source of advice and helping forge business partnerships.

*The first academy, devoted to Human Resources, was launched in 2011 with a bold ambition: to develop a new HR culture and create a sense of family that shares the same values when it comes to roles, competencies, knowledge and language. By 2014 a training program called ONE will be introduced for 750 Sanofi HR managers from all countries.*

*Three ONE sessions, mixing participants from all Sanofi's Activities and Regions were organized in 2011. The 67 participants (43 women and 24 men) were 54% from Pharmaceutical Operations, 16% from Industrial Affairs, 15% from Support Functions, 7.5% from R&D and 7.5% from Vaccines.*

*A rich network also developed, including a collaboration platform and specialized training modules (compensation and benefits; people and organization development; etc.). Local training modules for different countries were also developed to take into account specific or urgent development needs. \**

The other academies are slated to begin in 2012 with 23 priority programs: 45 sessions in France and 25 in the U.S.

In the long term, the Support Function Academies will enhance career development and in-house mobility, help create a sense of belonging and commitment, and strengthen Sanofi's image as an employer.

Distributing and understanding the Code of Ethics: a major 2011 accomplishment

Sanofi also implemented training programs at a broad scale for transversal issues. For instance, the Group distributed a new Code of Ethics at all sites worldwide in April 2011. Wishing to enable as many employees as possible to read it in their own language, Sanofi decided to provide translations of the new code in numerous languages. By late 2011, it had been translated into 30 languages. All versions are available on the Group's intranet as well as our corporate website. Other languages should be available in 2012. By late 2011, 76,000 employees had receiving training about the new Code of Ethics in 90 countries.

For more information:

- [Our vision / Policies and management systems / internal policies / code of ethics](#)

## Pharmaceutical sector specific training

### Employee training for regulated activities

The Group organizes training sessions at all levels to maintain and develop employee skills, including for regulated activities. In 2011, a total of 19,942 employees successfully completed Pharmacovigilance awareness training.

Within Sanofi's Industrial Affairs function, employees received training on Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), Good Distribution Practices (GDP) and other practices. Designed to ensure compliance with regulations, this type of employee training is mandatory and subject to inspections by health authorities. In 2011 for instance, the average hours of training per employee in Industrial Affairs activities is 29.51 hours.

For more information:

- [Pharmacovigilance section](#)

### Biotechnology training for employees in France

Within the scope of the Sanofi industrial network's increasing focus on biotechnology, it is our responsibility to provide training for all affected employees so that they can acquire new technical skills. Sanofi has created various programs to facilitate the transition to biotechnologies.

#### Campus Biotech

This is a Group initiative to develop tailored employee training programs in bioproduction and bioanalysis. Organized in partnership with recognized universities in France and Germany, it aims to build bridges among various functions and divisions, including Industrial Affairs, R&D, Sanofi Pasteur, Merial and Genzyme.

In addition to providing employee training, Campus Biotech has become a reference within the Group as an in-house university of sorts that capitalizes on the Group's technical achievements as well as experts' networks inside the Group and with outside partners. A catalogue and on-line database of Biotech training modules are currently being developed.

- In 2010, 84 people were trained.
- In 2011, 81 people were trained.

### Biolaunch Passport in Vitry-sur-Seine

Following the conversion of Sanofi's Vitry-sur-Seine site for the production of monoclonal antibodies, it will become one of Europe's largest production units dedicated to biotechnology. The Biolaunch project includes training employees for new jobs in biotechnology thanks to two programs called Biolaunch Passport (for production) and Biotech Certificate (for analysis) that offer both theoretical and hands-on courses. To date, 221 people have received training.

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#### For more information:

- [People / Supporting change / Actions](#)

## Awarding performance

### Employee awards program at Sanofi Pasteur in the United States

Because strong teamwork is critical to Sanofi Pasteur's success, in 2011 the vaccines business in the United States introduced an employee awards program called BRAVO Team! This new initiative has proven to be an excellent way for employees to receive recognition for their efforts and accomplishments.

Employees can nominate their own team, or be nominated by their managers or internal customers, in recognition of their outstanding performance in one of three categories: improving business results, increasing productivity and efficiency, and exemplifying the Sanofi culture.

Since the launch of the BRAVO Team program, more than 3,200 rewards and e-cards have been presented to distinguish employees.

On a quarterly basis, each nominated team is asked to give a five-minute presentation about their project to the BRAVO Team Committee. A winning team is then selected by the Committee to contend for the BRAVO Team President's Award, which is given annually to one team from each of the three categories. The winners receive a trophy, recognition at the all-employee meeting in 2012, and \$300 per person.

## Sanofi distinguished as a preferred employer

### Brazil

Sanofi was distinguished as the most admired pharmaceutical company in Brazil in 2011. Based on Fortune Magazine's "Most Admired Companies" model, this award recognizes firms in Brazil's principal economic sectors and highlights the factors that contribute to building their image and reputation: innovation, ethics, customer service, quality of management, and CSR performance, as well as overall commitment to the country.

A panel of 1,300 opinion leaders from 40 economic sectors selected the winning companies. Ten ministers, the Governor, and the Mayor of Sao Paulo all attended the awards ceremony. In addition to the political prestige associated with this distinction, it is representative of the considerable standing and brand awareness achieved by the Group in Brazil in recent years.

### France

In the Rhone-Alpes region of France, Sanofi received the Employeur 2011 award, which is given to the most attractive companies. Sanofi was selected for this award based on opportunities for employees to develop their careers and their professional competencies. With Genzyme, Merial and Sanofi Pasteur, the Group is the largest private employer in the greater Lyon area and the third largest in the Rhone-Alpes region. As a center of excellence in industrial biology, Sanofi provides employees with multiple opportunities to further their careers.

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Business Case

### Retaining valuable employees thanks to the China Talent Center

#### The challenge

To build a talent pipeline that will meet the requirements of China's business growth and provide a platform to develop leadership competencies across businesses and functions.

#### Our response

The China Talent Center was set up to attract and develop talents using the Global competency model to enrich a talent pipeline that will satisfy tomorrow's needs in line with China's business growth.

Across businesses and functions we select talented individuals who will receive training based on Sanofi's global LEAD competency model. Their preparation goes beyond industrial and technical knowledge and experience.

We have developed three key programs based on LEAD competencies:

- **Strategic Sourcing:** This is the 'Build' model. The LEAD competencies are applied on campuses (undergraduate college and business schools) and for recruitment purposes. We create specific programs to fill critical talent gaps, such as the Brand Management Trainees program, the Purchasing program, etc.
- **Assessment and Career Development:** The LEAD competencies are applied in leadership assessment, talent readiness assessment, and career path design. We have created a talent acceleration program (TAP) for future potential managers, and built a strong team of 46 assessors. We also have developed a new, systemic way to fill internal first-line manager vacancies.
- **Leadership Development,** designed to meet two types of needs: Level 1 is for managers leading individual contributors and Level 2 is for managers leading other managers.

## Benefits for stakeholders

For employees:

Individual employees benefit from this program because they are able to develop their leadership skills based on LEAD.

Managers are better able to evaluate employees' performance, which contributes to driving the long-term success of China's business operations.

## Opportunities for the Group

The China Talent Center allows the Group to match the right skills and experience to the right job while ensuring we retain talented employees. In addition, it gives us the opportunity to replicate proven tools and approaches in the Asian region and further leverage existing practices. It helps preserve our capacity to meet growing needs during expansion, so that our current operational performance will be sustained.

It moreover provides a solution to the problem of high turnover in Shanghai and helps feed a talent pool for brand management by product.

Last but not least, this initiative improves the Group's visibility and strengthens our reputation in China as an employer that values talent and allows individuals to develop professionally to their full potential.

## The Future

Originally launched in April 2010, the China Talent Center has been an excellent global pilot program for the Group. In the future we plan to progressively replicate this type of initiative in emerging markets.

## Relationships with schools and universities

### Background and Policy

Attracting future talent is a vital challenge for Sanofi. We continue to strengthen our reputation and strive to remain a preferred employer.

As a diversified healthcare leader focused on patients' needs, Sanofi offers careers with a higher purpose – starting with our internships and entry-level programs. The Group's relationships with a growing number of schools and universities and the International Corporate Volunteer (VIE) Program provide students with numerous opportunities to learn about and apply to join the Group.

In 2011, Sanofi's strategy with respect to schools and universities was aligned with our new business approach and market needs, based on:

- Formalizing relationships and sponsorships with global academic institutions in line with our business needs through healthcare (core business) and regional areas (emerging and growing markets)
- Building targeted relationships and partnerships with global academic institutions and campuses
- Enhancing our global capacity to source and attract graduate talent
- Attracting recent graduates through local and country graduate development programs
- Developing and deploying our renewed global employer brand
- Increasing our visibility on campuses and making Sanofi an attractive employer of choice



## Actions

- ▼ [International Corporate Volunteer Program \(VIE\) Sponsored by the French Government](#)
- ▼ [Collaborating with schools and universities](#)

### International Corporate Volunteer Program (VIE) Sponsored by the French Government

Sanofi is the largest VIE recruiter in the healthcare industry, with around 150 volunteers (interns) on assignment all over the world. Our VIE program is an integral part of our global talent development policy.

We recently implemented a new VIE strategy to build a comprehensive graduate development program, starting with an internship period within Sanofi prior to a VIE assignment. We offer VIE positions for 12 to 24 month assignments with our affiliates in Africa, Asia, Australia, Europe, the Middle East, North America, and Latin America. These are positions in functions ranging from finance to marketing and purchasing, supply chain, and R&D. Volunteers (interns) are entrusted with real responsibilities in a competitive, complex environment that provides them with genuine opportunities to learn, grow, and acquire new skills.

We pay close attention to the performance of VIE participants, with the aim of recruiting the most talented among them for our worldwide organizations. Each year, between 15 and 20 VIE participants are hired by Sanofi.

For the second consecutive year, V.I.E at Sanofi in Vietnam once again won the Grand Prix V.I.E. The prize-winner was rewarded among 77 VIE working in 47 companies due to her overall missions, performances and integration in our Vietnamese affiliate and within the Group.

**For more information:** [Careers section of the Sanofi website](#)

- [en.sanofi.com / Careers / V.I.E](https://en.sanofi.com/Careers/V.I.E)

### Collaborating with schools and universities

In many countries, we take part in career fairs as a means to meet our recruitment needs. Sanofi has built collaborations with a selection of schools and universities worldwide, offering students the opportunity to learn about a wide range of positions in the pharmaceutical industry.

To help those school and university graduates who are selected develop their talents and abilities, Sanofi has established internships and development programs in several countries to introduce recent graduates to the world of healthcare. Today we are strengthening these ties in growing markets, particularly in the BRIC countries. See examples below.

## Global programs

### Sanofi sponsors the INSEAD Alumni Healthcare Summit

Sanofi recently collaborated with the INSEAD Healthcare Alumni network as the principal sponsor of the annual summit conference entitled “Incumbents and Insurgents,” held in Berlin in early October 2011. The summit allowed Sanofi to strengthen our campus relations and meet future INSEAD graduates. 150 thought-leaders, industry experts and entrepreneurs from pharmaceuticals, medical devices, diagnostics, healthcare services, academia, finance and non-profit organizations came together during panel sessions and focused workshops to share their perspectives on cutting edge developments in science, technology, new business models and new societal demands.

Ten MBA students were invited to attend and were able to meet Sanofi’s Chief Strategy Officer and Group HR graduate development team for one-on-one interviews for consideration for potential opportunities within our worldwide organizations. For more details about this event:

- [www.inseadhealthalumni.net](http://www.inseadhealthalumni.net)

Sanofi sponsored the INSEAD Alumni Healthcare Summit in Berlin and invited 10 MBA students who were given an opportunity to meet Sanofi’s Chief Strategy Officer and Group HR graduate development team for one-on-one interviews.

### Diabetes division trainee program to develop a diabetes talent pool

To attract top talent, the Group developed a trainee program to support the development of expertise in diabetes. Potential candidates have earned a university degree, are mobile and flexible, and are ready to take their first steps in developing a potential international pharma marketing and medical career. Following completion of the program, they may have acquired skills to support potential development into responsibility and leadership roles.

Trainees are recruited in close cooperation with selected affiliates, and during the 18-month program they travel between our diabetes central division in Frankfurt, Germany, and their

home affiliates. In addition to project assignments, they receive diabetes training and take part in development programs. Ultimately, the trainees may be asked to join their home affiliate.

The first four European participants who recently completed the program will join Sanofi as project and product managers in Switzerland and Germany. In addition, two new candidates began orientation in China in mid-2011.

In the diabetes division, a trainee program supports the development of a talent pool focused on diabetes. The first 4 European participants who recently completed the program will join Sanofi as project and product managers in Switzerland and Germany. In addition, 2 new candidates began orientation in China in mid-2011.

## Country programs

### France

#### Creation of the Biotech Sanofi–ENSTBB Chair

Sanofi has formed a collaboration with two institutions in Bordeaux, France: École Nationale Supérieure de Technologies des Biomolécules de Bordeaux (ENSTBB) and Fondation Bordeaux Université. To support the growing emphasis on biotechnology, together they decided to create and fund the Biotech Sanofi-ENSTBB chair.

A number of other initiatives were implemented in 2011 and will continue in 2012. Three “Introduction to Biotechnology” conferences were held in Paris, Bordeaux, and Lyon, bringing together students, teachers, scientists, and Sanofi employees. Speakers addressed the world of biotechnology and applications in the field of healthcare, particularly for the development of new drugs.

The biotechnology chair sponsors also welcomed ENSTBB students at the European Parental Drug Association (PDA) Congress in December 2011, giving them an opportunity to meet experts attending the congress, which was held in Bordeaux.

One of the purposes of this chair is to provide support for projects and to promote sharing expertise among ENSTBB faculty and biotechnology specialists from Sanofi.

## Merial organizes initiatives with veterinary schools

For over 20 years, Merial, Sanofi's animal health division, has developed initiatives as part of a long-term collaboration with the four veterinary schools in France and their students. These initiatives illustrate Merial's involvement in the veterinary community to help train future veterinarians and promote research and exchange.

Merial teams provide educational support including conferences and technical documentation. They also invite vet students to visit Merial sites in France. The Merial Veterinary Scholars Program, a U.S. initiative that was recently introduced in Europe, allows three French students to attend an American veterinary school for a research internship. Another initiative consists of an annual challenge to encourage students to suggest ideas to improve animal health. In addition, scientific collaborations between veterinary school faculty and Merial's veterinarians are organized on a regular basis.

## Charter to promote the development of work / training programs

Sanofi signed the charter to facilitate the development of work / training programs to encourage this option and simplify implementation. The Group made commitments in 2011 to:

- Increase the number of trainees by mobilizing all Human Resources managers to host 1,033 trainees with the Group in France.
- Promote integration into the workforce for trainees or support their integration.
- Mobilize institutes of higher learning and grandes écoles when taking part in job fairs they organize.

**For more information:** (in French)



[\*Charte de mobilisation en faveur du développement des formations par alternance dans les entreprises\*](#) (PDF, 849Kb)

In 2011, Sanofi signed the Charter to promote the development of work / training programs and committed to increase the number of interns by mobilizing all managers and Human Resources directors to host 1,033 trainees with the Group in France.

## Spain

The Talent Graduate Program was initiated four years ago in Spain to attract recent graduates with high potential and give them access to their first experience with a multinational company. The program is designed to prepare these recent graduates for the professional world and future job challenges.

This 12-month talent program consists of full-time training, allowing trainees to acquire extensive business exposure and work on specific projects in various areas of the pharmaceutical sector.

Since 2007, 70 trainees have taken part in this program. At the end of their training, 34 were asked to stay on with Sanofi, either at our Spanish affiliate or in other countries. This initiative has bolstered Sanofi's partnership with selected Spanish universities and business schools. It also enables the Group to stay in contact with students.

In Spain, a 12-month full-time training program allows trainees to acquire extensive business experience and work on specific projects in various areas of the pharmaceutical sector. Since 2007, 70 trainees have taken part in this program; 34 were given the opportunity to continue with Sanofi after completing the program, either with our Spanish affiliate or in other countries.

## United States

To encourage new university students to develop their talent and skills, Sanofi has set up three leadership development programs for recent university graduates, providing them an introduction to the world of healthcare.

### MBA Internships: Minds Matter Program

Our highly selective, two-tier MBA Internship Program is designed to encourage the development of talented Sanofi interns and associates. Students selected for summer internships are offered the opportunity to collaborate on important projects within US Pharmaceutical Operations. This program aims to challenge and motivate participants through meaningful assignments in marketing, field sales, and strategic development while enhancing business and leadership skills.

The best performing participants may be invited upon graduation to take part in a rotation (approximately two years) of strategic opportunities throughout the organization. Potential

assignments may include rotations in sales & strategy, integrated health, marketing and other projects or assignments.

## MBA graduates: Management Associate Program, Sanofi Pasteur (Vaccines)

This three-year program provides recent MBA graduates an opportunity to develop skills through extensive rotational assignments within Sanofi Pasteur's marketing and sales organization. Associates rotate through three to four assignments, gaining broad exposure to a number of functions and areas.

One of the most important components of the program is developing close working relationships with senior level managers and colleagues. Working alongside people with various levels of expertise and working styles further allows participants to accelerate the development of personal strengths, discover their unique approach to leadership, and build potentially long-lasting business relationships.

## Undergraduates: Management Associate Program, Sanofi Pasteur (Vaccines)

Throughout this two-year intensive Marketing and Sales program for recent undergraduates, associates develop skills as they rotate through four assignments within the organization, gaining experience in many facets of the business. Each rotation is designed to be a building block preparing participants to excel.

One of the critical aspects of the program is the close working relationship with senior level managers and other members of our extended team. The guidance and feedback they may provide helps play a role in setting goals and monitoring participants' progress and development. Another highlight is the ability to build a network of mentors who may contribute to shaping participants' careers.

In addition to these important collaborations, participants are encouraged to further their formal education through application to participate in our tuition reimbursement program. From pursuing higher education to utilizing e-Learning courses and taking part in internal training, Sanofi Pasteur endeavors to help participants achieve immediate and future career goals.

**For more information:** Careers section of the Sanofi website

- [en.sanofi.com / Careers / Careers](https://en.sanofi.com/Careers/Careers)

## India

- Internship program

In the last quarter of 2011, Sanofi established ties with selected schools to focus on developing a talent pipeline for 2012. Sanofi initiated contact with over 100 colleges in India, reaching approximately 1,000 students. In the second quarter of 2012, we will select around 15 students from across India to participate in summer internship projects for a period of two months. This will help the Group carry out projects through academic institutions that bring new perspectives and also allow us to identify students with strong potential who could be asked to join the organization.

## Thailand

- Pharmacy school partnership

Every year Sanofi organizes a campus visit to eight universities nationwide to introduce the company and present the pharmaceutical industry to senior pharmacy students as a way to provide them with a view of potential future careers. Sanofi “Ambassadors” or volunteer staff, who are either student alumni or people working in neighboring areas, take part by sharing with students their professional stories, key achievements, and positive experiences working at Sanofi. The company provides internship opportunities, ranging from six weeks to three months, to around 30 pharmacy students so that they can understand the business, acquire knowledge and training as well as practice in the field in areas such as sales, marketing, and regulatory affairs. Upon completion of the internship, students receive a certificate from the company management.

## The Philippines

- Work appreciation program

Through our work appreciation program, Sanofi offers university students the opportunity to gain understanding of workplace experience and develop a work ethic by exposing them to professional situations. This gives the students a chance to gain the necessary skills and experience in working environments relevant to their field of study under the guidance of sponsoring departments in the company. The program is also open to young applicants from underprivileged backgrounds in line with Sanofi’s commitment to attract a diverse and talented workforce.

## Compensation and employee benefits

Sanofi strives to ensure suitable recognition for both individual and collective performance. Regardless of an individual's country, position or function, the Group seeks to offer high-quality benefits for all employees.

In addition, Sanofi has programs and has put in place specific organizations to promote work life balance. We also support employees' children in order to deliver on employees' expectations and provide assistance to their children who may be faced with difficulties.

Group compensation, and employee benefits policies, work life balance programs and initiatives to support employees' children are implemented in each country in accordance with local practices, laws and regulations.



## Compensation

### Background and Policy

Sanofi's compensation policy is designed to reconcile recognition for individual performance and internal equity, while taking into account the Group's position in the local economic environment.

In line with Sanofi's ambition to be a global, diversified and sustainable healthcare partner focused on patients needs, a culture of performance drives all our Human Resources processes.

All employees must be recognized for their contributions and our top performers must be substantially differentiated.

### Actions

▼ [Worldwide performance and recognition process](#)

▼ [Examples of local initiatives](#)

### Worldwide performance and recognition process

In **2011**, Sanofi implemented a new global performance and recognition process worldwide.

In 2011, a new global performance and recognition process was implemented worldwide.

With a strong emphasis on harmonization, this new process uses one global annual compensation review cycle, one tool and one calendar, so that compensation decisions:

- Take place based on performance assessment
- Adhere to established guidelines and principles
- Are clearly communicated to employees

Employees are compensated on the basis of their business achievements, the contribution they make in relation to their own achievements and also to their peers, as well as benchmarking of compensation offered by other companies in the same industry, for the same job and at a standard level of performance.

Our compensation policy is designed to reward short-term achievements, mid-term contributions (i.e., sustainable value for the organization) and the Group's long-term success.

The levels of base pay used by the Group as well as our targeted compensation mix (including fixed wages, variable compensation and long-term incentives) must be aligned with market practices. Sanofi's objective is to pay all employees at a competitive level. A competitive wage range is established for each position.

- Individual variable remuneration (IVR) is an important component of the total remuneration for eligible employees. Through IVR, we wish to reward employees for their contribution to business success at various levels in Sanofi. The rules governing the plan are identical across all activities and geographic zones to ensure employees are treated in a fair and consistent manner. With the changes implemented in 2011, we aim to increase flexibility and differentiation in the IVR recommendations.
- Long-term incentives represent a formal and explicit way of expressing to key employees how much we value them.

The Group also pays particular attention to ensuring that there is no discrimination in compensation between women and men in like roles and to preventing all forms of unlawful discrimination.

## Examples of local initiatives

### In France: Variable collective compensation

In France, the Group distributed variable collective compensation to more than 28,600 employees in 2011.

The goal of variable collective compensation, which brings together voluntary and statutory profit-sharing, is to give all employees in France an interest in the company's performance by favoring lower-paid employees. The company enhances this collective program by topping up employee contributions to the employee savings plan (PEG) and / or the collective pension savings plan (PERCO).

The amounts distributed or allocated in 2011 (for financial year 2010) to 28,617 beneficiaries amounted to €253.3 million, which represents 16% of the total payroll (including the employer's top-up of employee contributions).

In June 2011, 81% of employees who were eligible for variable collective compensation for financial year 2010 chose to invest in the PERCO plan.

In 2011, a new Group profit-sharing agreement was concluded for a three-year period. Sanofi and employee representatives also approved new agreements to enable the Group to contribute more to employees savings within the PEG and PERCO plans, so that as many employees in France as possible will have access to greater top-ups for smaller amounts invested.

In addition, in November 2011, each eligible employee in France received a €600 (gross) bonus following new French legislation enacted on July 28, 2011. In total, Sanofi distributed €17.9 million to employees through this additional profit sharing scheme.

### Ensuring a minimum wage to cover essential living expenses in various countries

In the Group's efforts to attract and retain talent, Sanofi applies a compensation policy that is broadly superior to local legal minimums.

In France, for example, the Sanofi minimum wage at hire in 2011 was 25% higher than the legal minimum wage (SMIC). After one year of employment with the Group, employees receive a minimum wage that is nearly 39% higher than the SMIC.

This incentive compensation policy is extended internationally, in particular in emerging countries.

In India, the Sanofi minimum wage at hire is 11% above the local minimum wage. Once employees have been with the company for one year, this minimum wage is raised to 45% above the legal minimum.

In Hungary, the lowest wage paid by the Group has just been raised to 45% above the legal minimum wage.

Similarly, the lowest wage paid by Sanofi in Turkey is 67% above the legal minimum wage.

## Employee benefits

### Background and Policy

Sanofi strives to ensure that all employees worldwide have high-quality benefits and income for retirement.

Sanofi takes part in an annual survey of employee benefits in 67 countries around the globe. 17 major pharmaceutical multinationals participate in this survey.

Each plan must aspire to equitability, respect for others and compliance with local regulations and cultures. It must also encourage individual accountability. In order to facilitate this approach, and to allow benchmarking, Sanofi participates in an annual survey of employee benefits in 67 countries around the globe. The participants in this survey are 17 major pharmaceutical multinationals.

The Group is careful to ensure such employee benefit plans are designed for the long term:

- The guarantees provided must not be excessive, but must cover all local needs and complement any state-run plans that may already exist. They also must be competitive in the market place.
- Financial commitments must be contained over the years and not create future debt that will burden tomorrow's workforce and hinder growth.
- Insofar as possible, strong local partners are in charge of management and implementation of coverage.

### Actions

In 2011, Sanofi continued the implementation of its global employee benefits policy, which was introduced in 2004.

Further to the acquisition of Genzyme in 2011, Sanofi underwent a country-by-country review of the benefits programs in all concerned countries. This review included medical, disability, life insurance and retirement plans. The objective is to ensure, starting from 2012, that there is a plan for full harmonization of employee benefits within the different entities of the Sanofi Group.

In addition to this review, in 2011 the Group undertook the following initiatives:

In Angola:

We implemented a local medical plan.

In West and Central Africa (12 countries):

We completed a review paving the way for implementation of a supplementary pension plan for all employees.

In Egypt:

We put in place a new medium-term retention plan for high and early potentials in order to retain our key talent. A new savings / retirement plan is also being prepared for implementation in January 2012.

In Jordan, Palestine and the Gulf States:

We improved life, disability and health coverage.

In Pakistan:

We improved the pension plan by harmonizing pension retirement dates and increasing the accrued years limit.

## Work-life balance

### Background and Policy

The balance between private and professional life figures prominently in the Sanofi HR and Diversity policy. This issue is taking on growing importance for the Group because it corresponds to employees' personal needs and expectations.

Today, more and more employees seek to establish a balance between their private and professional lives. This balance is important for individuals' personal development, while for businesses it represents a strategic challenge. When company policies and corporate culture respect the need to harmonize personal and professional life, they are in a better position to attract, motivate and retain employees.

| Opportunities to support work life balance  | Actions  |
|---|--|
| Increase workplace flexibility              | Focus on respect for schedules, meeting etiquette, flexibility concerning hours worked per day, part-time work   |
| Increase services to help with daily duties | <ul style="list-style-type: none"><li>● Offer grocery shopping, post-office, gift provider</li><li>● Administrative tasks – documents</li><li>● On site cleaners</li></ul>           |
| Increase services to help families          | <ul style="list-style-type: none"><li>● Support daycare solutions</li><li>● Offer generous maternity leave and parental leave</li><li>● Manage unexpected events – illness</li></ul> |
| Develop activities outside the workplace    | Offer activities to build stronger ties among employees- sports and/or cultural association  |

Sanofi is committed to respecting our employees' private lives (see below, Sanofi Social Charter, Article 7) and, as much as possible, to providing conditions that allow employees to harmonize their professional and private lives, in accordance with local practices and circumstances. Sanofi encourages local initiatives on this issue at the country, and even the site level, in order to better respond to employees' personal needs and expectations.



[\*Sanofi Social Charter\*](#) (PDF, 298Kb)

“Sanofi undertakes to respect its employees' private lives and, as much as possible, to provide conditions that allow employees to reconcile their professional and private lives.”

Excerpt from the Group Social Charter, Article 7



## Actions

- ▼ Initiatives to promote workplace flexibility and balance
- ▼ Facilitating family life for male and female employees

### Initiatives to promote workplace flexibility and balance

Striking a balance between employees' private and professional lives motivates employees and promotes higher productivity. Mindful of the importance of maintaining this balance, Sanofi has implemented specific programs for the benefit of both male and female employees worldwide. Such initiatives include, for example:

- Allowing flex time for arrival and departure (in over 20 countries)
- Offering to allow employees to work part time (in 17 countries)
- Enabling employees to work from home occasionally or in an “organized” manner (in approximately 15 countries)

In 2011, Sanofi U.S. launched a new flexible work policy within the scope of their work-life balance program. They introduced new ways of working and updated policies with respect to flexible hours, occasionally working from home, working part time and job sharing...

In France several sites have implemented concierge services to provide a range of services to ease the burden of a number of personal daily constraints for the residents: home services (babysitting, housekeeping, tutoring), delivery of gifts, car services, various reservations etc.

In addition, in line with Sanofi's commitments regarding employment of disabled persons, sheltered workplace (a company that employs people with disability) offers laundry, dry-cleaning and sewing services on-site for our employees.

In an effort to reduce traveling, teleconference and IT equipment have been installed to facilitate virtual meetings for employees at various sites, including Brazil, China, Japan, the U.S., France and Germany.

In Japan, the project called “La Maison” organized events to celebrate Diversity Week in October 2011. One initiative focused on supporting women to improve their work-life balance and to develop their professional careers. Another highlighted expanding job categories at “La Maison” Service Center, which employs individuals with disabilities. Displays at the cafeteria

of the Hatsudai head office addressed a range of topics, such as improving the health of mothers and infants and discussion groups for women employees with children.

In Mexico, during the first Franco-Mexican Forum on Social Responsibility, the Vice President of Sanofi Pasteur for Latin America participated in an encounter on quality of life in the workplace where he discussed Sanofi's work-life balance program.

In Spain, the Armoniza project focuses on best practices for scheduling meetings and greater flexibility in arranging working hours and vacation dates.

In Australia, since 2010 a very complete Flexible Work Arrangement policy is in place which benefits both men and women.

In many sites in France and other countries, have a fitness room on site or are providing special membership rates to exercise clubs because the health and wellness of employees is important.

This year again, several sites and countries have organized "open doors" day in order to have employees' family members visiting the offices so that especially children can see where the parents spend their time during working hours. This is part of our actions to promote family life.

### Facilitating family life for male and female employees

- Throughout the world, the Group supports the creation of daycare centers. Today, four countries have daycare centers: France (5 sites), Canada (1 site), Germany (Frankfurt and Berlin) and Brazil (1 at MEDLEY site). In other countries, employees can choose from a variety of childcare options. In some countries, Sanofi has arranged special rates with daycare providers.
- The number of children enrolled worldwide is 534. Among those enrolled, 31% are the children of male employees and 69% the children of female employees.
- At Sanofi sites in the Paris area, one of the services offered by the "Conciergerie" is childcare in the event of an emergency or for last-minute events.
- In Germany, a program was designed specifically for men and women employees on parental leave. Working part time and flexible scheduling are also strongly encouraged.
- In France, the Group Professional Gender Equity agreement provides for a childcare allowance for parents who must attend training classes outside their regular working hours.
- Aid in the form of prepaid checks is provided to French Sanofi Pasteur employees with small children.

## Supporting employees children

### Background and Policy

Since its creation in 1994, The Association has helped 2,000 families representing more than 3,000 children through individual actions in 63 countries.

Sanofi provides assistance to employees worldwide when their children are faced with difficulties that could impact their future. “The Association Our Children Matter” was created outside the framework of management structures to take an innovative approach to providing support for employees’ children.

The Association was designed to offer support when the child of an employee, from birth to age 25, faces physical, moral or material hardship. At certain times in a child’s life, events such as the loss of a parent, unemployment in the family or disability may constitute a threat for his or her future. When no other source of help is available via traditional company benefits, social or family structures, The Association can be a source of advice, information, guidance and financial support.

Sanofi also organizes operations to support children and their families following a natural disaster, such as an earthquake or flood.

The Association is funded by employee donations and an annual endowment from Sanofi. In addition, the Group provides the funds necessary for its operating expenses.



## Actions

▼ Individual assistance

▼ Collective initiatives

### Individual assistance

In 2011, The Association provided individual assistance to 250 families in 34 countries (not including the United States, where The Association has its own status.

Locally, when other sources of aid are not available, individual assistance may be provided at an employee's request to cover medical expenses – for example, medicines, hospitalization fees that are inadequately covered by medical insurance, disability-related expenses such as prostheses, and specialized care for children with a motor or mental disability. In 2011, 45% of individual requests received by The Association concerned medical expenses.

Individual assistance may also take the form of educational support. Following an unexpected event such as the death of a parent, the loss of a job in the family, or a divorce, The Association can provide financial support to cover school or university fees, as well as educational grants. In 2011, 43% of financial support provided by The Association's was related to education.

The Association also provides support for families – for example, if the parent in a single-parent family must be hospitalized, The Association can pay for childcare. In 2011, 12% of financial support was dedicated to this kind of support.

## Collective initiatives

Over 25,000 employees' children have participated in collective initiatives funded by The Association.

Actions organized by The Association include vaccination campaigns, dental care, eye care and education and information campaigns on topics such as childhood obesity, nutrition, HIV / AIDS, alcohol and drug addiction among teenagers.

In 2011, The Association set up influenza vaccination in Thailand, the Philippines and Vietnam as well sight tests and vaccinations in Hungary and medical check-ups in China.

A specific day devoted to "Bullying at school" was organized in Mexico. In Colombia, a day was devoted to dental care, eyesight and hearing tests at the Cali industrial site.



In addition, 2011 witnessed the launch of an innovative and ambitious program in Brazil to help employees' children attend public universities.

## BUSINESS CASE



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In 2011, The Association introduced a program to support employees' children who wish to study at Brazil's major public universities. The program covers school fees and books for 13 children of employees from two of the Group's industrial sites, giving them the opportunity to enroll in Objetivo private schools to prepare for the competitive entrance exams required to attend public universities.

- Business case: Compensation Employee benefits

## Business case: Compensation Employee benefits

### ■ Helping employees' children prepare to study at Brazil's leading universities

#### The challenge

Our challenge was to support employees' children who wish to study at the leading schools in Brazil, where the major public universities are also the country's most prestigious institutions. Young people who wish to be admitted to these universities must pass highly competitive entrance exams. Only a few private, fee-charging high schools in Brazil prepare students for the entrance exams, and not all Group employees can afford to send their children to these schools.

#### Our response

In 2011, a program was launched by "The Association: Our children matter" to support employees' children who wish to study at Brazil's leading schools. The program covers school fees and books for 13 children of employees from two of the Group's industrial sites, and gives them the opportunity to enroll in Objetivo private schools.

Certain conditions must be met for children to be eligible for the program. For example, their parents must be employees with permanent contracts who have worked with the Group for at least one year and who earn up to BRL 2,000 (around EUR 830) monthly. Students must be 14 to 15 years old and must have attended a public junior high school. Candidates are required to take tests in Portuguese and mathematics; only those students with the best grades are selected for the program.

This initiative aims to ensure that all students who have completed the program will be prepared to successfully pass the entrance exams at Brazil's major public universities.

Historically, Brazil has been a major donor to The Association. Each year, Brazilian employees collect funds on behalf of the organization.

#### Benefits for stakeholders

For employees: This project allows the children of employees to have access to a top-notch public education, paving the way for a bright professional career. It provides recognition for employees and gives them a sense of pride and satisfaction to work for the Group.

In addition, it expresses Sanofi's values and improves the Group's visibility, while forging ties with the local community and with institutes of higher learning in Brazil.

## Opportunities for the Group

As a showcase for Sanofi's actions on behalf of our employees in Brazil, programs of this type contribute to the excellent reputation the Group has acquired in this country in recent years.

Sanofi was chosen as the most admired pharmaceutical company in Brazil in 2011. The criteria used to select the winner of this annual prize include a company's innovation, ethics, customer service, quality of management and CSR performance, as well as its commitment to the country.

Some 1,300 opinion leaders from 40 economic sectors picked the winners. Ten ministers, the Governor and the Mayor of Sao Paulo all attended the awards ceremony, a sign of the political prestige associated with this distinction.

## The future

If The Association remains successful in Brazil and donations from employees increase over the next three years, it will be possible to help more employees' children. In addition, other countries with similar needs could model their own programs after this initiative in Brazil.

Currently The Association is providing financial support for employees' children to have access to higher education in countries such as South Africa, Indonesia, and Mexico.

## Employee representation and information

### Background and policy

With the health sector undergoing far-reaching transformation, Sanofi is developing new strategic directions and adapting the Group's organizations to promote sustainable growth. The transformation process is addressed on a regular basis with the various employee representative bodies, and the Group updates all employees about new developments.

### Social dialogue: A priority

The Group seeks to develop high-quality social dialogue with all employees and their representatives while taking into account local laws and practices in each country.

Industrial relations within the Group are founded on mutual respect and dialogue. In addition to compliance with legal obligations, dialogue with employee representative bodies is important in order to:

- Provide transparent information on a regular basis by communicating about changes within the Group (strategy, results, organizational changes, etc.).
- Address ways to support employees and anticipate all necessary changes to enable the success of the Sanofi transformation. This interaction with employee representatives may cover topics ranging from compensation to training to organizational changes. Discussions are subsequently made official through business agreements, which are necessary to the Group's development.

In this spirit, employee representatives and management meet on a regular basis to exchange views, negotiate and enter into agreements, and to ensure these agreements are being implemented.

In 2011, employee representative bodies, which are engaged in social dialogue in most countries where Sanofi operates, were kept regularly informed about the Group's progress, organizational changes and recent acquisitions (Genzyme and Merial).



## A solid foundation

In the field of social dialogue, the Group applies the principles of the UN Global Compact, to which Sanofi has subscribed. Sanofi supports freedom of association and recognizes the right to collective bargaining. The Group's social policy is detailed in the Social Charter, which is distributed to all employees so they can apply its principles in their work.

For more information:

"Workplace relations within the Group are based on mutual respect and dialogue."

Excerpt from the Sanofi Social Charter

For more information:



[\*Sanofi Social Charter\*](#)

For more information: The UN Global Compact, the Human Rights Policy

- [\*Human Right - Policy\*](#)

## Actions

- ▼ At the Group level
- ▼ Worldwide
- ▼ In France
- ▼ Implementing engagement surveys

### At the Group level

Social dialogue is based on transparency and employee access to information. Various means of communication are available in all countries to keep employees informed, at the Group level as well as the affiliate level. Communication tools are adapted to the local environment (language, available communication methods such as intranet, billboards, etc.) and the different types of job functions (sedentary, mobile workforce, etc.).

The Group strives to achieve a balance between communications originating from on-site management and communications based on new technologies. The goal of communications is to foster employees' buy-in of the Group's strategy at all sites worldwide.

Communication efforts use all available distribution channels:

- Informational meetings organized for managers and employees,
- Intranet sites providing access to a great deal of information, videos of senior management or members of the Executive Committee,
- eLearning in order to train employees and managers on new tools or new HR policy,
- More traditional information tools, such as local newsletters and billboards.

### Worldwide

In November 2011, Sanofi announced plans for the worldwide reorganization of R&D with the creation of integrated research hubs to provide structures where highly innovative collaborations can develop. This approach more closely corresponds to today's world of science, medicine and finding solutions for patients' unmet needs.

In Europe, consultations with employee representatives were initiated in Germany, Hungary, Italy, the UK and the Netherlands. In the United States, the Boston's R&D Hub will consolidate discovery and early development activities. The creation of the North American Development

Center in Bridgewater, New Jersey, will bring together clinical development, regulatory affairs and other development platforms.

Employee representative bodies engage in social dialogue in countries where the Group operates. In 2011, these bodies were kept regularly informed about the Group's progress, results, strategy and new organizational projects.

#### Communicating with the European Works Council

European Works Council:  
80 employee representatives from the 27 European Union countries where the Group operates received training about the management of organizational changes.

The Sanofi European Works Council is composed of 40 permanent members and 40 deputies, representing employees from the 27 countries in the European Union member states where the Group operates. In 2011, members of the European Works Council received training about the management of organizational changes. The Council met in February, April, May and November for regular updates about reorganizations within the Group's various entities (Research & Development, Industrial Affairs, Commercial Operations and support functions). These developments reflect the adaptations that are necessary for the Group to remain competitive internationally, to migrate research and industrial facilities toward biotechnologies, and to adjust our sales forces in response to increasing regulatory constraints at local level (such as exclusion from reimbursement and regulation of drug prices) and to generic competition for some of the

Group's flagship products.

Additionally, regular meetings with the European works council restricted committee allow for a timely update on Sanofi Group developments in the EU.

In 2011, a joint working group on employment was created. It met three times to review jobs that are in high or low demand so that proper support can be provided to employees to anticipate skills and career evolutions (trainings and other developments).

#### Negotiating with employee representative bodies in every applicable country

In each country affected by organizational changes, negotiations with employee representative bodies took place throughout the year in 2011 to address changes (commercial and support functions with the creation of a multi-country organization in Europe; transfer of the Alcorcón site in Spain, etc.) and to establish measures to support employees that are best suited to their local

context (internal training, outplacement, voluntary departures, early retirement, etc.). The objective is to inform employee representatives at the earliest possible stage so their viewpoints and suggestions may be taken into account.

In most of the countries, the percentage of employees covered by collective bargaining agreements is very high. For example, in Brazil, Colombia, Venezuela and Indonesia, 100% of employees are covered by such agreements; in Japan the figure is 98.3%. In countries where the percentage of employees covered by agreements is low, management initiated programs address employee's needs and other programs are set up to provide a voice for employees and to help look after their well-being.

For example, two bi-annual meetings are organized in India. One involves unionized field employees, which represent 12% of employees. For the other 88% of the workforce, the meeting is organized under the banner of SAY ("Sanofi and You") with non-unionized employees. In both cases, the purpose of the meetings is to proactively address all issues related to operations and grievances, if any. This system encourages participative management and allows employees to contribute their ideas with regards to Group policies and procedures on products, customers, business processes and people processes. The entire senior management, including general managers, takes part in these meetings.

## In France

The Sanofi Group Works Council in France is composed of 25 permanent members and 25 deputies as well as trade union representatives. In 2011, it was renewed for a period of two years. Representatives of Merial and Genzyme, newly acquired by the Group, now sit on the Council, which met in May, June, September and December 2011.

During these meetings, the Council received progress reports about Sanofi's activities financial position, employment trends within the Group in France, and integration process of Merial and Genzyme. In addition, presentations addressed changes in the economic and regulatory landscapes for the pharmaceutical industry.

In 2011, 8 agreements and 5 amendments were discussed with employee representative bodies in France.

In 2011, eight agreements and five amendments were discussed with employee representative bodies. These covered, in particular, hardship work conditions (agreement on methods as well as agreement concerning preventive and compensation measures), gender equality, implementing a workforce planning agreement (GPEC) at Group level, methods of calculation for the Group profit-sharing agreement, Sanofi's top-up of employee contributions into the employee savings plan (PEG) and the collective pension savings plan (PERCO). At the end

of the year, negotiations were initiated on teleworking, special leave. They should be finalized in 2012.

In addition, specific agreements were entered into with certain Group companies (Sanofi Research and Development, Sanofi Winthrop Industrie, Sanofi Chimie, Sanofi France, Sanofi Pasteur and Sanofi Group).

## Implementing engagement surveys

Employee representative bodies exist in most countries where the Group operates. In 2011, these bodies were regularly informed about the Group's progress and transformation program. In 2011, some affiliates conducted engagement surveys. An excellent employee response rate was reported in countries such as Taiwan (over 87%). Following the surveys, the affiliates implemented action plans tailored to meet local challenges.

Examples of surveys conducted in other countries:

### In Egypt

Based on the engagement survey results, Egypt launched an initiative to set up focus group to address several business and employee concerns highlighted by the survey – for instance, taskforces focusing on performance and recognition, training and development, and people empowerment.

Additional surveys were conducted in countries where the Group operates.

### In China

A China-wide employee engagement survey ("Sanofi & Me") was conducted covering all activities in China. Survey responses identified various areas for improvement, and six teams of cross-functional managers are working together to propose solutions in each of these areas. In

addition, employees in 11 different regions decided to create over twenty activity clubs that will organize social, sports and family events to promote a sense of belonging.

### In Australia and New Zealand

Sanofi Australia and New Zealand also actively engage staff and seek their feedback through company surveys. In 2011, Sanofi Australia and New Zealand introduced a 90-day survey for new staff. They believe it is important to conduct employee attachment measures for three key reasons:

- To understand and manage the impact of individual managers on retention, engagement and performance,
- To better understand and subsequently manage the patterns or trends associated with attachment across the organization.

On the basis of the information obtained via such surveys, the affiliates can take targeted actions to achieve increased retention, enhanced discretionary effort and performance, and return on recruitment and on-boarding investment. The number of completed surveys is still relatively low at this stage (<12) due to the number of reorganizations, the integration of new companies, such as Genzyme and Merial and also due to the fact that there is an intention in the future to propose to countries and business divisions a global methodology for conducting future employee engagement surveys.

This new initiative is slated to continue in 2012.

## Health and Safety

Protecting the safety and promoting the health of our full-time and temporary employees as well as independent contractors is of critical concern to Sanofi. The Group adopted a new HSE policy in 2011 [Sanofi's HSE Policy](#) to assess and control risks. We have also established new objectives to ensure that we are working towards common goals.

Sanofi has developed training over the last four years to strengthen the Group's safety culture. This training is aimed at HSE professionals and operational managers. The objective for HSE professionals is to enhance their expertise. For operational managers, the goal is to strengthen a safety culture based on the fundamentals of risk management and the implementation of behavioral safety.



« Ensuring safety and protecting the health of each employee, keeping our environmental footprint to a minimum, improving human health everywhere, and working to reduce climate change – these are some of the key challenges that motivate Sanofi's work each day. »

**Alain Lamaud,**  
Vice President, Health Safety Environment

## Safety in the workplace

A nearly **40%** decrease in the lost time injury frequency rate between 2006 and 2011

### Background and policy

When it comes to occupational safety, Sanofi's goal is to reduce the occurrence of workplace accidents to the lowest possible level. This involves implementing prevention and protection systems that are subject to ongoing monitoring and continuous training.

Safety and prevention is the responsibility of each and every employee, irrespective of their role within the Group: full-time employees, temporary employees or contractors working at our sites.

This process involves:

- Assessing current risks
- Anticipating new risks
- Developing expertise
- Offering support through training and feedback about experiences

The HSE Department's goal is to make continuous improvements in these areas.

For more information:

- [Our vision / HSE management systems](#)

The Group sets qualitative goals for programs and training within the different Group functions, and it also establishes a quantitative objective for the lost time injury frequency rate.

### 2015 Objectives

- 30% reduction in the lost time injury frequency rate
- 25% motor vehicle accident reduction (absolute value)



## Actions

One of our major achievements in 2011 was the reduction in the lost time injury frequency rate for the sixth consecutive year, reaching a record low of 1.8, with only 0.5% of our employees involved in an injury. This is the first time we passed this threshold thanks to individual as well as top management involvement in promoting and taking responsibility for safety.

To build a culture of safety and also to reduce the occurrence of workplace injuries, Sanofi has the following safety initiatives, which are outlined below.

- ▼ Ensuring Safety
- ▼ Process Safety Training
- ▼ Considerable improvement in road safety for our medical sales representatives
- ▼ Ensuring employees' security

## Ensuring Safety

Sanofi's HSE department promotes employee safety year round through HSE Culture Training, HSE weeks and the newly launched HSE Academy. HSE Culture training is targeted towards managers. To date 6000 managers have been trained between 2005 - 2011. HSE weeks are planned at sites to increase awareness about health, safety and environment among all plant staff. The Group established an "HSE academy" which will be implemented in 2012 to improve expertise among the HSE function and facilitate a strong partnership with the businesses. Academies are expected to facilitate best practice sharing and networking.

Also new in 2011, are the HSE Awards, which recognize best practices at all Sanofi entities. 70 applications were received world wide and 10 winners will be announced at the ceremony in 2012.

For more information:

- [Our Vision / Policies and Management Systems / Management systems / HSE / Actions](#)

An example of an HSE week is the "Safety Week" which is a special week-long event organized at our sites to recognize the attainment of safety goals and to provide theoretical training and

practical demonstrations. For example, the Winthrop Pharma Senegal Industrial Affairs site in Dakar organized a Safety Week from August 1 to 5, 2011, for the entire plant staff. They celebrated 1,000 days with no lost time injuries, and announced a new goal of 2,000 days with no lost time injuries.



Our priority during 2011 was to build a training program for HSE family in order to increase HSE awareness, in order to improve prevention within the field. The three main developed programs are occupational Hygiene, Biosafety and Human and Organizational Factors of Safety. They will be performed in 2012

**Fabienne Perekrestow,**  
Director, Health and Safety

## BUSINESS CASE



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In 2010, this creative initiative to improve employee safety at the Suzano site (Brazil) led to a 50% reduction in the number of accidents. After a new version of the Safety Game was introduced in 2011, the lost time injury frequency rate for Sanofi employees went from 0.6 to zero.

- *Business Case: Health Safety*

## Managing employees' health and safety following a natural disaster: events in Japan

Immediately after a devastating earthquake struck Fukushima, Japan, on March 11, 2011, Sanofi took action to ensure the health and safety of all employees working in the disaster zone, as well as their families; 3,100 employees were working for the Japan affiliate at the time of the incident.

After the emergency team responded by checking employees' safety and damage to buildings, a crisis management team was formed. This team remained operational until April 15, 2011, working closely with the corporate HSE team. It was made up of 15 members, including the General Manager and the Security Officer, as well as representatives of Human Resources,

Information Systems, Business Development, R&D, Regulatory, and other functions. The team's primary role was to ensure the safety of employees and their families' safety. In response to the disaster, a variety of actions were undertaken, such as: evacuating employees and their families in Fukushima; delivering food, water and basic necessities to employees in the affected area (such as the Tohoku Region); providing regular updates and information for employees via the intranet; monitoring radiation levels; and supplying employees with radiation counters and sheltering procedure as preventive and protective measures.

**For more information:** about the Group's response to the Fukushima earthquake and subsequent events, see these sections of the 2011 CSR Report

- [\*Patient - Humanitarian Emergencies\*](#)
- [\*Patient – Safety / Product Risk management – Continuity of activities and supplies\*](#)

**For more information:** see our 2011 safety

- [\*Our 2011 safety results\*](#)

## Process Safety Training

Minimization of major risks consists of the following key actions:

- Conducting risk assessments of the Group's processes as early as the stage of fundamental research
- Taking into account methods to minimize major risks at all Group sites, and in all situations, processes and projects
- Using the “Hazard Vetting ” method each time manufacturing or equipment is scaled up or down

Additionally, Sanofi has implemented process safety training to improve technical knowledge and on-site expertise.

Process safety training allows for a decentralized approach to process safety risks at each of the Group's relevant sites.

Technical training is provided to chemical development laboratory managers and workshop supervisors as well as chemical and pharmaceutical production engineers. To date, over 136 people have received process safety training.

The case studies used for training are primarily based on learning from Sanofi experience – using past events to underscore the need to systematically assess the prevention and protection measures implemented for Group facilities.

### Considerable improvement in road safety for our medical sales representatives

From 2000 to 2006, the significant number of motor vehicle accidents involving medical sales representatives led Sanofi to embark on a long-term road safety program. Introduced in 2006, this program was designed to reverse this unacceptable and alarming trend. Management's involvement and commitment were decisive to the program's approach and ultimate success. It made use of many tools, including a dedicated communication campaign, defensive driving training, road safety coaching as well as Road Safety Awards and the new Driving Excellence Program. We are happy to report about this program's success.

Since 2006, with management support, the Road Safety program has resulted in:

- zero fatalities due to road accidents over the past two years
- 57% decrease in the number of lost time injuries consecutive to a motor vehicle accident
- 44% reduction of vehicle accidents (car & motorcycle)

### Driving Excellence Program

The latest initiative, begun in 2011, was the "Driving Excellence Program" to recognize individual safety results on the road. The program is implemented at the local level with core expectations that each affiliate must respect. The objective is to recognize safe drivers consistently across all affiliates at Sanofi based on the number of years of safe driving:

- Platinum award: zero vehicle accidents for 3 or more years
- Gold award: zero vehicle accidents for 2 years
- Silver award: zero vehicle accidents for 1 year
- Bronze award: zero vehicle accidents for less than 1 year

In addition to these core conditions, affiliates may add local cultural safe driving options, such as training and safety assignments completed, etc.

## Road Safety Awards

In 2011, for the third year, the Road Safety Awards was presented during the Sales Champion Ceremony. Executive Committee members, senior management from affiliates, and over 350 of the Group's leading medical sales representatives attended the ceremony. This year, the awards highlighted the five safest sales representatives worldwide. Award winners from Australia, Brazil, Canada, the U.S. and Vietnam were commended for their commitments to safe driving. The Road Safety is an excellent showcase of employees' readiness to embrace change and to improve road safety performance. Countries participating in the Third Road Safety Awards accounted for 75% of the Group's vehicle fleet. Next year, the contest will focus on line management to identify five individuals who, with respect to their teams and peers, promote the importance of safe behavior not only during working hours, but at all times.

## Motorcycle road safety training in India

Motorcycles are the principal mode of transportation for sales representatives in India. Since 90% of accidents could have been avoided with the application of a few safety techniques, coaching was considered of paramount importance to keep our colleagues safe. As a result, three "Road Safety Coaching" sessions took place in 2011. About 100 participants attended the sessions in Mumbai, Chennai and New Delhi. Training sessions focused on HSE road safety techniques to ensure that this topic is the focus of concern and discussion, among district managers as well as sales professionals. This HSE training program was warmly received by all participants.

For more information:

- [Our 2011 safety results](#)

## Improving independent contractors' safety

In 2011, the Group's special safety program for independent contractors continued implementation at sites at operational Sanofi locations. The program is based on five points:

- Choose a contractor based on their safety record at other sites
- Contractor accommodations at the sites
- Analysis of intrinsic risks specific to the contractors' work, work areas and related protective measures
- Contractor work site and work area audits and inspections
- Review of annual results

The Group is committed to ensure the ongoing safety of all people working at our sites, whether they are Group employees, temporary employees or persons working for an independent contractor.

On February 13, 2012, Sanofi organized an annual meeting for outside contractors at the (companies that Sanofi contracts with) was organized on Vitry R&D site. This initiative which has been in place for three years and is an opportunity to raise awareness among our partners and to remind them of good HSE practices that should be adopted when working at our sites.

During the meeting, three contractors were awarded for their efforts in safety. This included improving their performance, innovation or progress regarding compliance with Sanofi safety rules and the use of equipments which conform to the specifications of Sanofi in the safety field. The results of such efforts enabled Sanofi to reduce the number of contractor injuries with lost time and to reach 3 injuries with lost time in 2011. Sanofi re-committed to preserve the health and safety of our employees and contractors.

For more information:

- [Our 2011 safety results](#)

For more information:

- [Contractor safety: Subcontractors and suppliers](#)

## Ensuring employees' security

As part of Sanofi's Corporate Economic Security, the People Protection Department is in charge of ensuring employee safety during business travel or expatriation in countries considered to be at risk.

Strengthening and harmonizing expertise among its security partners in various countries is a Group priority. In 2010 and 2011, special training sessions were held to improve employees' awareness of threats and risks in countries they visit or stay in for extended periods. They were taught appropriate behavior in the event of political, social, criminal or terrorist risks and threats.

By providing security training, Sanofi wants to reduce employee vulnerability and exposure to risk. Training sessions are conducted in person or using eLearning tools. The Group also provides training for country security partners and regional security directors.

## Indicators

The main indicator for safety in the workplace is the lost time injury frequency rate of accidents. The chart contains the LTI-FR trending from 2006-2011 based on Sanofi business units / functions.

▼ Consolidated lost time injury frequency rate by function (2011)

▼ Improving the severity rate trend

▼ Occupational injuries (medical sales representatives)

▼ Safety indicators for independent contractors

### Consolidated lost time injury frequency rate by function (2011)

| LOST TIME INJURY FREQUENCY RATE (1)                        |            |            |                    |            |            |             |                        |
|--|------------|------------|--------------------|------------|------------|-------------|------------------------|
| Lost Time Injury Frequency rate <sup>(1)</sup>             | 2006       | 2007       | 2008               | 2009       | 2010       | 2011        | Variation<br>2006/2011 |
| Research and Development                                   | 2.0        | 1.9        | 1.7<br>(2)         | 2.0<br>(2) | 1.5<br>(2) | <b>0.9</b>  | -55%                   |
| Industrial Affairs   | 2.5        | 2.3        | 3.0<br>(2)         | 2.0        | 2.1        | <b>1.7</b>  | -32%                   |
| Commercial Pharmaceutical<br>Operations (including Merial) | 3.7        | 3.4        | 2.9                | 2.6        | 2.1        | <b>2.2</b>  | -41%                   |
| Vaccines   | 1.6        | 1.5        | 2.0                | 1.1        | 2.3        | <b>1.2</b>  | -25%                   |
| Support Functions  | 1.2        | 0.9        | 1.5<br>(2)         | 1.4        | 1.9<br>(2) | <b>1.7</b>  | +42%                   |
| Sanofi total   | <b>2.9</b> | <b>2.6</b> | <b>2.6<br/>(2)</b> | <b>2.2</b> | <b>2.1</b> | <b>1.8*</b> | <b>-38%</b>            |
| Temporary employees  | 2.0        | 2.1<br>(2) | 2.3<br>(2)         | 1.0<br>(2) | 2.3<br>(2) | <b>2.2</b>  | +10%                   |

(1) Number of occupational related lost time injuries per one million hours worked. These data are consolidated for all Group companies.

(2) Previous years frequency rates were adjusted in 2011 based on: eliminating injuries dismissed by regulatory authorities, including injuries reported late, changes in reporting scope.

## Comments

Nearly all our business units experienced a decrease in the lost time injury frequency rate, in particular Commercial Operations, which reduced the number of lost time injuries from 2006 to 2011 by 40%. Rates continued to be low for Vaccines and R&D, whereas the Support Functions observed a slight increase over the past two years.

Sanofi's objective for 2015 is to further decrease by 30% the number of lost days at the Group level, which represents a challenge for one fourth of countries worldwide where Sanofi has operations.

## Improving the severity rate trend

**Definition**  
**Severity rate:**  
Number of lost  
days per one  
million hours  
worked.

For the first time in 2011, Sanofi is communicating the trend in severity rate externally. External auditors have conducted a severity rate blank (pilot) audit for the second time between 2006 and 2011; Sanofi's severity rate followed the lost time injury frequency rate trend. Sanofi personnel were out of work following an occupational injury two times less often than in 2006.

## Occupational injuries (medical sales representatives)

| Occupational accidents<br>(medical sales<br>representatives)                                 | 2006   | 2007  | 2008  | 2009  | 2010  | 2011  | Variation<br>2006-2011 |
|--|--------|-------|-------|-------|-------|-------|------------------------|
| Number of vehicle accidents<br>(2)   | 11,062 | 8,843 | 7,769 | 6,829 | 6,649 | 6,214 | <b>-44 %</b>           |
| Lost time injury frequency<br>rate involving medical sales<br>representatives <sup>(1)</sup> | 4.7    | 4.4   | 3.7   | 3.4   | 2.8   | 2.9   | <b>-37 %</b>           |
| Fatalities   | 5      | 1     | 0     | 3     | 0     | 0     |                        |

(1) Number of occupational related lost time injuries per one million hours worked.

(2) The 2006-2010 numbers reported have been adjusted to include motorcycle accidents.



**For more information:** The European Road Safety Charter of the European Commission:

- [www.erscharter.eu](http://www.erscharter.eu)

## Safety indicators for independent contractors

One of the indicators that allow the Group to assess our partners' compliance with HSE rules is the lost time injury frequency rate for contractors.

| Lost time injury frequency rate<br>(1) | 2006 | 2007               | 2008 | 2009               | 2010 | 2011 | Variation<br>2006-2011 |
|--|------|--------------------|------|--------------------|------|------|------------------------|
| Independent contractor                 | 5.7  | 5.0 <sup>(2)</sup> | 4.1  | 3.3 <sup>(2)</sup> | 2.5  | 2.9  | <b>-49%</b>            |

(1) Number of occupational related lost time injuries per one million hours worked. These data are consolidated for all Group companies.

(2) Frequency rates have been adjusted in 2011 based on the following factors: eliminating injuries dismissed by regulatory authorities, including injuries reported late, and changes in the scope of reporting.

**Independent contractors** = Employees of outside contractors to which Sanofi subcontracts operations, work or provision of services on a Sanofi site, under their own supervision, on a contract drawn up between Sanofi and the company specifying the terms under which the work is to be performed.

The lost time injury frequency rate fell to 2.9 in 2011. Sanofi's Industrial Affairs, Corporate Headquarter Sites and R&D have all observed significant decreases in this rate over the last six years. Although lost time injuries have increased for Commercial Operations, the lost time injury frequency rate remains very low.

Thanks to the occupational safety programs instituted over the last several years, the Group has been able to significantly reduce the lost time injury frequency rate and the severity rate for contractors. Over the last five years, the frequency rate has decreased by nearly 50%.

\*Indicator identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this sanofi-aventis CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)

## Business case: Health Safety

### Continued success of the Safety Game in Suzano, Brazil

#### The challenge

In early 2009, Sanofi noted a decline in safety performance at the Suzano industrial site in Brazil. The lost time injury frequency rate was the highest it had been in six years, and 61 individual accidents had happened in 12 months. A closer analysis revealed that most of the accidents were due to behaviors such as being distracted, not adhering to standard procedures or simply not being careful.

After the Safety Game was introduced in 2010, the number of accidents at the site was reduced by 50%. In 2011, the challenge was to build on the success of this initiative and improve the site's safety record even further.

#### Our response

In 2011, a new version of the Safety Game was created, continuing the original idea of an entertaining way to promote awareness and improve behaviors at the Suzano site. The new version of the game made a clear impact on the site's safety record: The lost time injury frequency rate for Sanofi employees went from 0.6 in 2010 to ZERO in 2011.

The new Safety Game was based on distributing a sticker album to employees across the site. The drawings on the stickers represented several Health Safety and Environment situations and "dos and don'ts." The sticker album characters Captain CIPA and Juvenal were created by Suzano employees. To win, participants had to obtain all the stickers and complete the album. A total of 1,100 sticker albums were distributed and around 900 were returned completed. For each page of stickers completed, employees received a coupon to participate in a raffle. Some of the ways employees could obtain the stickers: bringing recyclables from home, suggesting or implementing safer and healthier ways of working, participating in warm-up sessions, and reporting potentially unsafe work conditions.

The game was organized from May to August 2011. When it ended in September, the raffle was held during Safety Week. Prizes such as bicycles, flash drives, mp4 players, etc. were distributed to employees.

When combined with other initiatives, the Safety Game motivated employees and had a positive effect on the site's performance, reducing the lost time injury frequency rate for Sanofi employees to zero in 2011.

### Benefits for stakeholders

For employees, this initiative led to an even safer working environment. With the new record of zero accidents, benefits for the Group include safeguarding employees' health and safety and a reduction in accident-related costs.

### Opportunities for the Group

The Safety Game is an effective tool to promote a culture of safety among employees. It is moreover an example of an innovative initiative devised by employees, for employees. In recognition of this initiative's success, the Safety Game received the Industrial Affairs "Health & Safety" Innovation Award in 2010. This award provides further incentive for employees to apply their creativity to improving the Group's performance.

### The future

In the future, Sanofi will continue to pursue efforts to encourage initiatives that promote improved occupational health and safety, and recognize and reward innovative ideas that make a positive impact on the Group's overall performance.

## Occupational health

### Background and policy

Sanofi is committed to safeguarding the health of each employee by minimizing exposure to chemical, biological, or physical factors and ensuring well-being at work. Sanofi also provides medical surveillance for employees as needed, according to their work area.

The health in the workplace approach is based on the following three steps:

- 1. Identification and assessment of Occupational Hazard
- 2. Technical inspection of work situations and medical surveillance of employees
- 3. Definition of methods for risk prevention and protection of workstations



## Defining risk

Risk is the result of exposure to a hazard. Hazards – inherent properties of an object, substance or physical situation that could lead to damage to human health and / or the environment – do not necessarily lead to risks if exposure can be prevented or controlled. A natural or technological phenomenon is only a risk if it applies to an area where human, economic or environmental issues are at stake. Risk is not material; it is the possibility that a dreaded event – of certain seriousness – may happen. Risk is therefore the result of the interaction between the probability of an event and one or more factors:

- Probability: the possibility that an event may occur and may have an impact on the system being studied (natural or technological)
- Factors: people, facilities or environments threatened by a hazard and vulnerable to related damage or injury

## Policy

Sanofi operates HSE management systems relating to safety, occupational health and protection of the environment adapted to each of our activities.

These systems are assessed periodically by measuring the results obtained, defining objectives for progress and implementing action plans called PASS with associated control systems. The process depends on information, learning from experience, dialogue and training.

The Group's policy is designed to continually assess occupational injury and health risks faced by our employees in the workplace, to take the appropriate preventive and protective measures, and to inform our employees and train them so they can ensure their own health and safety. Methods exist to assess potential exposure in the workplace, which has to be validated by measurement and specific analysis in order to comply with national and group requirements, as set out in the HSE Strategic Plan and further detailed in the 2012 PASS goals:

- Enhance industrial hygiene assessment
- Implement best technologies to protect people

**For more information:** The section on HSE management systems

- [HSE management](#)

## Actions

- ▼ [Sharing best practices among key medical doctors worldwide](#)
- ▼ [Providing information about handling of hazardous substances: the COVALIS committee](#)
- ▼ [Assessing exposure to biological agents: the TRIBIO Committee](#)
- ▼ [Implementing health programs](#)
- ▼ [Local Initiatives - promoting well-being](#)
- ▼ [Sanofi signs the Heart Charter / Charte Du Coeur](#)

### Sharing best practices among key medical doctors worldwide

Sanofi's Key Medical Doctors (KMDs) are seven occupational physicians that head up the network of occupational physicians working at Sanofi's sites around the world.

Key Medical Doctors promote HSE tools, programs and awareness campaigns established by Corporate HSE. Additionally, they collect feedback from sites occupational physicians for continuous improvement of the tools and programs. In February of 2011, HSE hosted a seminar for the KMDs to share best practices in various areas: well-being at work, reporting of occupational diseases and implementation of health promotion programs. Below are examples of health promotion programs that took place in 2011:

- For World Heart Day 2011, a heart disease awareness and screening program was put in place in Pakistan, Bangladesh, Philippines, India, Singapore and Japan. A similar blood pressure and cholesterol screening event was held in Brazil.
- In Pakistan, 200 people were screened for glucose cholesterol and blood pressure. After review of the results, those identified as borderline by the company physician were provided advice on preventive measures.
- In Japan as part of a country wide effort for health promotion and prevention of heart disease, almost all employees (99.5%) underwent medical-check up which included electrocardiogram, Blood Pressure, cholesterol, glucose and Hemoglobin HbA1C. Additionally, 263 workers were provided exercise and nutritional counseling.

- In Australia a program was put in place to support healthy eating at the company cafeteria by repositioning food display (i.e. healthy options close to the counter) and instituting a "traffic light" system for identifying healthy and unhealthy foods.
- In Latin America, 7000 flu vaccinations were given to sales force and their families in Latin America. This represents 70% participation of the sales force in Latin America.
- Other health promotion initiatives include efforts to reduce ergonomic injuries through a new approach: biofeedback electromyography (EMG). The biofeedback EMG is used in occupational medicine mainly to relax muscles contracted by poor ergonomic conditions.

#### Providing information about handling of hazardous substances: the COVALIS committee

The COVALIS committee is a multidisciplinary team of experts (physicians, toxicologists, chemists and product managers) who are in charge of characterizing the hazard associated with specific substances by evaluating their pharmacological and toxicological properties and to define occupational exposure limits (OEL/OEB). Sample analysis and monitoring of active materials are supported by the Central Industrial Hygiene Laboratory in France.

#### Assessing exposure to biological agents: the TRIBIO Committee

*The TRIBIO committee and its network assesses and classifies all biological agents to which Group employees may be exposed considering several criteria – pathogenicity, biological stability, and means of transmission, infection routes, and the existence of preventive measures or an effective treatment. Employees receive information and training about the type of risks and means of prevention, personal protective equipment and personal hygiene.\**

In order to continually decrease the occupational exposure level, each site implements industrial hygiene programs on the basis of these standards and local regulations, while emphasizing collective protection measures, as opposed to relying exclusively on personal protective equipment. In 2011, Merial representatives were included in the TRIBIO Committee.

In 2011, specialized biosafety audits were conducted at several Group sites. For more detailed information on HSE audits, see the HSE Policies and Management section of the 2011 CSR Report

For more information:

- [Our Vision / Policies and Management Systems / Management systems / HSE / Actions](#)

## Implementing health programs

Sanofi focuses on identifying and assessing risks, ensuring monitoring, promoting feedback about experience and developing a culture of prevention. Whether in terms of managing occupational illnesses or promoting well-being at work, the Group strives to ensure that all employees have a satisfactory working environment.

The Group's primary prevention programs cover:

- Biomonitoring of occupational exposure
- Promoting well-being in the workplace

### Biomonitoring of occupational exposure

Where permitted or required by law, biomonitoring of occupational exposure helps improve knowledge about chemical agents and their effects. Although the results may be difficult to interpret, biomonitoring makes it possible to obtain information in addition to atmospheric information, by including all types of exposure and factoring in actual conditions of exposure. It can also take into account previous chronic exposure. Biomonitoring helps to improve medical surveillance. Sanofi uses this kind of surveillance as a tool to improve risk control at Group sites. It is also used during the transfer of active ingredient production. Moreover, it makes possible to assess the effectiveness of protection measures implemented.

### Well-being at work

Sanofi instituted a new HSE requirement that could help create and work environment that promotes well-being and stress-relief. Each site must implement a program to identify, assess and manage stressful situations as well as prevent anxiety and depression in connection with working conditions.

In 2011, Sanofi's Human Resources (HR) and training teams introduced a program to raise awareness about well-being at work, in France. The program consisted of several complementary initiatives, including:

- 80 training sessions for HR managers, occupational physicians, social assistants and team managers. A total of 585 employees were trained.
- A letter sent to managers in October 2011. Entitled "15 Minutes of Management," it highlighted the manager's role in preventing psychosocial risks and creating a positive working environment.



- The creation of a web portal called *RESSOURCE & Moi* for employees at French sites. Accessible from mid-October to mid-November, the portal featured e-learning modules, training support tools and videos.
- Presentations about how to go "From stress to well-being" in November and December 2011, looking at steps to take to ensure well-being for oneself and others. A total of 730 participants attended ten presentations.
- A planned employee survey to evaluate the success of the 2011 offerings and assess 2012 needs.

In addition, a committee dedicated to well-being at work was created in France thanks to collaboration between Sanofi's Health Safety & Environment (HSE) and HR divisions. This pilot committee is in charge of promoting well being at the workplace. The committee includes representatives from HR, HSE, company doctors and site managers.

Other actions in 2011 included:

- Drafting a guide about measures to take for well-being in the workplace
- Organizing HR training for site managers, supervisors and others involved in promoting health in the workplace
- Defining indicators and an action plan to be introduced first in France, with the ultimate aim of global implementation

### Local Initiatives - promoting well-being

Sanofi's occupational health policy includes many initiatives implemented regionally in all countries where the Group operates.

In 2011, local initiatives at Group sites included screening for metabolic diseases, diabetes, high cholesterol, high blood pressure, obesity, blood in stools, PSA levels (prostate), melanomas and cancer. Incentives for healthy living, exercise promotion, and smoking cessation programs were also organized. Below are examples from two sites in France.

#### Well-being at La Boetie

As a responsible healthcare partner, Sanofi understands and is committed to helping employees lead healthier lives. Many and many programs have been implemented throughout our affiliates

and divisions across the globe. As part of a pilot program, the new Sanofi headquarters in Paris is establishing a comprehensive health & wellbeing program based on a framework of:

- Policy & environmental approaches
- Informational and educational strategies
- Behavioral and social strategies

Examples of initiatives include a new gym, with extended opening hours and personal coach; a dietician to advise on nutrition and diet with a restaurant that promotes healthy eating options and; campaigns on awareness of and prevention and awareness campaigns about chronic disease management of chronic diseases. The site is also tobacco free. Support and support initiatives are being put in place to help employees who decide to stop smoking. The program is being rolled out by a dedicated Well-Being team comprised of comprising the company medical team, a nutritionist and sports coach.

#### Health week at Toulouse's R&D site

In late March 2011, the Toulouse R&D site held a week long event focused on health and well-being. It addressed well being at work, other occupational risks, addiction, nutrition, sleep, and healthy living. This joint initiative was organized by site management, medical services, communications, HSE and HR.

Throughout the week, medical services made presentations about their services, healthy meals were served at the company restaurant, information was made available on the intranet site for employees, and exercise demonstrations were organized. Over 100 people attended a relaxation workshop. The psychosocial awareness activities included a play, a presentation by the site manager and the medical officer, a presentation by a psychologist and a Q&A session. The week's many events were well received by employees.

#### CEO Gold Standard Accreditation

CEO Gold Standard Accreditation Our U.S. organization is one of the 119 organizations accredited as a CEO Cancer Gold Standard™ Employer, an initiative of the CEO Roundtable on Cancer, of which Sanofisanofi is a member. This recognition reflects our efforts to help prevent cancer among Sanofisanofi U.S. employees and their families, provide early detection tools, and, when needed, ensure access to the best cancer treatments.

For more information:

- [www.cancergoldstandard.org](http://www.cancergoldstandard.org)

## Sanofi signs the Heart Charter / Charte Du Coeur

In France, stroke causes more than 40,000 out-of-hospital deaths each year and the survival rate following a cardio-respiratory arrest is between 2% to 3%. By comparison, in a U.S. city like Seattle the survival rate is about 30%.

As a major employer in France and a global healthcare leader, Sanofi wants to be part of improving the situation by working with public and private sectors to save lives.

On September 13, 2011, Sanofi was one of the 80 companies that signed the first Charte du Coeur (Heart Charter). The charter was created by the French Association RMC/BFM to enhance awareness about heart disease, stroke and first aid among companies and their employees. One of RMC/BFM's primary goals is to contribute to the widespread availability of Automatic External Defibrillators (AED) in all public and work environments and to provide first aid training.

Sanofi's Corporate Health, Safety & Environment Department has contributed to protecting employees' health through prevention campaigns and on-site training. In addition, to support the Heart Charter, Sanofi has committed to:

- Organize awareness campaigns about the survival chain, use of defibrillators, etc.
- Install 316 defibrillators at sites around the world
- Train more than 3,500 people in first aid techniques at sites in France
- Provide 15,000 hours of refresher training courses each year
- Increase awareness and information about heart disease, stroke and first aid

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Vision / CSR performance / Statutory auditors' review report*

## Indicators

The key indicator for occupational health is the number of occupational illnesses reported throughout the year.

## Methodology

Occupational illnesses and their causes have been divided into categories according to the CEFIC (European Chemical Industry Council) classification system. More than one occupational illness may be reported for a single individual.

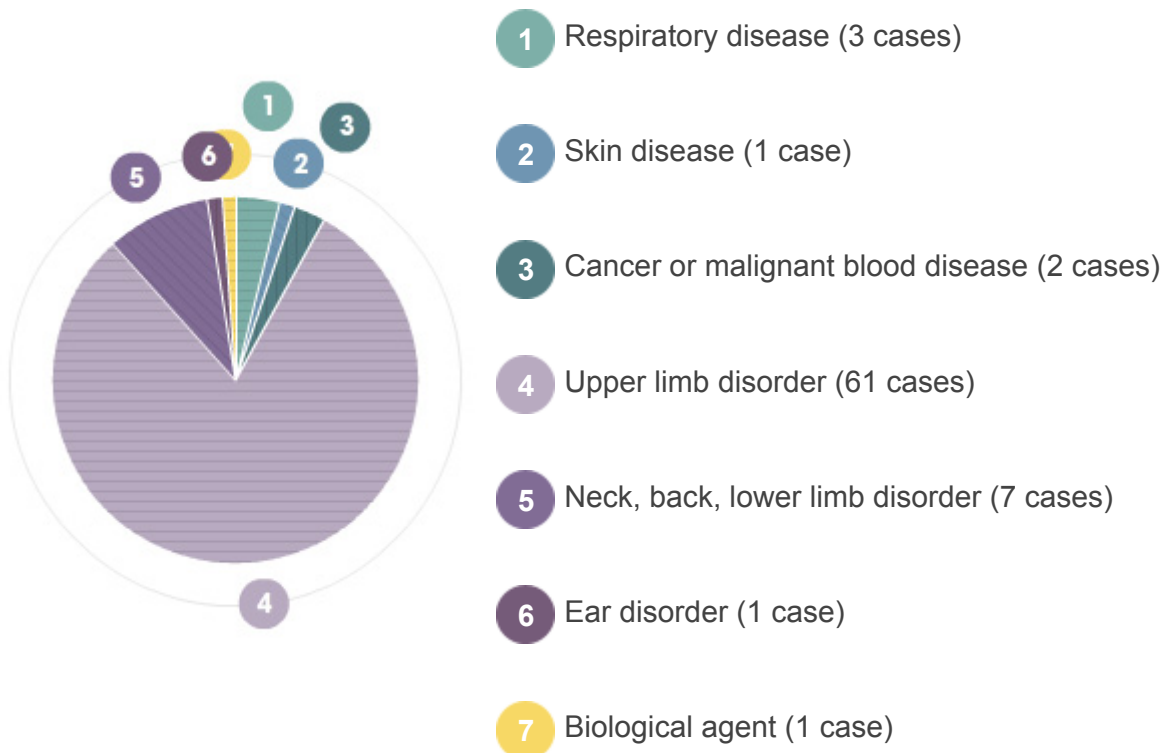
## Occupational Diseases reported in 2011

| Cause of the disease    | Category of the disease                       | Number          | %           |
|-------------------------|---|-----------------|-------------|
| <b>Chemical agent</b>   | 1.1 Respiratory disease                       | 3 cases         | 4%          |
|                         | 1.2 Skin disease                              | 1 case          | 1%          |
|                         | 1.3 Cancer or malignant blood disease         | 2 cases         | 3%          |
|                         | 1.4 Other illnesses caused by chemical agents | 0               | 0%          |
| <b>Physical agent</b>   | 2.1 Upper limb disorder                       | 61 cases        | 81%         |
|                         | 2.2 Neck, back, lower limb disorder           | 7 cases         | 9%          |
|                         | 2.3 Ear disorder                              | 1 case          | 1%          |
|                         | 2.4 Other Diseases caused by a physical agent | 0               | 0%          |
| <b>Biological agent</b> | 3. Disease caused by a biological agent       | 1 case          | 1%          |
| <b>Other</b>            | -   | 0               | 0%          |
| <b>TOTAL</b>            |   | <b>76 cases</b> | <b>100%</b> |

After a net increase in 2010, the number of the declared occupational diseases has stabilized.

The total number of occupational diseases reported decreased from 93 in 2010 to 76 in 2011. There has been a steady increase in musculo-skeletal disorders, which represents 90 % of the declared diseases.

## Sanofi employees (worldwide)



## Cause of the disease

- Chemical agent (6 cases ; 8%):**

1 Respiratory disease (3 cases) - 2 Skin disease (1 case) - 3 Cancer or malignant blood disease (2 cases)

Other illnesses caused by chemical agents (0 case)

- Physical agent (69 cases ; 91%):**

4 Upper limb disorder (61 cases) - 5 Neck, back, lower limb disorder (7 cases) - 6 Ear disorder (1 case)

Other Diseases caused by a physical agent (0 case)

- Biological agent (1 case ; 1%):**

7 Disease caused by a biological agent (1 case)

## HSE compliance for subcontractors and suppliers

In accordance with the Group's HSE policy, Sanofi maintains a transparent constructive attitude of transparency and dialogue with external partners with respect to health, safety and environmental protection.

### Background

Issues concerning supplier health, safety, and the environment have been the focus of growing attention in recent years. As a result, the number of actions implemented by industry has grown considerably.

Working in the pharmaceutical industry, several thousand suppliers and subcontractors are responsible for manufacturing chemical substances that will be used as raw materials or synthesis intermediates. Most companies have implemented programs to ensure that these external partners are able to carry out their work in strict compliance with rules concerning health, safety and protection of the environment.

### Policy

In accordance with the Group's HSE policy, Sanofi adopts a constructive attitude of transparency and dialogue toward external partners with respect to health, safety and environmental protection.

Each entity takes into account these issues during operations involving purchasing and outsourcing. The selection of a contractor or supplier includes HSE criteria, measured in proportion to the risk incurred based on information exchanged regarding products and processes.

This commitment makes it possible to ensure compliance of the operations performed by our partners. It is one of the key principles of the Group's HSE policy.

Sanofi ensures that our partners carry out their work responsibly and in keeping with the Group's HSE principles.

## Actions

### HSE evaluation of Sanofi's external manufacturers and strategic suppliers

HSE issues are taken into account in the relationships that Sanofi maintains with manufacturers and strategic suppliers by:

- Identifying all the Group's manufacturers and strategic suppliers
- Always including an HSE clause in contracts for subcontract work, setting out the Group's HSE requirements
- Providing manufacturers, when contracts are established, with all the HSE information relating to the products and processes concerned
- Conducting HSE validation assessments for strategic manufacturers before finalizing the contracts
- Conducting follow-up HSE assessments of all manufacturers based on their strategic importance and the level of risk for the products and processes implemented

**For more information:** HSE Management Audit section

- [\*Our Vision / Policies and Management Systems / Management systems / HSE / Actions\*](#)

## Glossary

- Manufacturers

For Sanofi, a manufacturer is any enterprise that manufactures a synthesis intermediate, an active ingredient from one of Group's processes, or a pharmaceutical product for the Group. Pharmaceutical manufacturers and chemical manufacturers of active ingredients or synthesis intermediates are mainly concerned. This definition also applies to any enterprise that carries out operations for the Group involving transformation, packaging, packing, storage, transport and distribution of chemicals or pharmaceutical products.

This also includes any enterprise from which the Group buys a service, which will be carried out in general outside the Group, and which applies to products that belong to the Group, for example storage, transport, waste treatment, record-keeping, etc.

- Strategic manufacturers
  - Strategic manufacturers include any subcontractors that manufacture or provide synthesis intermediates, active ingredients or strategic pharmaceutical products for the Group.
  - This refers to any contractor whose sales turnover and / or activity with the Group are significant and whose loss would harm the Group's businesses.
- Strategic suppliers
  - A strategic supplier is any supplier from which the Group buys synthesis intermediates or active ingredients that are needed for the manufacture of our strategic products and specialties.
  - This refers to any supplier whose sales turnover and / or activity with the Group are significant and whose failure to provide products and specialties would harm the Group's businesses.



## Local Economic Development

Participating in the local economic development of communities where Sanofi operates is a responsibility that we take seriously.

Some of the ways we contribute to the economic development of these communities include:

- Measures to support employees who are impacted by changes at the Group's sites
- Investment choices
- Decisions about where to locate production to be closer to patients

### In France: Supporting Sanofi employees who start their own business

As part of the Corporate Social Responsibility approach of a major company such as ours, Sanofi's willingness to play an active part in local economic development reflects our commitment to innovation and expresses our solidarity with the economic development of the communities that are home to our operations in France.

Sanofi believes that employees who, over the course of their career, wish to start their own business or acquire an existing company should receive support to facilitate administrative formalities and the various steps required to make their project a success.

Sanofi's business "start-up" unit assists employees in the different phases of project development by calling on the necessary expertise inside and outside the Group and by providing financial support.

This program, which is open to all Group employees, illustrates the Sanofi values of innovation and solidarity. It encourages employees' entrepreneurial spirit, sense of initiative and motivation to make a project in which they believe become a reality.

### Worldwide: Technology and knowledge transfer

Building a link between patents and technology transfer is essential, according to WIPO, the United Nations agency in charge of promoting innovation through a balanced intellectual property system. The agency's position is that the dissemination and transfer of technology constitutes a major pillar in support of the patent system and its *raison d'être*. In November 2010, WIPO's Committee on Development and Intellectual Property initiated a project to foster

developing countries' access to knowledge and technologies. New partners will be included in all aspects of technology transfer.

### **WIPO: The World Intellectual Property Organization**

WIPO is the United Nations agency to promote innovation and creativity for the economic, social and cultural development of all countries through an effective international intellectual property system. It is dedicated to the use of patents, copyright, trademarks and designs and other means to stimulate innovation and creativity.

**For more information:** What is WIPO

- [www.wipo.int / What is WIPO](http://www.wipo.int/What%20is%20WIPO)

According to the World Trade Organization's agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS), the protection and enforcement of intellectual property should contribute to the promotion and diffusion of the transfer of technology. However, transfer of technology is not yet fully implemented, and thus creates high expectations on the part of developing and emerging countries.

### **TRIPS: Trade-Related Aspect of Intellectual Property Rights**

TRIPS is an agreement covering many issues, from copyright to trademarks to patents for pharmaceuticals. TRIPS attempts to strike a balance between providing incentives for creation and invention in the long term, and allowing people to use existing inventions in the short term.

**For more information:** World Trade Organization's agreement on TRIPS

- [www.wto.org](http://www.wto.org)

## **Our position**

- Technology and know-how confer a competitive advantage to companies and therefore enhance their competitiveness. Nevertheless, for several years Sanofi has been committed to transferring technology and knowledge. Indeed, Sanofi is a global group, present in many

- developing and emerging countries, with a network of more than 30 industrial sites in developing economies. By encouraging harmonization of practices and quality levels in all its sites, Sanofi contributes actively to the transfer of knowledge and technology to countries in the South.
- Sanofi considers that the sharing of expertise through training and employment of local staff contributes to development, while fostering improvement in patients' health. Sanofi also works with local regulatory authorities and carries out clinical trials in many countries.
- Technology transfer is one of the many options that could increase the availability of vaccines in developing countries. Sanofi Pasteur is involved with many capacity-building projects and know-how transfer projects to build local production capacity in developing countries, and also has put into place some voluntary licenses.
- However, technology transfer is a major commitment for stakeholders and is certainly not a remedy for all ills. Sanofi Pasteur supports establishing local production capacity in developing countries under certain conditions: if the project can reasonably succeed, in a place where there are appropriate local practical conditions and where it reflects an ideal and sustainable use of resources. High investments can only be justified for sites that produce a sufficient amount of doses. Moreover, vaccine production is complex and is both capital and time-intensive, requiring highly qualified staff and an infallible supply chain.

## Actions

- ▼ Local economic development in France
- ▼ Support for individual entrepreneurs who start their own business
- ▼ Funding for businesses and job creation in seven French regions
- ▼ Emerging and developing countries: technology transfer to build vaccine production capacity locally
- ▼ Community programs around the globe

### Local economic development in France

With 49 sites and 27,000 employees, Sanofi has a very strong presence in France, which is also home to the Group's global corporate headquarters.

**Sanofi Développement** is a Sanofi affiliate in charge of local economic development activities.

It maintains an active presence in the communities around our sites.

The Group pays particular attention to local economic development aid in France, which takes many forms. Examples throughout the country in 2011 included:

- In the Rhône department and the Pays de Tarare community of municipalities, eight small- and medium-sized firms under development received aid from Sanofi Développement, which led to the creation of 28 jobs with fixed-term contracts.  
In addition, Sanofi provided more than € 250,000 to the Pays de Tarare community of municipalities to help finance the construction of a business incubator and a business center providing approximately 5,000 m<sup>2</sup> of space for artisans, industry and service sector firms. This aid helped create 45 jobs.
- In the Bouches-du-Rhône and the Pays d'Arles communities, seven small- and medium-sized enterprises under development received funding from Sanofi Développement for the creation of 39 jobs with fixed-term contracts.

- In addition, Sanofi provided over € 250,000 in funding to the Rhône Alpes Durance community of municipalities to help build a new business incubator, creating 40 to 60 new jobs, and to the township of Arles for the creation of an employer group (sharing services for small- and medium-sized firms). The Group also provided aid to set up a platform specialized in the restoration of heritage objects.

## Support for individual entrepreneurs who start their own business

For over 30 years, Sanofi has provided support for employees who are impacted by transformations at the Group's 49 sites in France, through entities such as Sanofi Développement and the entrepreneurial "start-up" unit. The purpose of these structures is to take an active part in local economic development by promoting job creation and encouraging the start-up of new businesses.

Sanofi Développement is in charge of:

- Implementing local economic development initiatives around Sanofi sites in France and supporting the development and creation of jobs, particularly with small and medium-sized firms
- Overseeing Sanofi's revitalization agreements in France
- Providing financing for Sanofi employees who start their own companies, create jobs and develop their businesses
- Coordinating Sanofi's involvement in strategic workforce planning programs

## Funding for businesses and job creation in seven French regions

In 2011, seven geographical areas particularly impacted by job cuts for medical sales representatives benefited from a 2009 agreement between the Group in France and the French government. These locations include the greater Paris area, Provence-Alpes-Cote d'Azur, Aquitaine and Rhone-Alpes. The agreement provides for loans to new businesses that create new jobs, as well as mentoring and skill-sharing programs and subsidies to local economic players.

Within the scope of this agreement, Sanofi mobilized over € 6 million to benefit these seven areas. Sanofi Développement provided aid for 67 very small businesses as well as small and medium-sized enterprises and industries under development. This in turn helped to create 348 jobs with fixed-term contracts.

In addition, Sanofi provided funding for several economic development programs run by local economic players, which led to the creation of approximately 700 new jobs.

## Emerging and developing countries: technology transfer to build vaccine production capacity locally

- Sanofi has established more than 30 factories in emerging and developing countries. For example, the antimalarial ASAQ Winthrop® is manufactured in a factory in Casablanca, in Morocco, close to the region most affected by malaria. The site has been “Good Manufacturing Practices” (GMP) certified by the World Health Organization (WHO).
- Sanofi Pasteur has initiated major local manufacturing projects in Thailand, Argentina, Brazil, Mexico, China and India. Due to the vast human expertise required for such initiatives, Sanofi Pasteur is limited in the number of projects we can support. Local manufacturers must have GMP processes and stronger bio-security laws. Sanofi Pasteur also participates in raising awareness about these diseases and is heavily involved in Dengue Day.
- Sanofi is also involved in knowledge transfer in many different ways: the company enables local professionals to participate in clinical trials in developing countries, we support various training and information initiatives for health professionals and works with many different academic institutions throughout the world.

## Community programs around the globe

Worldwide, Sanofi and Sanofi Espoir Foundation maintain a strong presence in local communities through:

- Health and education programs
- Primary education programs
- Emergency relief
- Helping the underprivileged
- Donations of medicines
- Many other actions

The programs below provide examples of the Group’s efforts in different parts of the world.

| Country   | Program name  | Type of program  | Partners  | Source of support   | Facts & Figures  |
|-----------|---|--|---|---|--|
| Argentina | Comedor "El Pastorcito" & "Casa de Galilea Association" | <ul style="list-style-type: none"> <li>● Vaccination campaign</li> <li>● Workshops: Women &amp; addiction; Arts</li> <li>● Academic support and sports programs for children</li> <li>● Donations: food and other</li> </ul> |   |   |  |
| Australia | Ssave grants  | Allows Hospital Pharmacy employees to use their healthcare expertise to assist local or international communities in need  | A joint initiative between Sanofi and Symbion Hospital Services |   | Annual grants of \$30,000 total  |
| China     | Reading in Childhood & Library Project                  | Offers First Aid training and opportunities to practice  |   | <ul style="list-style-type: none"> <li>● Sanofi</li> <li>● Group employees</li> </ul> | Reached over 2,000 migrant children in Beijing   |
| Columbia  | Vaccination programs & Health promotion                 | <ul style="list-style-type: none"> <li>● Flu, meningitis and HPV (human papilloma virus) immunizations for employees</li> </ul>  |   |   | Vaccination stats: <ul style="list-style-type: none"> <li>● Influenza: 1,521 people (729 employees, 792 family members)</li> <li>● Meningitis: 231 people</li> </ul> |

| Country | Program name   | Type of program   | Partners | Source of support  | Facts & Figures   |
|---------|--|---|----------|--|---|
|         |  | <ul style="list-style-type: none"> <li>and their families</li> <li>Health Promotion program</li> </ul>  |          |  | <ul style="list-style-type: none"> <li>HPV: 36 people</li> </ul> <p>Health Promotion program: 1,538 people nationwide</p>   |
| Egypt   | Fundraising campaign   | <p>Provides help and donations to SOS Children's Villages (international NGO for social development):</p> <ul style="list-style-type: none"> <li>Renovations of soccer pitch, playground, theater and some buildings</li> <li>English courses for children</li> <li>Purchase of essential supplies</li> </ul> |          | <ul style="list-style-type: none"> <li>Sanofi Egypt</li> <li>Sanofi employees</li> <li>CHC (Consumer Health Care) team donated all Selsun Blue revenues</li> </ul> | <p>Total EGP 60,000 (EUR 10,000)</p> <ul style="list-style-type: none"> <li>EGP 30,000 in employee donations matched by Sanofi Egypt</li> </ul>   |
| Germany | German Institute for Community Organizing ("Citizen Platform Berlin-Neukölln") | <p>Creation of a new social program in Neukölln, one of Berlin's most troubled neighborhoods. Health care issues may be included.</p>   |          | <ul style="list-style-type: none"> <li>Sanofi</li> </ul>   | <p>Approximately 80 citizens' groups to participate in the program</p> <ul style="list-style-type: none"> <li>2 similar programs have successfully operated for years in other</li> </ul> |



| Country   | Program name   | Type of program  | Partners                | Source of support | Facts & Figures   |
|-----------|--|--|-------------------------|-------------------|---|
|           |  |  |                         |                   | <ul style="list-style-type: none"> <li>high-risk neighborhoods</li> </ul> |
| Hong Kong | Discounted medicines for community drug store run by NGO | Collaboration between Sanofi Hong Kong and a community drug store to provide discounted medicines to underprivileged patients living with chronic disease                      |                         |                   | Since 2009  |
| India     | Health camps   | Semi-monthly health camps led by a team of dermatologists, pediatricians, ophthalmologists and dentists for school children in the villages around the Sanofi factory in Verna |                         |                   | 20 schools and 4,000 children reached per year                            |
| Japan     | Kawagoe summer festival                                  | Annual summer carnival organized by employees to reinforce community relationships   |                         |                   | 50 carnival booths set up by employees                                    |
| Mexico    | “Recorrido por la Salud”                                 | Diabetes detection program for Mexico City   | Mexican Health Ministry |                   | Approximately 1,000 people reached  |

| Country      | Program name                                     | Type of program   | Partners                             | Source of support | Facts & Figures   |
|--------------|--|---|--------------------------------------|-------------------|---|
| Pakistan     | Engaging young cancer patients in fun activities | <ul style="list-style-type: none"> <li>● Fun-Day for young cancer patients at the Head Office of Sanofi Pakistan.</li> <li>● Gift distribution to children with cancer at Children's Cancer Hospital in Lahore</li> </ul> | Children's Cancer Hospital in Lahore |                   |   |
| Philippines  | Little lamb center                               | <ul style="list-style-type: none"> <li>● Donations for the purchase of essential medicines for children</li> <li>● Clothing drive for children with multiple disabilities</li> </ul>                                      |                                      |                   |   |
| South Africa | Child care center for orphaned HIV children      | An orphanage providing education, nutrition, recreation, and safety for vulnerable Zulu children  |                                      | Sanofi employees  | EUR 200,000 collected from employees to open the center |
| Spain        | Support to "Fundacion Humanismo                  | Promotes good health habits among immigrant population to   |                                      |                   |   |

| Country       | Program name                          | Type of program   | Partners   | Source of support | Facts & Figures   |
|---------------|---------------------------------------|---|--|-------------------|---|
|               | y Democracia”                         | facilitate integration and social cohesion  |  |                   |   |
| Thailand      | Community outreach by management team | <ul style="list-style-type: none"> <li>Provides a clinic and necessary medicines to three schools in remote areas of Chiang Rai province</li> <li>Provides educational materials and tools for kids aged 5-15</li> <li>Provides sports equipment</li> </ul> |  |                   | 3 schools in 3 communities in Chiang Rai province                   |
| Turkey        | Diabetes in School                    | <ul style="list-style-type: none"> <li>Prevention of type 2 diabetes in children</li> <li>Provides support to children with type 1 diabetes by helping them feel safe in school</li> </ul>  | <ul style="list-style-type: none"> <li>Turkish Ministry of Health and Ministry of Education</li> <li>Local teachers</li> </ul> |                   |   |
| United States | Diabetes Education                    | Diabetes camps to help patients better understand   |  |                   | In 2011: <ul style="list-style-type: none"> <li>75 camps</li> </ul> |

| Country | Program name                          | Type of program  | Partners | Source of support | Facts & Figures  |
|---------|---------------------------------------|--|----------|-------------------|--|
|         |                                       | and live with diabetes while enjoying the fun of a camp experience |          |                   | <ul style="list-style-type: none"> <li>● over \$2.5 million donated in insulin products</li> </ul>   |
| Vietnam | Free medical examination and donation | Free health check-ups, medicine and medical equipment donations    |          |                   | <ul style="list-style-type: none"> <li>● 350 people in Thanh Hoa province</li> <li>● 769 female workers in Nghe An province</li> <li>● more than 500 disabled children in Ben Tre</li> </ul> |

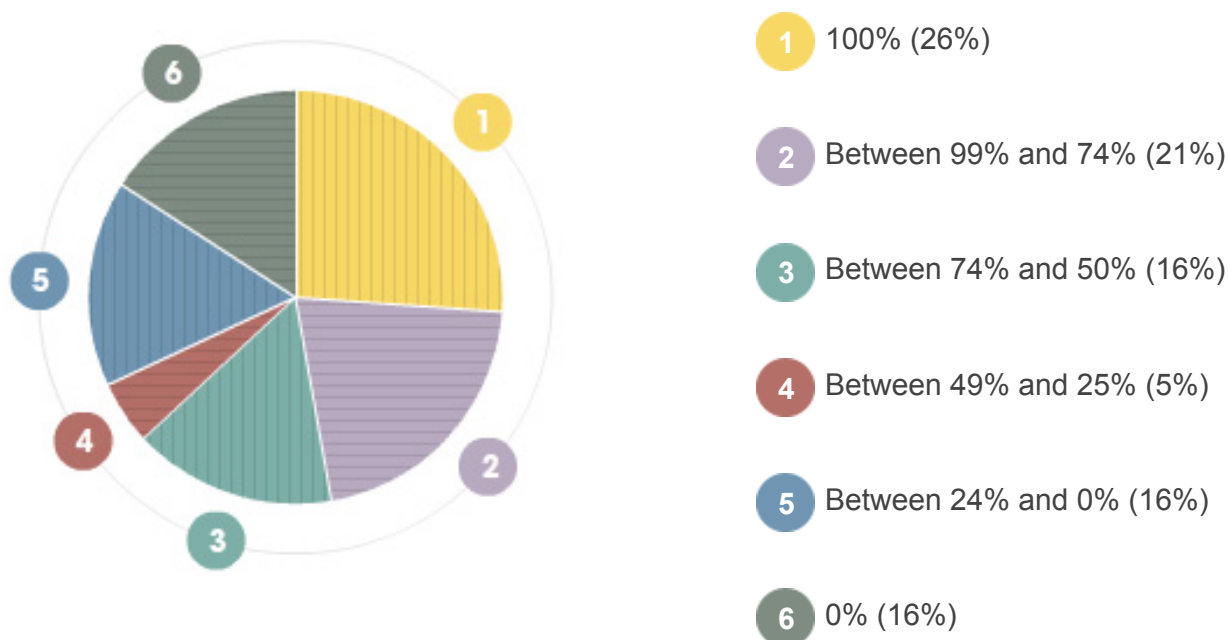
## Indicators

### Implementation of local community engagement, impact assessments and development programs.

- Among the 20 affiliates to which we asked the question, 45% have implemented local community engagement, impact assessments and development programs.

### Procedures for local hiring and proportion of senior management hired from the local community at locations of significant operation.

- 65% (of 26 affiliates who provided information) have procedures for local hiring. For the 35% which don't have procedures for local hiring, they explained that promoting local hiring was against the principle of equal opportunity employment to which they subscribe.
- When asked to provide information for this report, 19 affiliates answered the question: What is the proportion of senior management hired from the local community at locations of significant operation? A breakdown of their answers is shown in the pie chart.



## Employee volunteering

### Background

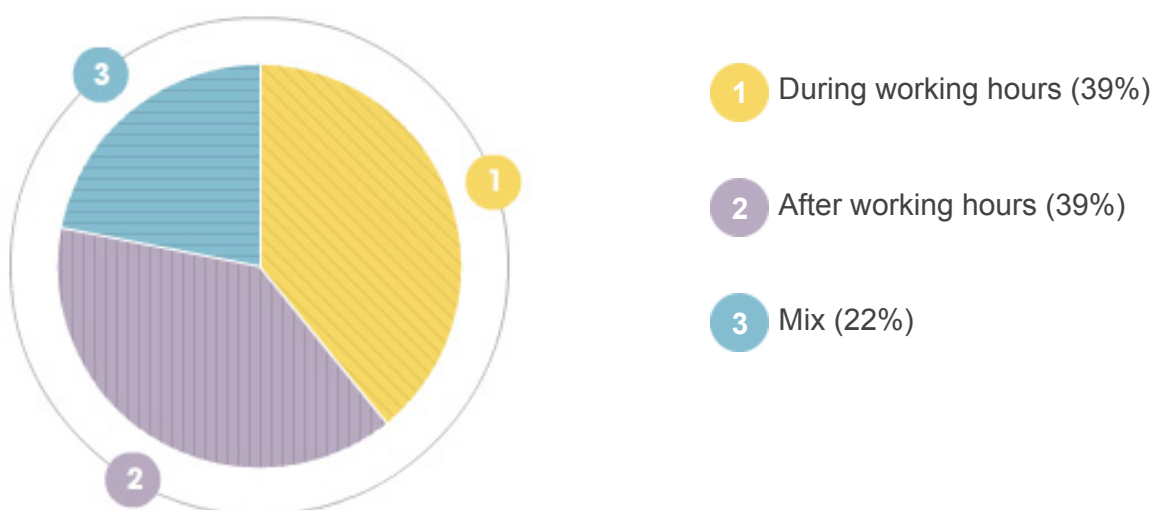
Throughout the world, Sanofi employees volunteer their time, energy and talents through corporate volunteering programs that benefit communities in need. These programs are designed to help individuals most in need.

For more information:

- [Sanofi corporate volunteering programs map](#)

In 2011, a total of 10,669 Sanofi employees took part in nearly 70 programs. The average amount of time spent on volunteering was close to five hours per employee. As is shown in the pie chart, programs are organized during working hours, after work and at times overlap onto both.

### Breakdown of time devoted to employee volunteering



## Actions

Below we highlight three of the major long-term employee volunteering initiatives organized by the Group. They are emblematic of Sanofi values such as solidarity, outreach and commitment.

- ▼ In Australia and New Zealand, community service abroad program supports employees who make a difference
- ▼ Volunteer Week in the United States
- ▼ In Brazil, employees take part in Bandeira Científica healthcare missions

In Australia and New Zealand, community service abroad program supports employees who make a difference



Sanofi ANZ offers many initiatives for employees to support local communities and healthcare groups through the affiliate's "Make a Difference" program. The Community Service Abroad is one such initiative. It gives employees the opportunity to take one month's leave with full pay to make a valuable and sustainable

in a local or overseas disadvantaged area of their choice.

This program is designed to give staff the opportunity to work overseas in disadvantaged areas and give something back to the community. The aims of the Community Service Abroad program are to:

- Make a valuable and sustainable contribution to communities in need, in line with Sanofi's Corporate Social Responsibility strategy
- Demonstrate solidarity
- Contribute to our vision of leadership in the Australian healthcare industry by providing a program that supports our strategic driver of engaged people



Each year, the affiliate selects up to four employees to embark on a mission of solidarity and participate in community service activities in local or global communities.

Maxine Sommer, Distribution Team Leader (Consumer Healthcare), recently went to South Africa, where she helped parents living with HIV / AIDS leave their legacy through memory books. The memory books allow their children and their community left behind them to preserve their memory. “Each time I return to Africa I lose a little bit more of my heart,” she said. “The society we live in means we know we have a roof over our head and food on the table. For me, the Kumbuka Project (formerly Memory Book Project) shows me the value of not only these material things but also having a shoulder to cry on and somebody to listen to your story.”



I would certainly encourage anybody who is thinking of participating in the ‘Make a Difference’ program to go for it. We are each an ordinary person living ordinary lives, but every one of us has the ability to make an extraordinary difference to somebody’s life.



**Maxine Sommer**  
Distribution Team Leader (Consumer Healthcare), Sanofi ANZ





## Volunteer Week in the United States

During the week of October 10, 2011, and throughout the remainder of the month, Sanofi employees across North America volunteered to touch the life of a patient. Altogether, employees from 29 sites volunteered in company-initiated projects, while other employees had the opportunity to give back in other ways, all in an effort to connect to patients through non-profit organizations.

Different project options were offered to employees, including company sponsored on- and off-site projects, virtual projects and individual day-off opportunities. To cite just a few examples:

- In Tucson, AZ, Sanofi R&D employees made “blood soup,” a tool used by the Leukemia & Lymphoma Society to educate patients about the composition of blood and leukemic cells.
- In Gainesville, GA, a Merial team walked large dogs at the Hall County Humane Society and spread mulch in three dog runs.
- In Toronto, Canada, a Genzyme team assembled “fun” kits for children with hemophilia or other inherited bleeding disorders
- In Cambridge, MA, Genzyme, Global Oncology, Sanofi Pasteur and Sanofi R&D employees painted murals to brighten hospital walls.

Over 20,000 North American Sanofi employees were invited to participate in such initiatives – from U.S. Pharmaceutical Operations, R&D, Industrial Operations, Global Oncology, Genzyme, Merial and Sanofi Pasteur. Sites in Puerto Rico and Canada were also included.

At latest count, close to 1,800 employees participated in 92 different projects, including gardening, cleaning animal cages, and volunteering directly with patients, serving lunch, playing games, and making crafts. For field employees, or those who could not take part in an organized company-sponsored project, there were opportunities to complete a virtual project or take up to a day off in October for patient-centric volunteering activities individually or in teams.



## In Brazil, employees take part in Bandeira Científica healthcare missions

Since 2005, Sanofi employee volunteers have been participating in medical missions to provide free access to healthcare for people in impoverished areas of Brazil. Employees from Sanofi, Sanofi Pasteur, Medley and Genzyme who have a background in healthcare are able to take part in the Bandeira Científica initiative to assist Brazilian physicians and medical students in providing primary healthcare services to communities in need.

For the last six years, Sanofi has been the principal sponsor of this program, considered to be one of Brazil's leading solidarity programs, organized with the University of São Paulo Faculty of Medicine and other partners.

Each year, a group of about 200 students from the medical and dentistry schools and other faculties take part in medical missions under the supervision of medical advisors. They join professionals and students from the localities being visited to provide primary healthcare services and assess the needs of these communities.

Sanofi has invested more than \$830,000 in this initiative since 2005, in addition to donating several of the medicines used to treat patients. Through this program, Sanofi has contributed to campaigns against dengue fever and leishmaniasis, as well as screening for hypothyroidism.

From 2005 to 2010, the mission has carried out over 34,000 consultations, thanks to the active participation of more than 1,000 people, including students and physicians from eight Brazilian cities.

Approximately 40 Sanofi employees have volunteered to participate directly in the activities of Bandeira Científica.



*Denis Félix*

## Worldmap

| Country          | Program name  |
|------------------|---|
| <b>Argentina</b> | <ul style="list-style-type: none"> <li>● Padrinos y Madrinas of Casa de Galilea</li> </ul>  |
| <b>Australia</b> | <ul style="list-style-type: none"> <li>● Sanofi ANZ "Make a Difference" volunteering</li> <li>● Sanofi ANZ "Make a Difference" Community Service Abroad</li> </ul>  |
| <b>Brazil</b>    | <ul style="list-style-type: none"> <li>● I AM SANOFI VOLUNTEER with children from the Fun Centers</li> <li>● Urban health mission</li> <li>● Bandeira Cientifica mission</li> </ul>   |
| <b>China</b>     | <ul style="list-style-type: none"> <li>● Sanofi Love Class</li> <li>● Help Disabled Persons with Love</li> <li>● First Aid &amp; Daily Healthy Program</li> <li>● Reading in Childhood &amp; Library Project</li> </ul>                 |
| <b>Columbia</b>  | <ul style="list-style-type: none"> <li>● Call to action campaign for victims of floods, "Colombia Humanitaria"</li> </ul>   |
| <b>Egypt</b>     | <ul style="list-style-type: none"> <li>● Orphans' day</li> <li>● Fundraising campaign</li> <li>● Renovation of one of the orphanages in Cairo</li> </ul>  |
| <b>France</b>    | <ul style="list-style-type: none"> <li>● Nos quartiers ont des talents</li> </ul>   |
| <b>Germany</b>   | <ul style="list-style-type: none"> <li>● Support of the Deutsche Knochenmarkspenderdatei gemeinnützige Gesellschaft mbH (DKMS German Bone Marrow Donor Registry)</li> <li>● Chaker Rayes fundraising</li> </ul>                         |
| <b>Hong Kong</b> | <ul style="list-style-type: none"> <li>● Live broadcast program for hospitalized children</li> <li>● Earthquake relief in Japan</li> <li>● Fundraising cycling program</li> <li>● Walkathon for Children's Heart Association</li> </ul> |

| Country                        | Program name  |
|--------------------------------|---|
|                                | <ul style="list-style-type: none"> <li>● Fundraising program for World Vision HK</li> <li>● Diabetes Hong Kong</li> <li>● Care For Your Heart</li> <li>● World Heart Day</li> <li>● Walkathon for Breast Cancer Fund</li> </ul>   |
| <b>India</b>                   | <ul style="list-style-type: none"> <li>● Standard Chartered Mumbai Marathon</li> <li>● Joy Of Giving Week 2011</li> <li>● Joy of Giving Week at Sanofi (India)</li> </ul>   |
| <b>Indonesia</b>               | <ul style="list-style-type: none"> <li>● Blood donation</li> <li>● Free vaccination</li> <li>● Ramadan &amp; Eid festival</li> <li>● Christmas celebration</li> <li>● Employee family gathering</li> <li>● Employee engagement committee</li> </ul>   |
| <b>Japan</b>                   | <ul style="list-style-type: none"> <li>● Work for Japan Program (reconstruction assistance after the earthquake and tsunami disaster)</li> <li>● Happy Doll Project (financial support)</li> <li>● Happy Color Project</li> <li>● Christmas Charity</li> <li>● Ashinaga P-Walk (Philanthropy Walk)</li> <li>● Relay for Life</li> </ul> |
| <b>Korea</b>                   | <ul style="list-style-type: none"> <li>● Green Santa networking day</li> <li>● Helping Hands</li> </ul>   |
| <b>Malaysia/<br/>Singapore</b> | <ul style="list-style-type: none"> <li>● Ozanam Home</li> <li>● Viriya Community Services</li> </ul>  |
| <b>Mexico</b>                  | <ul style="list-style-type: none"> <li>● Reforest Cerro Gordo, Toluca</li> </ul>  |
| <b>Pakistan</b>                | <ul style="list-style-type: none"> <li>● Children's Cancer Hospital</li> </ul>  |

| Country              | Program name  |
|----------------------|---|
|                      | <ul style="list-style-type: none"> <li>● TCF Rahbar program</li> <li>● Flood Survivor rehabilitation</li> </ul>   |
| <b>Paraguay</b>      | <ul style="list-style-type: none"> <li>● Monthly visit to San Antonio Chapel</li> </ul>   |
| <b>Philippines</b>   | <ul style="list-style-type: none"> <li>● Semi-annual blood drive</li> <li>● Ayala Museum tour for pediatric heart patients of the Philippine Heart Center (PHC)</li> <li>● PHC year-end gathering Halloween trick or treat for PCMC patients</li> <li>● PCMC painting session and art contest</li> <li>● PCMC Christmas get-together</li> <li>● Little Lamb Center</li> </ul> |
| <b>Russia</b>        | <ul style="list-style-type: none"> <li>● Charity program “Give a Smile”</li> </ul>  |
| <b>Spain</b>         | <ul style="list-style-type: none"> <li>● Cado paso Cuenta</li> </ul>  |
| <b>Taiwan</b>        | <ul style="list-style-type: none"> <li>● 2012 TW Staff Volunteering Program for Childhood Cancer</li> </ul>   |
| <b>Thailand</b>      | <ul style="list-style-type: none"> <li>● Solidarity during natural disaster (flood)</li> <li>● Rural schools classroom renovation and educational equipment donation project</li> </ul>   |
| <b>Turkey</b>        | <ul style="list-style-type: none"> <li>● Van Earthquake Project</li> <li>● World Diabetes Day Donation Project</li> <li>● Spring Cleaning</li> <li>● Theodora “Love Doctors”</li> <li>● Technological Recycling</li> <li>● Book donations to Schools</li> </ul>   |
| <b>Ukraine</b>       | <ul style="list-style-type: none"> <li>● Employee Aid Program</li> </ul>  |
| <b>United States</b> | <ul style="list-style-type: none"> <li>● 11 volunteer events on one NJ Community Service Day</li> <li>● Hurricane Irene Relief Assistance</li> <li>● Food Network of Somerset County Department Volunteer Event</li> </ul>  |

| Country          | Program name   |
|------------------|--|
|                  | <ul style="list-style-type: none"> <li>● Sanofi U.S. Volunteer Week</li> <li>● Sanofi U.S. Oncology Sales Professionals - American Cancer Society Hope Lodge Patient/Kaleidoscope Volunteer Project</li> </ul> |
| <b>Venezuela</b> | <ul style="list-style-type: none"> <li>● Sanofi Corporate Volunteerism (pediatric initiative)</li> </ul>   |

# PLANET

## Preserving the planet: A vital responsibility

Sanofi continuously seeks ways to minimize the environmental impact of its business activities, protect public health and combat climate changes.



## Planet Indicators

## Energy and carbon footprint

### Energy and carbon footprint

As a major economic player, Sanofi has adopted an ambitious policy to address climate change. The Group seeks to limit our carbon footprint by reducing energy consumption and minimizing greenhouse gas emissions.

The Group's initiatives focus on three principal areas:

- Optimizing energy consumption
- reducing CO<sub>2</sub> emissions at all sites
- Improving energy performance related to transportation



For several years, Sanofi has been committed to an ambitious plan to fight against climate change. The actions of the Group are the optimization of energy consumption and the use of renewable energy, which lead to decreased CO<sub>2</sub> emissions from Industrial sites, R&D campuses and office buildings.

**Alain Lamaud,**  
HSE Vice-president.

## Background

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▼ Risks

▼ Opportunities

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### Background

The world is facing two major issues of growing importance: Anthropogenic greenhouse gas emissions leading to climate change, and a limited supply of fossil fuels.

Climate change triggers natural disasters and can cause the migration of populations as well as a shift in the geographical distribution of diseases. Energy shortages lead to volatile and rising energy prices, which impact businesses and make forecasting difficult.

Even though the pharmaceutical industry as a whole is considered to be a minor contributor to climate change, Sanofi as a leader in the diversified healthcare industry, feels there is still a need to address this topic. This is because the pharmaceutical industry uses energy for every aspect of our business activity – from the manufacture and storage of medicines to the distribution and marketing of our products.

During manufacturing, energy is used for:

- The transformation of purchased energies (natural gas, electricity, etc.) into usable energies (steam, compressed air, cold water, etc.).
- Active ingredient production
- Product formulation, filling and packaging
- Heating and air conditioning for pharmaceutical plants
- Effluent and waste treatment at every stage of production

### Risks

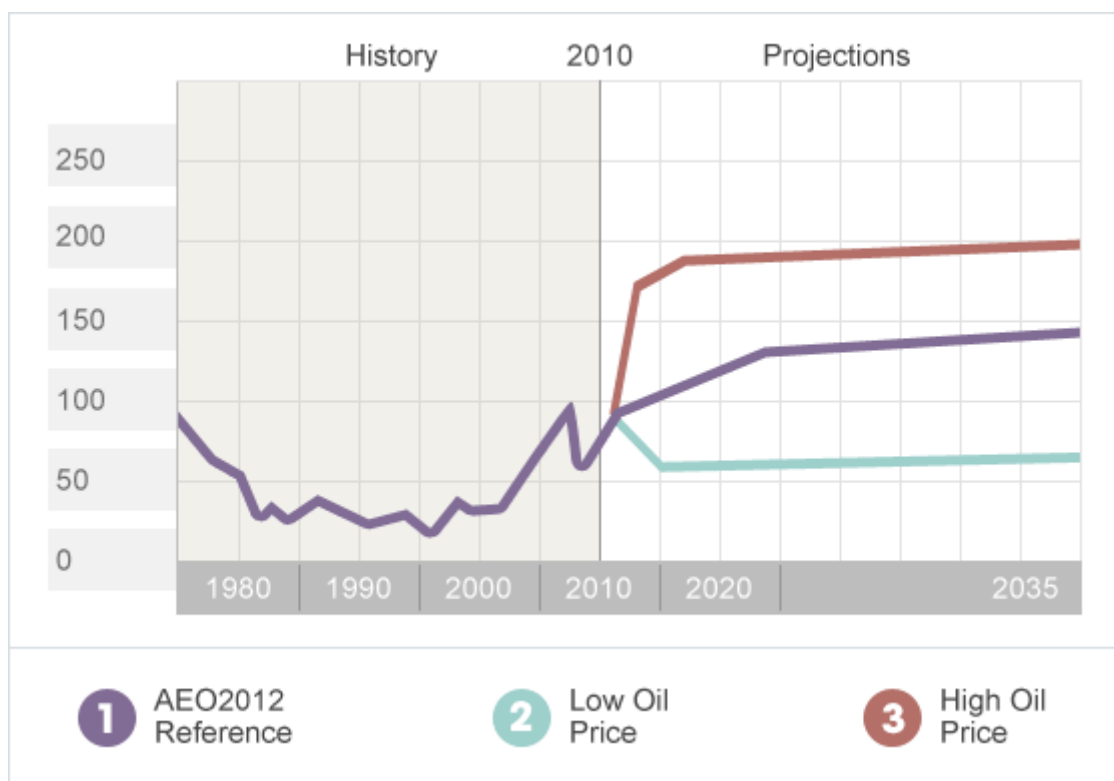
When considering climate change from a purely financial perspective, one of the principal risks concerns energy and CO<sub>2</sub> pricing.

Aside from the additional costs generated by more stringent regulations (the cap and trade system, in addition to taxes on CO<sub>2</sub> and energy), there are other significant financial risks directly related to a potential shortage of fossil fuels. Such a shortage, combined with a strong

demand from emerging countries and high extraction costs, would lead to a long-term increase as well as high volatility in energy prices over short periods of time.

Another issue that appeared after Fukushima, Japan “catastrophe” is the phasing-out of nuclear power plants that is occurring in many countries (i.e. Germany) and this will further increase energy prices due to the return of fossil fuel use.

The chart below shows the estimated average annual world oil prices for three situations (with a low oil price, with a reference case and a high oil price) from 1980-2035 period based on the value of the US dollar in 2010, per barrel (source: Annual Energy Outlook 2012 early Release Overview of the IEA International Energy Agency)



According to the reference case (AEO2012 Reference = Annual Energy Outlook 2012 Reference), the price of crude oil is forecasted to reach about \$145 per barrel (in 2010 dollars) by 2035.

In response to these issues, we aim to:

- Optimize and reduce our energy consumption in order to limit the effect of volatility and decrease our average cost of energy
- Track variations in energy prices to forecast their impact

Another financial issue concerns CO<sub>2</sub> taxes and especially the revision of the European Emission Trading Scheme (ETS) Directive. This system, introduced in 2005, consists of a European “cap and trade” system on CO<sub>2</sub> emissions. Today, many countries beyond Europe are also considering putting into place such a system – including Australia, China, and certain states within the United States.

The cap and trade system consists of defining a global CO<sub>2</sub> industrial emissions threshold. So-called virtuous companies (i.e., those that emit less than the threshold amount) would then be able to “sell” their emissions credits to companies that cause the most pollution. The companies whose emissions are above the threshold must pay for their excess of emissions.

The most recent revision of the European Directive (2009/29/EC) establishes additional binding calculation methodologies based on the best technologies. They therefore lead to a significant decrease in the quotas allotted to companies. This system represents a potential opportunity to promote greater energy savings and CO<sub>2</sub> reduction for the Group as an environmentally responsible corporate citizen.

This new directive will become effective in early 2013. At that point, nine Sanofi sites (including Genzyme) will be subject to the new ETS directive with a total amount of allotted quotas of around 145000 tons of CO<sub>2</sub>. All these European sites will be included in the ETS as they are all equipped with more than 20 Megawatts combustion capacity.

Apart from the financial risk discussed above, Sanofi is a responsible company that pays attention to stakeholders’ (rating agencies, NGOs, customers, etc.) needs and expectations in order to be a trusted sustainable partner over the long term.

## Opportunities

Climate change has triggered changing distribution and prevalence of diseases such as certain tropical diseases for which Sanofi already provides treatments and preventive vaccines. Thanks to the work of our R&D organization, the Group has several compounds in development. Implementing CO<sub>2</sub> emissions credits represents a double opportunity: first, for resale of credits thanks to our own reduced emissions, and second, for investment in efficient equipment and systems that consume less energy and generate lower maintenance costs.

### For more information:

- Our actual treatments and preventive vaccines: [\*Patient / Access to healthcare\*](#)
- The compounds in development: [\*Patient / Innovation for the patient\*](#)
- The Group’s position paper on Climate Change and Health: [\*Responsible Lobbying / Climate Change and Health position paper\*](#)

## Policy

▼ Goals

▼ Strategy

▼ Energy Network

▼ Performance Monitoring

The Group's HSE policy highlights the importance of protecting the Planet's natural resources and minimizing the residual impact of atmospheric emissions in all industrial activities. Sanofi's HSE policy seeks to "preserve the natural environment".

In support of this goal, several years ago Sanofi adopted an ambitious action plan to address climate change and reduce our energy consumption and carbon dioxide emissions.

This plan is making an impact across the Group. In 2011, Genzyme was awarded a Climate Leadership Awards Excellence in Greenhouse Gas Goal Management Achievement. And Sanofi Australia was recognized as a bronze partner in the Sustainability Advantage Program organized by the New South Wales local government.

## Goals

Sanofi established goals in 2005 to reduce CO<sub>2</sub> emissions per unit produced in order to limit the impact of the Group's activities on climate change. The Group goals were:

- 15% on direct CO<sub>2</sub> emissions in 2013 vs. 2005
- 15% on indirect CO<sub>2</sub> emissions in 2013 vs. 2005

At the end of 2011, Sanofi (Merial not included) had reached a decrease of 9.5% on direct CO<sub>2</sub> emissions and a decrease of 15.6% for indirect CO<sub>2</sub> emissions. This gap is due primarily to the start-up of cogeneration plants during this period. However, we did achieve 86% of our 2013 objectives for combined direct and indirect emissions.

In addition, Sanofi has undergone a major transformation in business scope, with the integration of Genzyme and Merial, among others. The Group has created new objective for both direct and indirect CO<sub>2</sub> emissions by accumulating CO<sub>2</sub> savings, which amount to 20% of the Group's 2010 emissions.

At the beginning of 2010, Sanofi launched a 2011 objective to assess Scope 3 CO<sub>2</sub> emissions, in accordance with international accounting methodologies. Striving for continuous improvement, Sanofi developed a new tool and methods to evaluate scope 3 emissions. These new methodologies were reviewed during our 2011 verification audits. The Group scope 3 emissions will then be published by beginning 2013.

In addition, the categories that will be subject to detailed assessments were defined. Therefore we will focus our efforts on the following categories:

- Purchased goods and services.
- Downstream supply chain
- Business travel

#### Direct, indirect and third-party emissions

The Group differentiates between three different types of CO<sub>2</sub> emissions:

- **Scope 1** emissions or direct CO<sub>2</sub> emissions are generated by the combustion of fossil fuel sources by the Group's entities, for example during manufacturing processes, and during promotional activities (sales car fleet).
- **Scope 2** emissions or indirect CO<sub>2</sub> emissions refer to emissions generated by producers from whom the Group purchases energy (electricity, brine, steam, etc.).
- **Scope 3** emissions or third-party emissions are generated as a result of the Group's purchases (raw materials, packaging supplies, services to organize international congresses and seminars) as well as the transport of goods (raw materials, pharmaceutical intermediates, medicines, etc.), business travel and employee commuting

## Strategy

As with many of our industrial processes and methodologies, Sanofi has adopted a three-fold strategy based on:



## Measuring

The first step in an effective CO<sub>2</sub> emissions reduction program is to develop the means to measure them. A consistent measurement tool is necessary to identify the sites and entities that generate the highest emission levels. This information determines where we need to focus our efforts. In addition, it provides a clear picture of our CO<sub>2</sub> emissions, improves awareness and motivates senior management to commit to reducing energy consumption and emissions.

## Raising awareness

Sanofi strives to raise awareness and provide information to managers and employees about challenges facing the Group. The Group considers climate change as an important challenge. Therefore, we regularly organize working groups, seminars and lectures addressing this topic. These events are good opportunities to share best practices on reducing CO<sub>2</sub> emissions and to communicate about the goals set by the Group.

**For more information:** The training and awareness programs organized by the Sanofi HSE Department

- [Vision / Policies and Management Systems / HSE](#)



## Taking action

When the sites with the highest emission levels are identified, our corporate Environmental Affairs Division makes recommendations to Group entities and monitors action plans and investments that are designed to:

- Reduce energy consumption
- Improve our facilities' performance and yields
- Increase the use of renewable energies whenever possible

## Energy Network

To coordinate efforts across the Group, Sanofi created a Climate Change Committee, which is in charge of:

- Sharing best practices and knowledge
- Keeping abreast of emerging regulatory requirements
- Making recommendations to implement the goals, function by function
- Monitoring progress towards achieving objectives
- Tracking variations in energy prices

All functions and business units are represented on the climate change committee: HSE, CSR, R&D, Industrial Affairs, Purchasing, Vaccines, Supply Chain, Facility Management, etc.

Today the Energy Network is fully operational. All Sanofi's industrial and R&D sites as well as each business function have an energy task force, which is in charge of establishing goals and drawing up action plans to reduce energy consumption and meet CO<sub>2</sub> emissions objectives. In addition, an energy manager and / or energy specialists have been appointed at each site.

These task forces meet on a regular basis to address technical issues and to monitor progress, discuss achievements and provide updated information to all energy site managers and specialists. In addition, they publish technical guides which are distributed to improve global understanding of the relevant issues for each site.

Thanks to this well built network, Sanofi's HSE department and its business units (Facility Management, Supply Chain, Industrial Affairs, etc.) deliver the Group's strategy and policy on reducing energy savings and CO<sub>2</sub> emissions.

## Performance Monitoring

The figures regarding Industrial, R&D sites and sales fleet are covered by the GREEN reporting tool, which is internal software used by the Group to collect, consolidate and publish the Group's environmental performance each year.

**For more information:** The environmental indicators

- [Planet / Energy and Carbon Footprint / Indicators](#)

Our administrative buildings and sales offices are mostly leased and energy invoices are sometimes not available. Therefore, the related data are not consolidated using the GREEN reporting tool. However, CO<sub>2</sub> emissions from our administrative buildings represent a small part of the Group's total CO<sub>2</sub> emissions (roughly 60,000 tons on combined direct and indirect emissions compared to a total of 1,999,111 tons including Genzyme generated by industrial & R&D sites). The Facility Management Department carries out annual mapping to reconcile and analyze the energy performance of Sanofi's administrative buildings.

In addition, as part of our Supply Chain performance, the carbon footprint of cross-border deliveries is monitored and assessed by Supply Chain teams at the Group level. These emissions will be included as part of the ongoing Scope 3 CO<sub>2</sub> emissions assessment.

## Actions

Sanofi has many initiatives to optimize energy consumption and reduce the Group's carbon footprint in line with our internal policy. Our efforts focus on several areas, such as:

- ▼ Limiting CO<sub>2</sub> emissions generated by the transport of medicines
- ▼ Improving facilities by relying on alternative sources of energy
- ▼ Making our buildings and facilities more eco-friendly
- ▼ Reducing the environmental impact of business travel and employee commuting

### Transporting medicines

The Group is aware that our business activities have an impact on the environment. This has led us to encourage developing alternative modes of transport for Group products. Whenever possible, Sanofi chooses international transport means that optimize energy consumption and limit CO<sub>2</sub> emissions.

#### Photo of an electric van



#### Sanofi

The Group has implemented several initiatives to:

- Load trucks more efficiently to decrease total shipping by truck

- Increase the use of barges and trains to reach ports instead of road shipping
- Increase the use of maritime shipment instead of air freight
- Optimize forecasts and inventories in destination countries

### Transporting medicines by rail



#### *Sanofi*

### Shipments from France to North Africa

One of the indicators monitored in transporting medicines is the number of pallets and the number of shipments. Sanofi makes every effort to increase the number of pallets shipped by barge and train.

**For more information:** The indicators related to transporting medicines

- [Planet / Energy and carbon footprint / Indicators](#)

In 2011, medicines shipments to North Africa (Algeria, Tunisia, Morocco, Egypt) represented 690 shipments, falling by 10% compared to 2010. 16,200 pallets were sent in 2011, which represents 15% pallets less than in 2010. Despite this, in 2011, 73% of pallets to Algeria from our Marne La Vallee site were sent to Marseille port by rail against 66% in 2010.

In 2010 and 2011, over 16% of pallets (on a total of 72,000 pallets) dispatched from the Marne Valley site to all countries served by sea were transported by barge to the port of embarkation (primarily to Le Havre) instead of using road transportation.

This demonstrates the Group efforts to encourage the use of barges instead of road transportation.

## Shipments of vaccines

In January 2011, Sanofi Pasteur tested sea shipment of vaccines between Val de Reuil (France) and Toronto (Canada). One ten-pallet container of Act-Hib® vaccine will be sent to Canada every three weeks using this new means of transport.

Compared to air freight, maritime shipping reduces CO<sub>2</sub> emissions more than 60-fold and cuts costs by 50%. Sea shipment also provides excellent performance in maintaining the cold chain. In all likelihood, it will now be used for destinations such as China or South Africa and for other vaccines which do not have to reach the market too quickly.

For 10 pallets of vaccines going from Val de Reuil to Toronto, maritime shipping generates approximately 0.5 tons of CO<sub>2</sub>, whereas shipping the same volume of vaccines by air freight generates 41 tons of CO<sub>2</sub>.

## Improving our facilities

As the Group explores ways to reduce energy consumption, one of our priority areas is improving the energy efficiency and yields of equipment and facilities. Sanofi's HSE Department focuses on reaching this goal by considering alternative energy sources.

Less emissive energies change the way certain equipment operates. For this reason, Sanofi's switch from light or heavy fuel to natural gas will be described in this section of the CSR Report, as well as the use of renewable energies.

## Enhanced industrial cooling techniques

Industrial cooling encompasses all the systems used to reach and maintain temperatures for facilities or products when they are lower than the outside temperature.

A centralized cooling unit was installed at the Sanofi site in Jurong, Singapore, this year. This system will save 3,600 Megawatt-hour (MWh) per year and reduce CO<sub>2</sub> emissions by 2,000 tons per year. This project was initiated in early 2011 and the initial results confirm the anticipated impact on energy consumption.

In 2010, the Jurong site consumed 17,000 MWh of electricity. With this new system, electricity consumption is expected to be reduced by 5300 MWh per year. Because such energy savings reduce costs (by EUR 500,000 per year), this initiative is expected to achieve return on investment in just three and a half years.

## Installing combined heat and power systems

Cogeneration involves producing thermal and mechanical energy simultaneously - in the same facility that is converted into electricity. Cogeneration requires considerable investment to install gas turbines and engines with boilers that recover waste heat in the form of steam or hot water.

In 2011, a combined heat and power system was installed at the Genzyme Allston, Massachusetts site, following the example of Haverhill (Suffolk, UK) site. This project involved the installation a new combustion turbine and Heat Recovery Steam Generator (HRSG). Such an initiative will make it possible to reduce energy costs by 1 million USD annually and reduce greenhouse gas emissions by 3,000 tons.

## Installing a condensing economizer

In 2011, our Sanofi Pasteur Toronto site initiated a plan to install a condensing economizer at its cogeneration facility .This mechanical device recovers waste heat from boilers in order to preheat incoming water to the cogeneration facility.

This project is scheduled to begin in 2012 and should help reduce natural gas consumption by 10,472 MWh.and save 1,898 tons of direct CO<sub>2</sub> emissions. This initiative should demonstrate a return on investment in 5 years.

## Using renewable energies

### Biomass

Sanofi encourages the move to new and greener technologies, such as biomass, which produces energy through combustion in a boiler or by the methanation to biogas.

In India, Sanofi's Goa plant took an important step to reduce reliance on fossil fuels by installing a biomass boiler that will burn agricultural waste (generated on farms, e.g., ground nut husks, etc.) to generate steam. One of the catalysts for this project was the rising price of furnace oil. Goa emits around 600 Tons of direct CO<sub>2</sub> emissions in 2011, which will be saved thanks to this project.

**Biogas** is a type of biofuel. It is produced by the biological breakdown of organic matter in the absence of oxygen, making use of organic waste such as dead plant and animal material, kitchen waste, animal dung, etc.

## Solar energy

In 2010, Sanofi entered into a partnership agreement with EDF Energies Nouvelles to install solar panels on the premises of five Group sites in France. Installation began in 2011 and will continue in 2012.

Sanofi rents parking lots to EDF Energies Nouvelles, where photovoltaic panels will be installed to make a covered parking area. This project, which is emblematic of Sanofi's commitment to promote sustainability and combat climate change, is to date the largest initiative carried out at Sanofi's industrial sites. The total surface area covered represents 22,000 m<sup>2</sup>, and the annual global production of electricity is estimated to be 3,650 MWh, which represent the annual consumption of more than 6,000 inhabitants.

EDF Energies Nouvelles invests in installing the panels and then recovers its investment by selling the electricity produced. This project concerns five sites in France: Ambarès, Aramon, Saint Loubès, Sisteron and Toulouse.

In addition, the Group strives to select green energy providers. For example, in Istanbul (Turkey), 100% of the energy consumed is produced by wind turbines and is therefore renewable. As a result, there are no CO<sub>2</sub> emissions and the site expects a 24% savings on its energy bill.

In its energetic program, Genzyme implemented an initiative to secure electricity from renewable sources such as water and wind, for all Genzyme new green buildings as well as for new energy contracts for existing buildings. To date, 24% of Genzyme's global electricity is coming from renewable sources. Due to this program, Genzyme was able to reduced carbon emissions by 40,000 tons in 2011 .Genzyme was named an EPA Green Power partner in 2004 due to their efforts in renewable energy.

## Building and enhancing eco-friendly facilities

Several initiatives target improvements to the Group's buildings, including measures for the use of renewable energies.

### Measuring energy consumption at each site

The Group encourages all sites and affiliates to be aware of their energy consumption by obtaining detailed information. Sanofi invests in accurate measurement systems so that employees can see how much energy is used by their site and will be motivated to participate in the Group's energy program.

In 2011, the Sanofi Pasteur vaccines site in Marcy L'Etoile (France) organized a project to assess and closely monitor the site's total energy consumption. For the same purpose, our affiliate in Ujpest, Hungary, installed 647 measurement points across the site. These measuring systems use dedicated software for the automatic data collection that tracks the energy performance of each building on a site. Determining which facilities consume the most energy helps raise awareness among employees and facility managers, who have a clear idea of energy costs and total consumption. Sanofi uses the GREEN software tool to record and consolidate our sites' energy consumption and CO<sub>2</sub> emissions.

### Controlling heat and air conditioning systems

Air conditioning (HVAC) systems account for approximately 70% of energy consumption for a pharmaceutical production site and from 10% to 30% of consumption for a chemical or biotechnology site.

In 2011, the Sanofi site in Parisud, France, introduced a program to reduce CO<sub>2</sub> emissions and energy consumption. By making three very specific adjustments simultaneously, the site reduced greenhouse gas emissions by 23%, generating an annual savings of EUR 200,000 as of 2011.

Efforts focused on:

- Adapting air conditioning to computer services needs
- Adjusting the flow of fresh air into office spaces.

Our site in Le Trait, France initiated a project to control the air conditioning systems, which led to energy savings by modifying the temperature ranges of non-classified areas. This system offers an "eco" mode that provides for a controlled shut-down on weekends and during public holidays, depending on the room temperature, and for a widened control range of between 16° and 24°C on working days. The "eco" option helps optimize use of the central air conditioning units and limits electricity consumption. This system led to an 8% reduction in energy bills, expected to generate savings of approximately EUR 200,000 per year.

### Encouraging "green" buildings

One aspect of eco-responsible facilities is to assure that they are built to provide environmentally sound, profitable and healthy workplaces. In order to accomplish this, sites may seek LEED certification. Since 2010, Sanofi U.S. sites have achieved LEED certification for buildings in Cambridge (Massachusetts), Tucson (Arizona), Bridgewater (New Jersey) and at the Forest Park Distribution Center (Georgia). Genzyme, a Sanofi company, sought building



certifications for its major facilities. Since 2007, 11 green buildings have been certified and five more are in the pipeline.

LEED, which stands for Leadership in Energy and Environmental Design, is a building rating system that was developed by the U.S. Green Building Council in 2000. It is a nationally accepted benchmark for design, construction and operation of high performance "green" buildings. LEED certification provides third-party validation of a project's green features and verifies that the building is operating exactly the way in which it was designed.

All types of buildings can achieve LEED certification. They include new construction and major renovation; existing buildings; commercial interiors; core and shell; schools and even homes.

Recently, the fourth floor fit-out project at Genzyme Biosurgery in Ridgefield, NJ, was awarded the highest possible certification (Platinum) under the LEED Commercial Interior Standard, version 2009. Among the specifications of these green buildings, 100% of appliances and electronics are Energy Star certified and the lights turn off automatically when there is insufficient daylight through windows or when there is no activity in an office space.

In addition, Sanofi US's Tucson Research Center received Gold LEED certification for the new construction at the Oro Valley site near Tucson, Arizona in March of 2011.

The French Equivalent for green building certification is HQE (Haute Qualité Environnementale) certification. Three Sanofi sites in France are currently seeking green building certification, including La Boétie, Massy . The Genzyme Lyon site is HQE certified.

## BUSINESS CASE



- [Business Case: Genzyme](#)

## Business travel and employee commuting

Sanofi is mindful of effect business travel and employee commuting has on our environmental footprint. Therefore, the Group encourages the use of environmentally friendly means of transportation.

## Public transportation

Sanofi ensures that wherever the Group operates, employees can use public transportation to commute to and from work. In support of this commitment, for all Parisian region sites, Sanofi reimburses 80 % of the cost of public transportation, provides shuttles and develops tools to organize employee carpooling. Among employees at Sanofi's 15 largest administrative buildings worldwide, 46% use public transportation.

For the fourth consecutive year, Sanofi US received the highest-level New Jersey Smart Workplaces award, a New Jersey Department of Transportation honor that recognizes organizations that help reduce traffic congestion and improve air quality by providing commuter benefits to employees.

The Sanofi Tucson Research Center site was honored in September by the League of American Bicyclists for its Bike-to-Work Friendliness program. It is now among more than 350 U.S. workplaces designated as bicycle-friendly by the League of American Bicyclists, taking the bronze honor.

## Developing a new vehicle policy

In 2011, the Group renewed our vehicle policy so that it requires more fuel efficient cars. The policy encourages drivers to optimize the use of their vehicles in terms of cost and energy efficiency by attending training sessions on eco-driving. From 2006 to 2010, the Group's policy coupled with eco-training helped reduce CO<sub>2</sub> emissions from the sales fleet by 25%. We expect to reduce CO<sub>2</sub> emissions an additional 10% between 2011 to 2015.

In 2011 and 2012, several pilot projects will be rolled out at a limited number of affiliates, to be expanded to all affiliates by 2015. In 2011, this type of training program was held at 21 Group administrative sites. In addition, Sanofi continues to promote the use of hybrid cars for sales representatives and management teams. In 2011, the Group had 1,461 hybrid cars worldwide for Global Operations (excluding Industrial Affairs and R&D) in eight countries (U.S., Netherlands, Italy, Japan, Germany, United Kingdom, Taiwan and Thailand).

## Encouraging virtual meetings

In 2011, Sanofi continued to install telepresence videoconferencing equipment, which are operational in 11 conference rooms in France, the United States, Canada, Sao Paulo, Shanghai and Tokyo. In 2012, this program will be extended to other sites. Virtual meetings allow participants to avoid traveling and significantly reduce travel-related CO<sub>2</sub> emissions.

**A telepresence room offers superior image quality and HD sound. In addition, participants feel like they are in the same room.**



### Support for green meetings

Sanofi promotes environmental sustainability at every meeting the Group organizes. Following the launch of the Green Meeting Task Force in 2009, this project gained fresh momentum with a creation of a task force involving members of the Meetings & Events Department of Innovative Pharmaceutical Customer Solutions (iPCS) and Intercontinental Region to establish and share environmental sustainability best practices for company events.

In particular, this taskforce launched the Green Meetings Charter in 2010, which details nine key points to be applied whenever the Group events are organized.

#### 2010 Green Meeting Charter

- Systematically analyze all possible solutions to avoid travel by those participating in meetings: e.g., videoconferences, conference calls, web casts, telepresence conferencing, etc.
- Promote local meetings
- Limit the use of paper
- Print as few copies as possible of documents and use recycled paper
- Promote reducing, reusing, and recycling materials for meetings (furniture, stands, etc.)
- Reduce energy consumption
- Select hotels and convention centers that are widely recognized as being environmentally friendly
- Select eco-responsible suppliers (transport carriers, food and beverage suppliers, etc.)
- Reduce waste for all aspects of meetings

In addition to this green meeting charter, a Carbon Footprint Calculator was designed and implemented to guide employees so that they can utilize the most sustainable practices by selecting eco-friendly hotels, caterers that support sustainability, booth builders in line with Sanofi's environmental philosophy, electronic documents instead of printed ones, recyclable materials, etc. This tool is also used to calculate the carbon footprint for the various solutions proposed.

Since its launch, improvements were made to the tool, which was updated in late 2011 in four pilot countries and in the Meetings & Events Department of innovative Pharmaceutical Customer Solutions (iPCS) and Intercontinental Region (ITC). It will be rolled out across the entire Group in early 2012 .

## Indicators

The HSE Department compiles information on the sites' CO<sub>2</sub> emissions that are directly related to energy consumption (fossil fuel at industrial sites, electrical power, and fuel fleet vehicles (used by medical sales representatives). In accordance with Group reporting policy, GENZYME environmental data is not included within Sanofi environmental data reported in 2011 due to its acquisition in the same year. However, Merial and Chattem figures are included in Sanofi data.

▼ Group CO<sub>2</sub> emissions

▼ Energy consumption

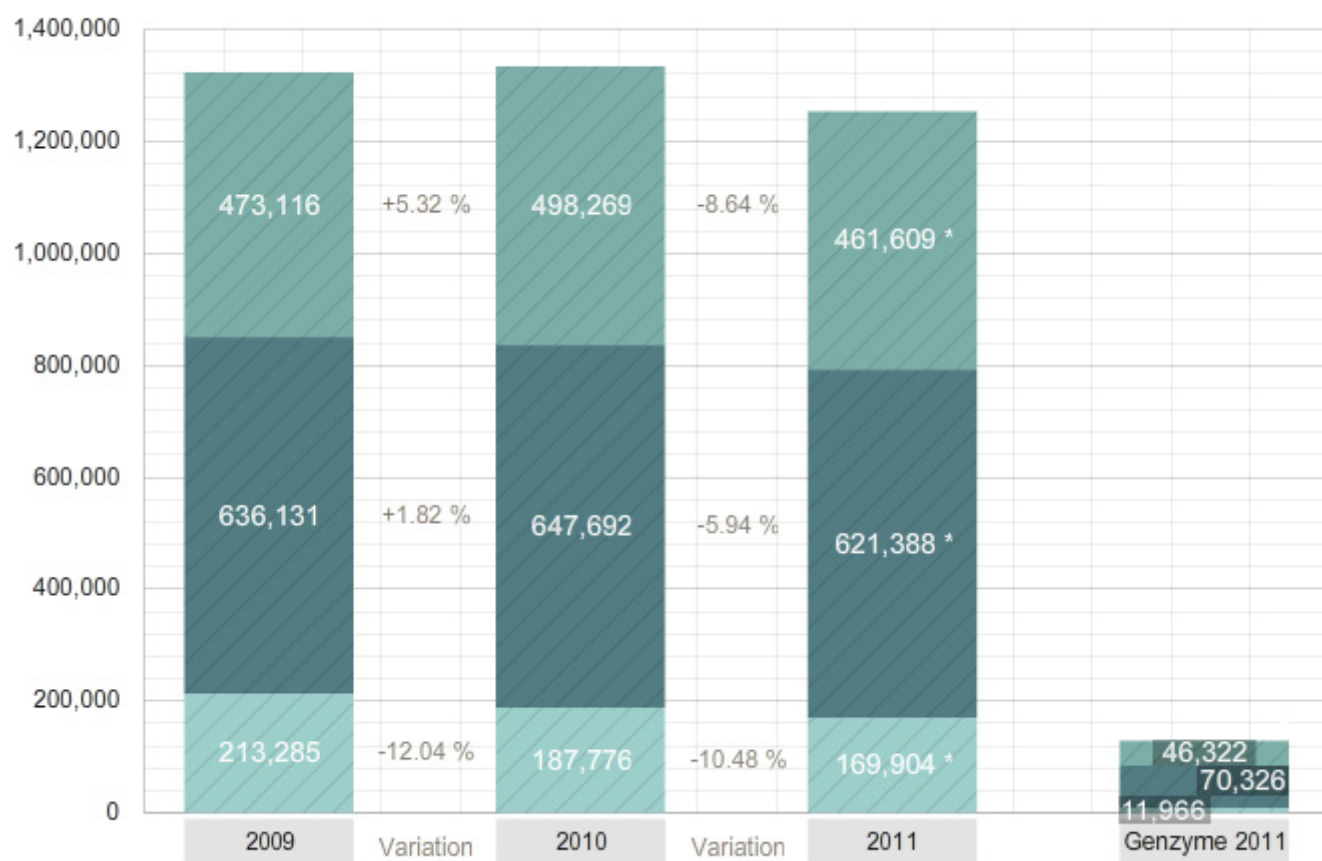
▼ CO<sub>2</sub> emissions from transport of medicines \*\*

## Group CO<sub>2</sub> emissions

Modifications in energy consumption (fossil fuel and electricity) resulted in decreases of both direct and indirect CO<sub>2</sub> emissions by 7.4% and 4.1% respectively from 2010 to 2011. This decrease resulted from the Group efforts to mitigate energy consumption and utilization of less emissive energy sources.

Sales fleet emissions were estimated on the basis of fuel consumption. The corresponding emissions have decreased by over 10% in 2011 on a comparable scope. This decrease was due to the continuous implementation of the vehicle policy to use safer and more energy efficient vehicles, as well as the reduction of vehicle fleet.

(Unit in tons)



- Fossil fuel (direct CO2)
- Production of electricity and steam (indirect CO2)
- Medical sales fleet vehicles (estimated)

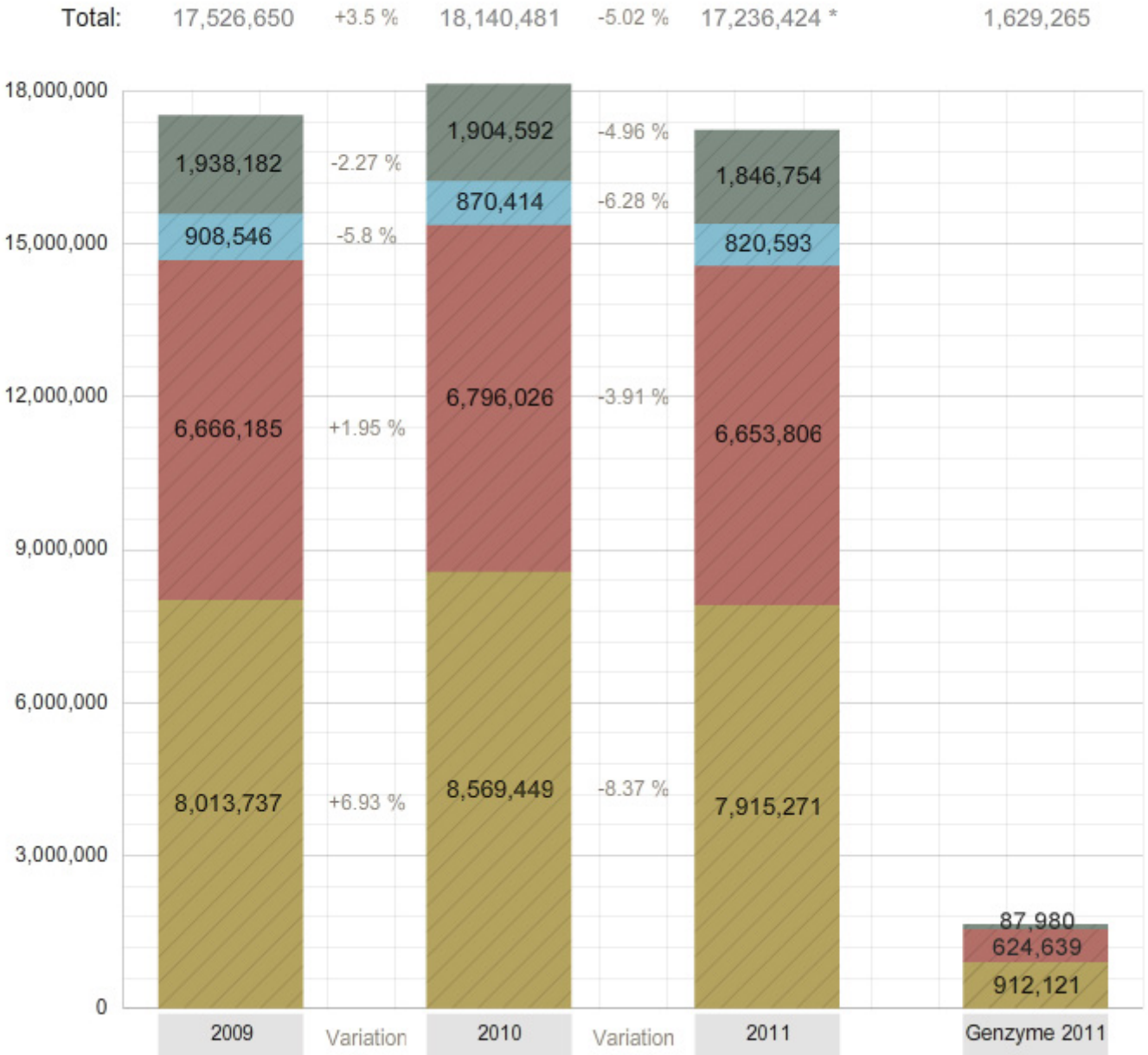
## Energy consumption

Even though the manufacturing activities of the pharmaceutical industry do not necessarily require a significant amount of energy the Group strives to control the amount of energy needed.

In 2011, energy consumption decreased by 5% compared to 2010. This decrease is the result of:

- the Group energy conservation program
- the reorganization of the R&D activities
- the conversion of the chemistry manufacturing facilities to biotechnology processes.

(Unit Gigajoules)



CO<sub>2</sub> emissions from transport of medicines \*\*

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Many key indicators were established to measure the performance of drug product transport such as:

- the weight of CO<sub>2</sub> emitted for each pallet transported,
- the TOR (Truck Occupation Rate) = average number of pallets loaded in a truck reported to the theoretical maximum capacity
- and the WBS (Weight By Sea). = percentage of weight shipped by sea compared to the total weight shipped

We continually seek to optimize CO<sub>2</sub> emissions per pallet by increasing the TOR and the WBS. In addition Sanofi continues to reduce the use of air freight and road transportation.

In 2011, international transport activities for the Group's products from production sites to their various destinations (distribution centers, third-party customers, etc.) generated 84,600 tons of CO<sub>2</sub> emissions (vs. 55,000 in 2010 and 63,000 in 2009). These emissions represent approximately 95% of the CO<sub>2</sub> emissions generated by international transport for the Group's products. Initiatives put in place to reduce CO<sub>2</sub> emissions from transport will be continued in 2012.

#### Weight of CO<sub>2</sub> emitted by pallet

In 2011, 23,5 kg of CO<sub>2</sub> was emitted by pallet in drug product transportation between European sites. In addition, the increase of CO<sub>2</sub> emissions by pallet between intercontinental sites (+33% in 2011 compared to 2010) is especially due to a temporary increase of requests, which required emergency air shipments in the US.

#### WEIGHT OF CO<sub>2</sub> EMITTED BY PALLET

| (kg of CO <sub>2</sub> /pallet)                    | 2010 | 2011 | Variation<br>2010-2011 |
|--|------|------|------------------------|
| Transport in Europe between sites (road transport) | 23.4 | 23.5 | <b>+0.01%</b>          |
| Intercontinental transport (by air or boat)        | 336  | 447  | <b>+33%</b>            |

#### Weight transported by sea (WBS)

In 2011, the percentage of weight transported by sea reached 76,3% of total intercontinental weight and decreased by 7.2% compared to 2010. This is due to the emergency air shipments in the US.

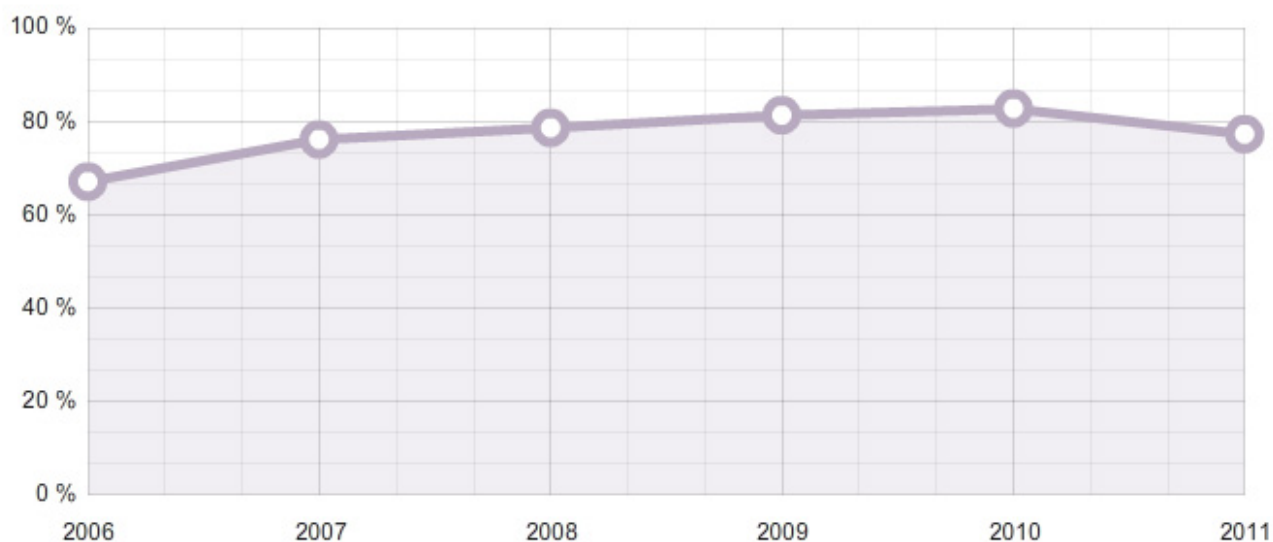
When there is a decline of one point in the WBS, this represents an additional 2,226 tons of CO<sub>2</sub> emissions per year.



### % WEIGHT TRANSPORTED BY SEA / TOTAL INTERCONTINENTAL WEIGHT

|  | 2010  | 2011  | Variation<br>2010-2011 |
|--|-------|-------|------------------------|
| % weight transported by sea<br>/ total intercontinental weight | 82.2% | 76.3% | <b>-7.2%</b>           |

### WBS evolution



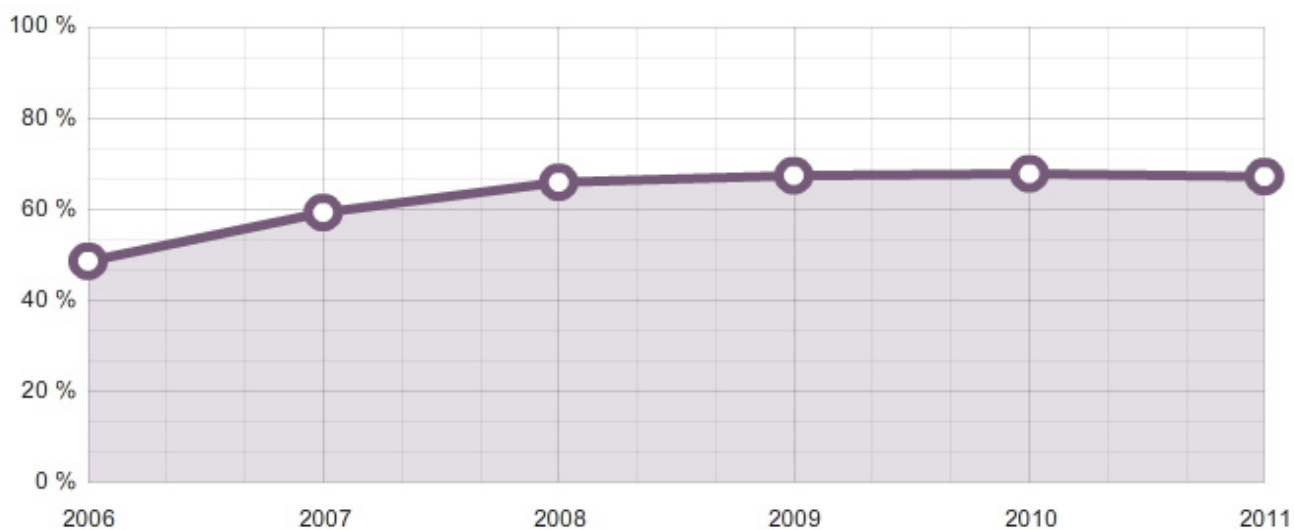
### Truck Occupation Rate (TOR)

In 2011, the truck occupation rate decreases slightly (< 1%) compared to 2010 and represents in 2011, 67.2% of the maximum capacity of trucks. Sanofi seeks to increase that number in order to optimize (or maximize) any trip and thus, to decrease CO<sub>2</sub> emissions related to transportation.

### TRUCK OCCUPATION RATE (TOR)

|                             | 2010  | 2011  | Variation<br>2010-2011 |
|-----------------------------|-------|-------|------------------------|
| Truck Occupation Rate (TOR) | 67.8% | 67.2% | <b>&lt; 1%</b>         |

## TOR evolution



\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)

\*\*The CO2 emissions from transport of medicines do not include Merial and Genzyme.

## Business case

Genzyme meets CO2 emissions reduction target two years early and receives Climate Leadership Award

## The challenge

Genzyme wished to develop an effective response to two pressing problems: climate change and the rising cost of energy.

## Our response

Genzyme responded to this challenge by implementing energy efficiency measures to reduce our carbon footprint and save million of dollars. Specifically, the company:

- Set an ambitious goal in 2007 (25% greenhouse gas reduction target, normalized to revenue) and reached this target two years ahead of schedule
- Created a Global Energy Sustainability Team, which is a cross-functional group of employees from the engineering, environmental and purchasing departments
- Worked closely with sites and capital project teams to implement energy conservation measures and green buildings
- Set site greenhouse gas reduction targets driven by the implementation of cost effective energy conservation measures
- Laid strong foundations for employee involvement in sustainability activities

This program has produced very tangible results – for example:

- Implementation of 75 energy conservation measures at an initial cost of \$1.2M that will save \$2.1M per year, with an annual reduction of 4,750 MtCO<sub>2</sub>e (metric tons of carbon dioxide equivalent)

- 24% of global electricity is now purchased from renewable sources, which avoids over 40,000 metric tons of carbon emissions. Genzyme has qualified as an EPA Green Power Partner (see [www.epa.gov / greenpower](http://www.epa.gov/greenpower))
- Two green buildings were certified in 2011, for a total of 10 (five more are in the pipeline)
- Nearly 2,000 Genzyme employees were surveyed to understand attitudes on energy efficiency in the workplace. The survey results have been used to create a web-based toolkit to engage Genzyme employees on energy and the environment.

## Benefits for stakeholders

### **For shareholders and investors**

This program has led to cost savings by reducing energy consumption. It helps reduce the company's financial risk in connection with energy contracts. Moreover, it motivates employees and promotes a culture of collaboration, which contributes to employee retention. Lastly, the program enhances ISO 14001 and ISO 50001 compliance for the company.

### **For employees**

Employees feel a sense of pride and community by taking part in this program, which offers internal leadership and networking opportunities for individuals beyond their regular jobs (e.g., leading an energy or green team). They participate in company and community energy projects. Employees who feel committed are more likely to support future energy conservation measures – for example, they will tolerate slightly warmer or cooler work areas if they understand and support climate change initiatives. Last but not least, employees bring home to their families what they have learned about energy efficiency technology.

## Opportunities for the Group

Thanks to this program, Genzyme was selected as a winner of the inaugural Climate Leadership Awards sponsored by the U.S. Environmental Protection Agency and its partners. In addition to attendance at the Awards Gala, Genzyme was invited to participate in the 2012 Climate Leadership Conference.

The Genzyme energy program has earned public recognition for the company's top tier global energy program as evidenced by a strong Carbon Disclosure Project score (Genzyme ranked 6th out of 33 global healthcare companies).

See the Carbon Disclosure Project (CDP) Results (May 2011):

- [www.cdproject.net / en-US / Pages / HomePage](http://www.cdproject.net/en-US/Pages/HomePage)

## The Future

For 2012, our goals focus on making further progress on procurement savings and energy reduction by:

- Supporting Sanofi's draft goal of 20% reduction for total CO2 emissions, 2010-2020 as published in 2012 HSE Progress Action Plan
- Coordinating site greenhouse gas reduction targets through the Corporate Ops "Common Site KPI" process
- Consolidating energy contracts with Sanofi where regional opportunities exist
- Implementing cost effective energy conservation measures identified in previous assessments and performing new site energy assessments
- Continuing the green building certification program

## Local environmental impact

### Key issues

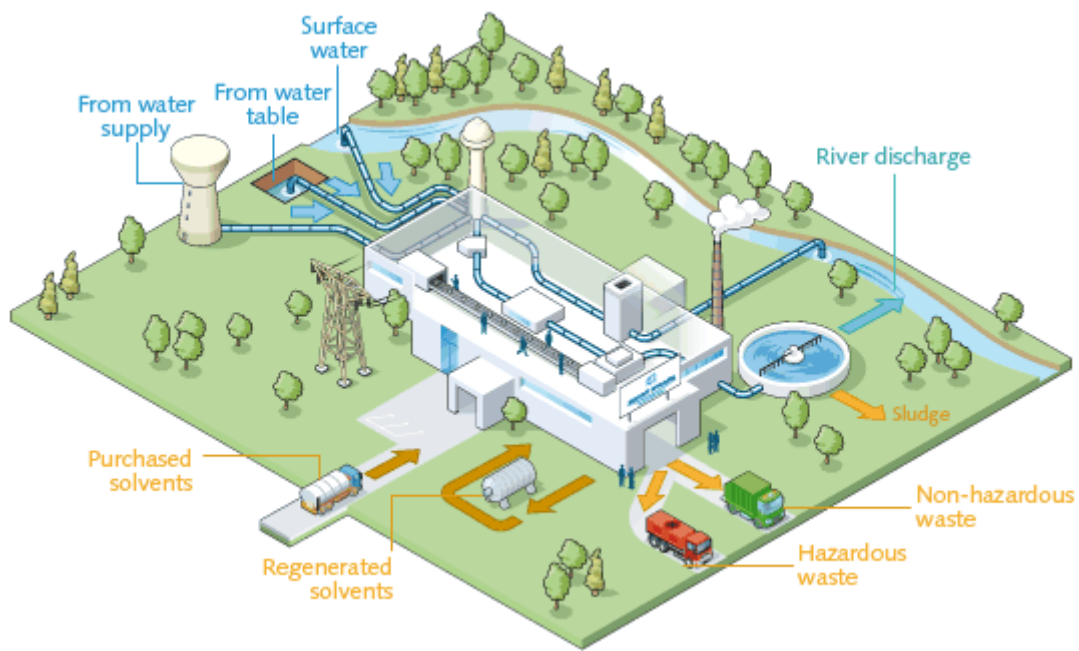
Many issues affect the local environmental footprint of a pharmaceutical group such as Sanofi:

- Various types of water usage
- Consumption of resources (raw materials and ingredients used to produce active ingredients and in the formulation of medicines and vaccines)
- Use of solvents for drug and vaccine synthesis and production phases
- Use of different materials to protect and package products
- Different types of emissions generated by the sites: These emissions include air emissions, wastewater effluents and waste of all kinds, and concern all types of sites – R&D sites, production sites for active ingredients, medicine and vaccine manufacturing sites, as well as logistics and administrative sites.

### Sanofi's commitment

Protecting the environment is a long-standing commitment at Sanofi. With numerous sites operating throughout the world, the Group strives to reduce the potential impact on the environment of manufacturing medicines and vaccines in order to reduce the local environmental footprint of its activities.

The HSE Department is responsible for overseeing initiatives to minimize environmental impact. All the Group's sites receive information about these issues, and various initiatives are carried out to limit water consumption and wastewater discharge, preserve air quality, manage waste responsibly and remediate contaminated soil.



## Green chemistry

### Background

Chemistry is an integral part of our pharmaceutical business. Green chemistry is understood to be superior innovative chemistry that is cost effective and has minimal impact on the environment.

Over the past decade, the pharmaceutical industry has been moving toward the application of green chemistry principles, mainly by introducing new production and analytical technologies, using greener solvents and emphasizing enzymatic chemistry.

Green chemistry focuses on making industrial chemistry safer, cleaner and more energy efficient while generating economic benefits. This concept is driven by efficiency combined with environmental responsibility to offer enhanced chemical process economics.

In the words of Paul Anastas, who introduced the term green chemistry in 1991, "It's more effective, it's more efficient, it's more elegant, and it's simply better chemistry!"

#### **The 12 Principles of Green Chemistry**

**For more information:** The ACS Green Chemistry Institute® website

- [portal.acs.org / ACS Green Chemistry Institute®](https://portal.acs.org/ACS-Green-Chemistry-Institute)

### Policy

With a long history in active ingredient manufacturing, Sanofi is committed to improving its drug manufacturing processes so that it minimally impacts the environment.

Each development team involved in the design and improvement of our chemical and biotechnical processes for producing our active ingredients is intently focused on this goal. In support of our corporate commitment, we have taken a number of tangible steps to reduce our environmental footprint – from the design of our R&D synthetic pathways to the production of active pharmaceutical ingredients in our plants.



## Actions

- ▼ [Optimizing raw material use and processes](#)
- ▼ [Tracking the greenness of our processes: the PMI metric](#)
- ▼ [Solvents](#)
- ▼ [Promoting green chemistry within the pharmaceutical industry](#)

### Optimizing raw material use and processes

Throughout the chemical and biochemical product development stages that are part of manufacturing drugs, Sanofi teams make decisions about the processes they use based on criteria designed to protect the health and safety of employees while preserving the environment.

### Tracking the greenness of our processes: the PMI metric

Medicines are often produced using large amounts of input materials to produce very small amounts of active ingredients, which corresponds to low mass efficiency. Developing and producing drugs this way is not only costly, but harmful for the environment.

Benchmarking shows that the pharmaceutical industry typically uses about 100 kg of material for every kg of active pharmaceutical ingredient (API) produced. This 1% mass efficiency compares to about 20% for fine chemicals and 50% for bulk chemicals.

Experts from within the industry as well as health authorities such as the FDA and EMEA recommend that drug companies focus greater attention on this issue. To this end, it is essential to adopt a common metric to measure progress towards more sustainable manufacturing.

To answer these needs, Sanofi recently implemented the Process Mass Intensity (PMI) indicator.

PMI measures the mass (weight) of the API produced compared to the mass (weight) of substrates, reagents, solvents and process water used to manufacture the API. Because the Group introduced the use of PMI relatively recently, some of our past data do not include this indicator.

The initial PMI assessments of our products reveal that our figures are clearly within the pharmaceutical industry range, as shown in the examples below:

- In the cardiovascular field, small molecules show a PMI of between 1.2 and 1.8%. In the last two to five years, improvements of 3% to 30% have been made. The production range is 30 tons per year for one API and 400 tons per year for the other API.
- Improving efficiencies of hemi-synthesis of molecules from natural substances is very difficult. These show a PMI of 0.33%, with improvements of 5% over the last two years. Our results may be explained by a loss of active ingredients during extraction, in addition to the fragility of these molecules.

Sanofi has also assessed the PMI of compounds produced using fermentation processes, which result in even smaller ratios due to the extraction and purification phases, as well as the need to use large amounts of water, which is also taken into account when calculating PMI.

Further investigations of PMI from our commercial API portfolio as well as mean values for product development are currently ongoing.

## BUSINESS CASES



To decrease the environmental footprint and costs associated with the production of clopidogrel hydrogen sulfate (trade name Plavix® or Iscover®), Sanofi set up an ongoing green chemistry project that has led to improved synthetic pathways, increased yields and smaller quantities of solvents in the manufacturing process. These important improvements meet the expectations of both internal and external stakeholders.

- *Business Case: Green Chemistry*

## Solvents

Making choices when it comes to solvent use

From the earliest stages of product development, teams are encouraged to use reagents and solvents that pose the least possible hazard. One of their tools is a scale that assigns

compounds to one of five categories according to their potential impact on health, safety and the environment. To help teams make decisions on a daily basis, Sanofi has developed an internal guide on the appropriate use of solvents for the design of drug manufacturing processes.

The vast majority of energy, chemical reagent and solvent reduction occurs during scale-up and manufacturing medicines, rather than during the drug research phase. Even after an active ingredient is in the production phase, industrial development teams continue to optimize synthesis and biosynthesis processes whenever possible. Choices made during the industrial development phase are often difficult to change later on, which is why it is important to make sustainable decisions early in the development process, taking into account future manufacturing and scale-up.

To choose substances and materials with the least environmental impact, the Group has established processes designed to:

- Select the least toxic solvent
- Reduce the quantities of solvents used in industrial processes
- Recycle solvents whenever possible

#### Optimizing solvent consumption

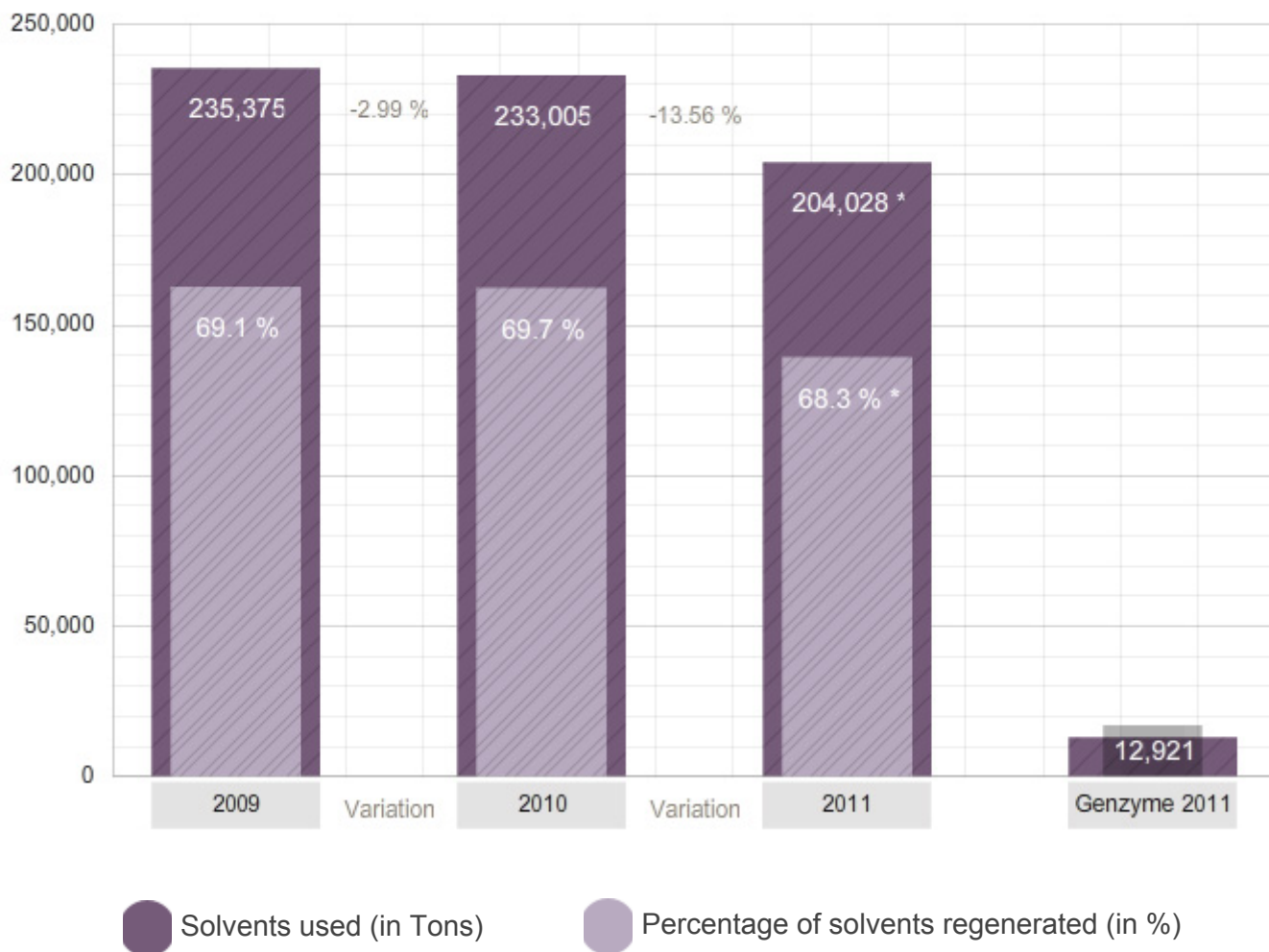
Solvents used in the production processes are either purchased (“consumed” quantities) or regenerated at Sanofi sites. To decrease the use of non-renewable raw materials, the Group focuses on three areas:

- Process optimization
- Recycling (when possible)
- Incineration with energy recovery

In 2011, 68.2% of solvents used by the Group were recycled solvents.

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(In tons)



International chemistry initiatives

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Sanofi was one of the sponsors of the International Year of Chemistry, with events held throughout 2011 at the behest of the United Nations. This initiative was organized to inform the public about chemistry's contributions to knowledge, environmental protection and economic development. Sanofi took part in the opening events at the UNESCO headquarters in Paris in January 2011.

**For more information:** The International Year of Chemistry

- [www.chemistry2011.org](http://www.chemistry2011.org)

Promoting green chemistry within the pharmaceutical industry

In 2011, Sanofi joined the American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable, which aims to catalyze the implementation of green chemistry and

engineering throughout the pharmaceutical industry globally.

Sanofi has launched various collaborative initiatives in line with these general objectives:

- Assessment of PMI improvements for the production of key active pharmaceutical ingredients
- Contribution to the training program developed by the Green Chemistry Institute Pharmaceutical Roundtable in Europe
- Participation in joint efforts to incorporate the PMI metric into the different electronic lab notebooks used
- Contribution to underwriting the Green reagent alternatives guide with the members of the Green Chemistry Institute Pharmaceutical Roundtable

**For more information:** The ACS GCI Pharmaceutical Roundtable

- [portal.acs.org / ACS GCI Pharmaceutical Roundtable](http://portal.acs.org / ACS GCI Pharmaceutical Roundtable)

#### Innovative Medicines Initiative (IMI) in Europe

The discovery of green and sustainable synthesis methodologies is a long-term endeavor. Today collaborations between academia and pharmaceutical companies provide an opportunity to develop green, safe and more effective processes to deliver medicines for the 21st century.

The Innovative Medicines Initiative (IMI) is a pan-European public-private partnership supported by EFPIA. It was created in 2007 to bolster R&D in the European pharmaceutical industry.

In 2011, Sanofi together with other European pharmaceutical companies (GSK, Janssen, Bayer and Orion) suggested that IMI launch a call for proposals in the field of sustainable chemistry. Sanofi plans to contribute up to EUR 7.5 million over four years to support this project. The academic consortium CHEM21 was selected, representing 13 teams from five European countries.

**For more information:** Innovative Medicines Initiative (IMI):

- [www.imi.europa.eu](http://www.imi.europa.eu)

#### Membership in learned societies

Sanofi is a member of several learned chemistry societies, such as the Société Française de Chimie (SFC), the American Chemical Society (ACS), and several others. In 2011 Sanofi took

an active part in a workshop organized by the Union des Industries Chimiques (UIC) on “Chemistry and Sustainable Raw Materials,” which focused on the importance of designing green processes.

#### Internal Green Chemistry workshop

To promote Green Chemistry, Sanofi organized a comprehensive internal workshop in Spring 2011 that gave rise to a wealth of proposals. Participants recommended introducing measures within the Group, such as new drug application (NDA) pathway selection taking into account the principles of Green Chemistry – in particular biotransformation, synthetic biology, process intensification and energy savings. They also suggested that action plans should include Green Chemistry objectives in projects for development and production teams.

Workshop participants also called for action plans to include the adoption of the global Process Mass Intensity (PMI) metric, which other companies also use, to measure improvement and set global targets, expressing the need to rapidly integrate this metric into the development process.

To encourage networking, Sanofi should participate in joint initiatives to promote sustainable development and create synergies with other pharmaceutical companies on pre-competitive targets. In addition, the Group should contribute to private-public partnerships in order to provide guidance to academics on mid-term research towards Green Chemistry objectives.



With other pharmaceutical companies, we will contribute to actively building further collaboration in greener chemistry.

**Philippe Mackiewicz,**  
Scientific Director of Chemistry and Biotechnology, Sanofi Industrial Affairs

\* Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

● [Vision / CSR performance / Statutory auditors' review report](#)

## Business Case

### The challenge

The active pharmaceutical ingredient (API) clopidogrel hydrogen sulfate has been marketed in a number of countries under the trade names Plavix® or Iscover® since 1997. In certain regions, pursuant to a license agreement between Sanofi and Bristol-Myers Squibb, this drug is marketed by both BMS and the local Sanofi affiliate. Patients take this anti-platelet agent for the prevention of cardiovascular events linked to the buildup of lipids in the blood vessels.

Sales of Plavix® / Iscover® have delivered steady growth since it was brought to market, reaching € 6.989 billion in 2011 (combined Sanofi / BMS sales worldwide). As of 2011, 3.4 billion tablets have been produced (by both groups), which represents 267 tons of API.

In line with the Group's policy on environmental protection and green chemistry, Sanofi began in the 1990s to develop initiatives to improve and optimize the synthesis processes for many of our APIs with the aim of reducing their environmental footprint. Naturally, these initiatives typically targeted the products that generate the largest volumes of API or those with the greatest potential impact on the environment.

Large quantities of API are required for the manufacture of Plavix® / Iscover®. Following the drug's launch on the market, and from a very early stage, Sanofi has continuously sought ways to improve our synthesis processes to help preserve the environment.

### Our response

Efforts to use more environmentally conscious processes for the synthesis of clopidogrel hydrogen sulfate began in the late 1990s and continue today. Since 1997, three consecutive synthetic pathways have been developed.

Although improvements to the initial process (Process A -> Process B) did bring about a degree of improvement on the environmental front, it was the third process (Process C) that resulted in a significant reduction in the number of chemical steps, as well as the number, volume and toxicity of the solvents used. At the same time, a marked overall increase in yields occurred.

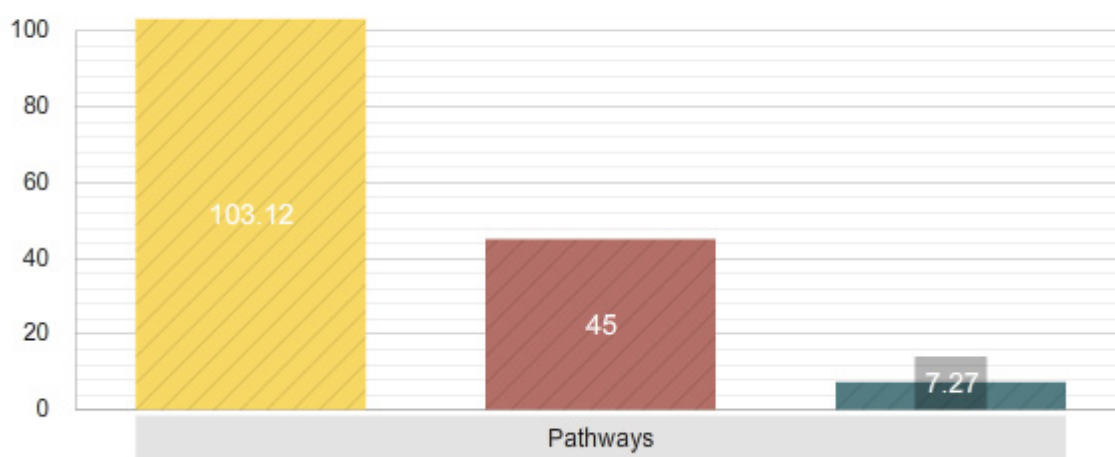
The table below summarizes the step-by-step improvements resulting from adopting each synthetic pathway.

| Synthetic pathway | Process A  | Process B   | Process C  |
|-------------------|--|---|--|
|                   | <ul style="list-style-type: none"> <li>7 chemical steps</li> <li>5 solvents</li> <li>&gt;100 kg of solvents / kg of active pharmaceutical ingredients (API)</li> <li>Yield: 15%</li> </ul> | <ul style="list-style-type: none"> <li>6 chemical steps</li> <li>4 solvents</li> <li>45 kg of solvents / kg of API</li> <li>Yield: 24%</li> </ul> | <ul style="list-style-type: none"> <li>4 chemical steps</li> <li>3 solvents</li> <li>7 kg of solvents / kg of API</li> <li>Yield: 66%</li> </ul> |

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As the following table shows, the quantities of solvents used were also reduced by a factor of more than 20.

Quantity of solvents (kg) / active ingredients (kg)



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Pathway A



Pathway B



Pathway C

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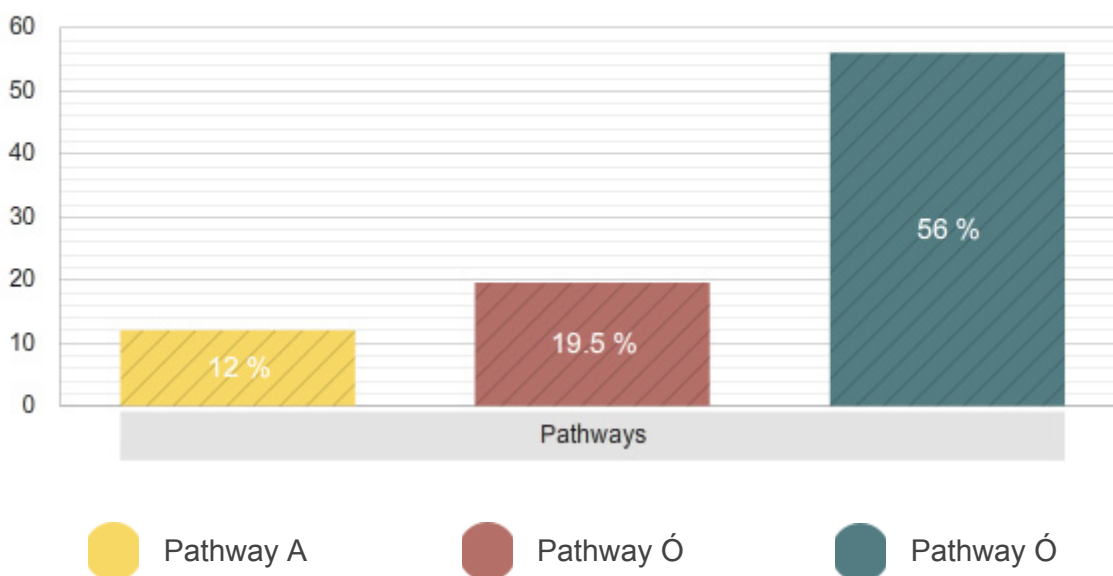
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Finally, yields were significantly improved, as demonstrated by the RME (reaction mass efficiency) values shown in the next table.

The RME indicator makes it possible to evaluate the efficiency of the process and identify the correlation between the mass (weight) of product obtained and the mass (weight) of reagents used. Therefore, in general, the higher the RME, the cleaner and the more optimized process is.



### Reaction mass efficiency, RME (%)



### Benefits for stakeholders

For local communities around our sites:

Although recycling and incineration methods are implemented at Group sites that are designed to prevent the potential release into the air of Volatile Organic Compounds (VOCs) resulting from the use of solvents, it is also critical to strive to reduce the quantity of solvents used, as is the case in Process C. This is a way of targeting the source of any potential VOCs and helps to control any environmental impacts.

For employees:

By using fewer solvents, potential toxicity risk is reduced for employees in compliance with the Group's HSE policy, which is designed to protect employees' health and safety.

### Opportunities for the Group

The synthesis process is cleaner, and yields are higher. Furthermore, reducing the number of solvents and the quantities used also reduces costs linked to raw materials.

And fewer chemical steps mean a shorter cycle time so that fewer operations are performed during production, which ultimately is expected to lead to lower energy consumption.

These improvements also contribute to reducing VOC emissions, facilitating compliance with applicable emissions limits prescribed by local law.

### The future

Similar initiatives are underway for other Group products. These ongoing efforts help demonstrate Sanofi's initiatives in green chemistry.

## Water management

### Background

Sanofi is committed to the sustainable management of clean water, which has become one of the most important issues of the 21st century. This is because water is a fundamental and scarce resource for life and the world's ecosystems.

Moreover, due to the increase of the world population (to reach seven billion), the demand for water has skyrocketed. Communities use clean water for a wide range of human activities: farming, domestic needs (through potable water supply) and industrial applications, to name a few. Clean water must therefore be managed responsibly.

Only 1% of worldwide water is potable. The ways in which Sanofi manages the use of water for the Group's activities must take into account both increasing demand and limited supply, so that communities and future generations will have access to this resource for years to come.

Industrial wastewater discharge and emissions resulting from use of medicines by patients are key issues for society and the Group as a whole.

**For more information:** The "Pharmaceuticals in the environment".

- [\*Pharmaceuticals in environment\*](#)

Industrial wastewater discharge comes from liquid effluents:

- From sites that manufacture active ingredients
- From sites that produce medicines and vaccines
- From R&D laboratories and pilot plants

Effluents (wastewater that flows out of a treatment plant or industrial site) primarily fall into two categories:

- Effluents from manufacturing active ingredients, medicines and vaccines and those generated by cleaning processes
- Water from refrigeration and condensation systems

As part of our commitment to manage water responsibly, Sanofi strives to minimize our wastewater discharge to preserve the availability of surface water.



Sanofi enhances its efforts towards less consumption and improved waste water treatment in its facilities. This is supported by different actions based on developing best practices and new technologies.

**Alain Lamaud**  
Vice-President HSE Sanofi

## Policy

Water is needed for many of the steps required to produce medicines and vaccines, and Sanofi is committed to responsibly managing this vital resource.

Most of the Group's water consumption takes place during the different stages of industrial processes – for cooling systems during manufacturing, for fermentation and vaccine manufacturing, and for cleaning processes.

Sanofi systematically assesses any areas where water can potentially be saved, makes investment decisions accordingly and takes measures to reduce consumption. As part of our Health, Safety and Environment (HSE) policy, we have implemented an environmental management system, which covers all levels of our operations and supports the continuous improvement of our performance.

The Group uses a dedicated reporting tool, the GREEN tool which includes data related to water management. Regular reviews are carried out to monitor current programs, assess progress and improve our strategy. Our water management policy describes the general approach to water management for our activities and sites. In addition, a guidance document describes further requirements applicable to all the Group's industrial, R&D and vaccines sites. These requirements cover reducing consumption and preventing water pollution as well as the control and monitoring effluents.

Sanofi's policy primarily concerns improving discharge treatment systems and implementing systematic quality controls for effluents. Management of waste water effluents from production sites is covered by one of the 78 HSE requirements developed by the Group. Industrial effluent wastewater is either treated on site in Sanofi's factories or at treatment plants in nearby cities or communities, with corresponding agreements with operators.

Based on environmental impact assessments and local regulatory requirements, each site's wastewater effluent management program includes the following:

- Characterization of the principal pollutants and sources of wastewater effluents
- Wastewater effluent treatment with appropriate technologies
- Effluent water pollution monitoring, control and reporting

Each site assesses and designs its own needs with respect to equipments such as equalization pools, wastewater treatment plants, storm water buffer basins, water containment basins after the extinction of a fire or following a pollution accident, etc.

The Group has set new goals to reduce water consumption by 25% by 2020, thanks to the continued optimization of existing facilities to limit consumption including “water scarcity areas.” In addition, assessment of regulatory compliance and the performance of wastewater treatment at our sites will be strengthened and compared to performances of best available technologies.

## Actions

- ▼ Using water responsibly
- ▼ The Global Water Tool
- ▼ Implementing the best treatment techniques
- ▼ Creating a dedicated working group

### Using water responsibly



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Sanofi is committed to using water responsibly in the course of running our business and, whenever possible, reducing water use. *Specifically, according to our internal standard, a sites that consumes more than 100,000 cubic meters of water per year must develop a five-year plan to reduce its water consumption in relation to its specificities.\**

Specific actions also support our commitment:

- We have achieved positive results over the past five years as a result of many initiatives at all our factories – to address, for example, better monitoring and automation of some valves, efforts to recycle more water, better use of cooling water, avoiding open loops and replacing vacuum pumps by so-called dry vacuum pumps.

- In the United States, at the Duluth (Georgia) site operated by Merial, a Sanofi company, a comprehensive sustainability program led to measurable and significant progress in sustainability performance. Water efficiency was an important area of focus, resulting in the following savings based on actions that have been on-going since 2008:
  - Annual reduction in water consumption of over 2,000,000 gallons (or approximately 7571 m<sup>3</sup>)
  - 10% reduction in water costs (despite supplier's 300% rate increase)

## The Global Water Tool

In 2011, Sanofi decided to implement a new tool to improve the Group's water management: the Global Water Tool. Developed by the World Business Council for Sustainable Development (WBCSD), this tool allows companies to assess and manage water-related risks by analyzing and forecasting water usage and water sensitivity in order to develop specific action plans.

### Definition - Water sensitivity

According to GRI index, water sensitivity is related to water bodies that are recognized by professionals to be particularly sensitive due to their relative size, function, or status as a rare, threatened, or endangered system (or support a particular endangered species of plant or animal), for example wetlands.

Sanofi used the WBCSD Water Tool for the first time this year. Thanks to this tool we determined that:

- 33% of our sites are located in areas with water scarcity
- The percentage of water consumed by our sites located in areas of water scarcity represents 43% of the global water consumption of Sanofi

### Definition - Water Scarcity

Physical scarcity occurs when demand on water in a region exceeds the supply due to limited physical availability. Economic scarcity occurs when the low supply is caused by inadequate water management practices due to lack of financial resources or capacity.

When annual renewable water supplies drop below 1,000 m<sup>3</sup> per person, the population faces water scarcity, and when below 500 m<sup>3</sup>, "absolute scarcity".

For more information:

- [www.wbcsd.org / global water tool](http://www.wbcsd.org/global_water_tool)

## Implementing the best treatment techniques

At all the Group's sites, Sanofi strives to identify and put in place the best techniques available to treat wastewater effluents based on their physico-chemical and biological characteristics. Various improvement projects for water treatment were carried out at several Group sites in 2011:

- Genzyme's Waltham (Massachusetts) facility designed a project to reuse condensate water in the cooling tower for HVAC systems. [\*Business case: Genzyme\*](#)
- Genzyme's Geel (Belgium) implemented a "CIP +" project to optimize its "Clean In Place" (CIP) installations (skids). CIP is a method to clean tanks and piping between production batches by automatically circulating detergent and rinse solutions. This CIP + project, which involves optimization of the controlling software, seeks to reduce water use by 25% in CIP. This initiative was started in 2011 with three CIP skids and will be followed by two other skids in the first quarter of 2012.

The new software helped reduce the fill volumes of rinse tanks and measure and optimizes both the time to fill the piping circuit with cleaning solution (prime) and the rinse times. In addition, the new software allows the cleaning process to be restarted at the sub-circuit where the system had stopped so the cleaning process can be resumed instead of restarting the entire CIP cycle

By the end of 2011, the expected volume of "water for injection" used for CIP skids was anticipated to have been reduced by approximately 44%. In 2012, this initiative will be expanded to an additional five skids at Genzyme's Geel facility.



## BUSINESS CASE



Genzyme's Waltham (Massachusetts) facility implemented a successful water reduction program that generated savings of 322,000 gallons over three months. This was accomplished by recovering condensate water and returning it to the cooling tower basin for Heating, Ventilation and Air-Conditioning (HVAC) operations.

- *Business case: Genzyme*

### Creating a dedicated working group

A "Water Network" working group was created in 2011 to focus on technical and regulatory water-related issues. Composed of internal experts, the working group is responsible for strengthening the Group's various initiatives on a range of topics, including:

- Gathering in-house expertise on water and wastewater issues
- Assessing water and wastewater issues at all Sanofi sites
- Gaining an overview of the sites' wastewater treatment technologies and providing support for sites when necessary
- Evaluating the best available techniques for wastewater treatment listed in European reference documents and anticipating consequences for Sanofi sites
- Sharing experiences within the Group and developing our strategy, standards and targets
- Integrating regulatory tracking of water and wastewater regulations and evaluating impact for sites
- Developing strategies on how to meet future regulatory requirements
- Surveying emerging technologies and assessing the most promising ones

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- *Vision / CSR performance / Statutory auditors' review report*

## Indicators

### ▼ Water consumption

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### ▼ Effluents in Water Discharged

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In accordance with standard reporting of the Group, the entity GENZYME was acquired during the year, therefore the environmental data of GENZYME is not consolidated in the Group structure.

## Water consumption

As indicated above, in 2011, Sanofi established new goals to reduce water consumption. Therefore, the Group set up actions to modernize cooling facilities (closed loop and dry cooling). In addition, the specific operating actions and the conversion of chemical production facilities to biotechnologies enabled to further reduce overall water consumption by 5% in 2011 compared to 2010 in absolute data.

(In m3)

Total water: 58,682,317 -3.06 % 56,958,242 -6.97 % 54,090,658 \* 2,401,001



## Effluents in Water Discharged

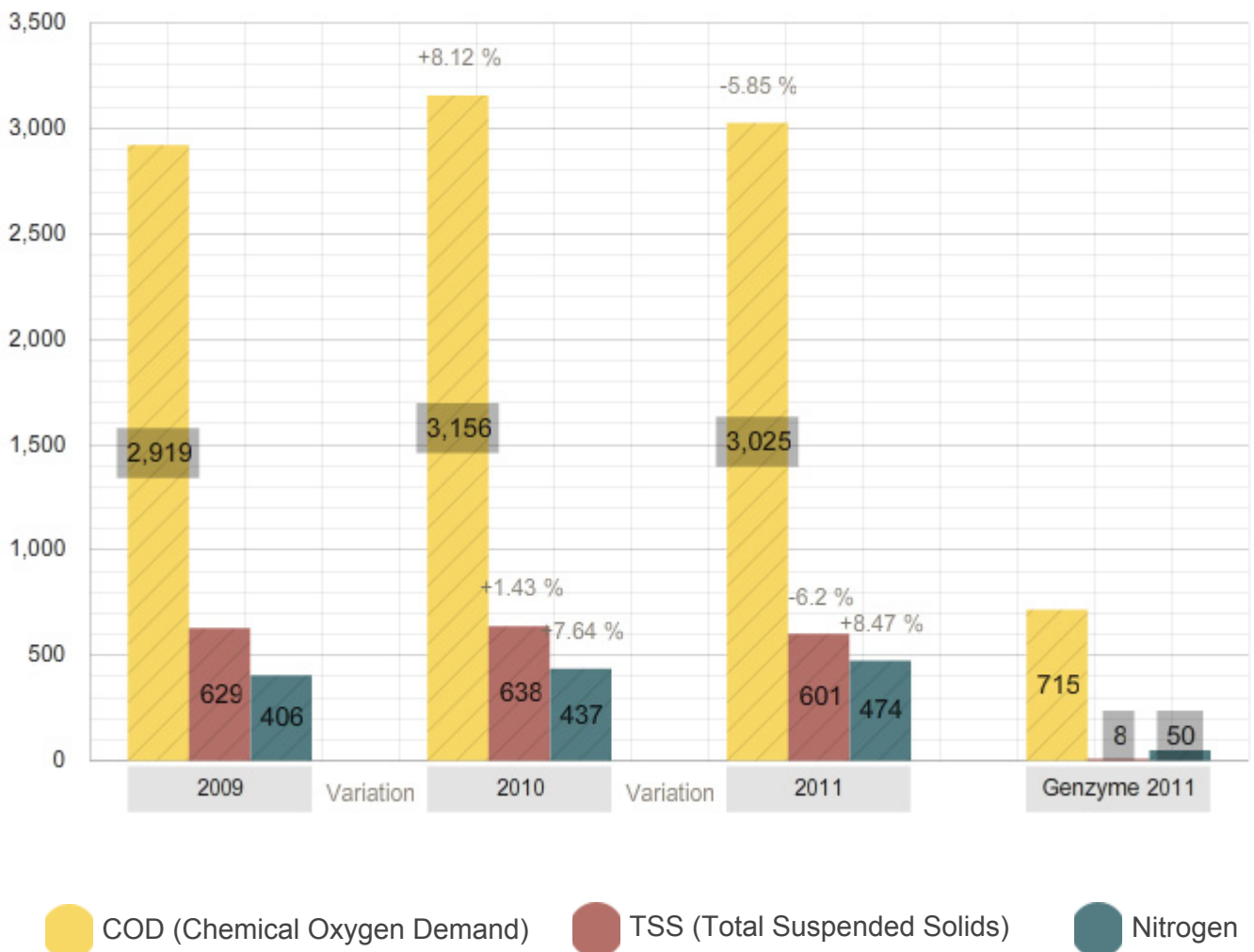
The conversion of chemical production equipment to biotechnology explains the decrease in Chemical Oxygen Demand (COD) discharges (characteristic parameter of chemical pollution) and the increase in nitrogen (characteristic feature of living things).

COD is a measure of how much oxygen is required to clean wastewater. The basis for the COD is that nearly all organic compounds can be fully oxidized to carbon dioxide with a strong

oxidizing agent under acidic conditions. Nitrogen and phosphorus are essential to maintain the health of the organisms that live in surface water. When too much nitrogen and phosphorus enter surface waters; however, they cause the ecosystem to become unbalanced. They speed up the growth of algae in surface waters to an unhealthy level and cause algal bloom. These algal blooms can cause many problems for underwater plants and animals, as well as humans.

In addition, the reduction in discharges of Total Suspended Solids (TSS) is related to the deletion of degraded operation of processing units observed last year. TSS is the weights of solids in wastewater. It is measured by pouring a carefully measured volume of water through a pre-weighed filter of a specified pore size, then weighing the filter again after drying to remove all water.

(In tons)



\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)

## Business case

### Successful water reduction program at Genzyme's Waltham facility

#### The challenge

Genzyme's Waltham (Massachusetts) facility was using increasing amounts of water for the laboratory HVAC system's cooling tower. The challenge was to significantly limit water consumption while maintaining efficient Laboratory HVAC operations, and to ensure that internal temperatures and humidity remained at acceptable levels during the warmer months of the year.

#### Our response

The solution consisted of reclaiming condensate water from the Direct Expansion (DX) coil and returning the water to the cooling tower basin.

Before this project was initiated, condensate water was discharged to drains (sewers). Measurements of the amount of water discharged on a typical summer day (80°F / 76% relative humidity) indicated that an estimated potential 2,200 gallons (8.3 m<sup>3</sup>) per day were discharged. The actual seasonal total was 4,200 gallons (15.8 m<sup>3</sup>) per day.

Within the scope of this project, a simple condensate reservoir (collector) was installed to reclaim the condensate along with water level meter, check valve, sump pump and piping. The system cost \$3,000 to install and requires minimal maintenance.

After this project was introduced, results for the three months from July to September 2011 showed total water use reduction of 322,000 gallons (1,218 m<sup>3</sup>) thanks to using reclaimed water.

Water use reduction takes place during the warmer months. Since the Waltham facility uses "custom evaporative cooling units" for cooling / dehumidification of the air supply, the units only operate the "condensing section" when the dry bulb temperature exceeds 56-58° Fahrenheit (approximately 13-14° Celsius). As a result, the cooling towers typically run less than 2,500 hours per year, which represents approximately 29% of the total run time per year of the HVAC system. When the condensers are off (below 55° F or approximately 12°C) there is no need to operate the cooling towers that require water, nor the condensing units that generate the evaporative condensate water.

## Benefits for stakeholders

Water is a valuable resource and reducing water consumption has a positive impact all around – for people, for the Planet and for business. In addition, this project has proven to be beneficial for specific stakeholders:

For the local community, one major benefit is the conservation of municipal water supplies thanks to the reduced consumption of city water. On an annual basis, the site consumes approximately 0.17 % of the total city water use. The project will reduce annual consumption at the site by 6.7%.

For the environment, there are several benefits:

- Using reclaimed water that has a lower temperature increases the cooling efficiency of tower operations.
- The water reclaim system is used when required (during warmer months).
- Analysis of the reclaimed water determined that there was no need to change the current chemical treatment program (preventive maintenance for the tower).

## Opportunities for the Group

For the Group, benefits include:

- A system that is easy to install and maintain
- Maintenance and operating costs for HVAC system have been lowered.
- Short payback: Annual savings thanks to water use reduction at the Waltham site are estimated to be \$1,840, which represents a 20-month payback on the initial investment (\$3,000).

This project at the Genzyme Waltham site has the potential for application at other Group sites, which could lead to a much greater aggregate reduction in water use. Implementing a project of this type at other sites could reduce water consumption costs, help preserve the environment and improve the Group's image.

## The future

Water use will be monitored in 2012 to verify the expected water use, and sewer discharge savings for a full year.

## Protection of the atmosphere

### Background

Emissions addressed in this section are all air emissions, except for carbon dioxide (CO<sub>2</sub>).

The primary substances that are responsible for local impacts on air quality are sulfur oxides (SO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), volatile organic compounds (VOCs) and fine particles and dust.

Two of these pollutants (NO<sub>x</sub> and VOCs) are responsible for the generation of tropospheric ozone (O<sub>3</sub>) or ground level ozone (harmful ozone), which causes respiratory diseases and allergies. The chemical reaction that occurs is the following: VOCs combined with light power catalyze the oxidation of O<sub>2</sub> (oxygen molecule) by nitrogen oxides (NO<sub>x</sub>), resulting in this harmful O<sub>3</sub> known as summertime air pollutant.

This section also addresses ozone-depleting substances (ODS), such as chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs), which are the main cause of ozone depletion in the stratosphere. Ozone depletion causes higher levels of ultraviolet radiation, leading to harmful effects such as skin cancer and melanoma as well as potential damage to crops, marine organisms and certain materials.

Fuel oils used in boilers for heating and steam production at Sanofi sites may be a source of SO<sub>x</sub> and NO<sub>x</sub>. In addition, the use of heavy fuel oil and coal could be a source of fine dust emissions.

Volatile organic compounds (VOCs) are primarily emitted by chemical processes and some pharmaceutical processes involving the use of solvents.

Definition of Chlorofluorocarbons (CFCs) and hydrobromofluorocarbons (HBFCs) are greenhouse gases.

For more information:

- [www.epa.gov / ozone](http://www.epa.gov/ozone)



**Definition of Ozone:** a gas composed of three atoms of oxygen. (O<sub>3</sub>: ozone) Ozone is a bluish gas that is harmful to breathe. Nearly 90% of the Earth's ozone is in the stratosphere and is referred to as the ozone layer. Ozone absorbs a band of ultraviolet radiation called UVB that is particularly harmful to living organisms. The ozone layer prevents most UVB from reaching the ground.

**For more information:**

- [www.epa.gov / ozone](http://www.epa.gov/ozone)

**Definition of Ozone-Depleting Substances (ODS):** a compound that contributes to stratospheric ozone depletion.

**For more information:**

- [www.epa.gov / ozone](http://www.epa.gov/ozone)

**Definition of Stratosphere:** the region of the atmosphere above the troposphere. The ozone layer lies 15 to 40 kilometers above the Earth's surface and commercial airlines fly in the lower stratosphere.

**For more information:**

- [www.epa.gov / ozone](http://www.epa.gov/ozone)

## Policy

Sanofi's goal is to gradually reduce emissions of organic solvents, sulfur oxides and nitrogen oxides released into the atmosphere and to be fully compliant with local regulations everywhere the Group operates.

The first approach to reducing VOCs consists of limiting the use of solvents, in particular those that pollute the most.

**For more information:** The "Green Chemistry"

- [Green chemistry](#)

Targeting sources of emissions is also very important, and Sanofi is carrying out initiatives to reduce the release of VOCs into the atmosphere. The next step consists of decreasing residual emissions, an objective the Group achieves by setting up and operating specific equipment in accordance with European regulations, which complies with the best available technologies:

- Cryogenic equipment to condensate and trap common VOCs
- Scrubbers
- Thermal oxidizers for VOCs that are most difficult to trap

Sanofi's objective is to comply with current local regulations while developing the capacity to respect more stringent standards in the future.

Nitrogen oxides (NOx) and sulfur oxides (SOx) are emitted by combustion facilities. To reduce emissions of dusts and oxides, nearly 100% of our sites use natural gas as their primary source of fossil energy. None of our sites use coal. These situation and action lead to less oxides and dust emissions and help to reduce our CO<sub>2</sub> emissions.

Sanofi's CO<sub>2</sub> emissions policy is described in the "CO<sub>2</sub> emissions and energy".

**For more information:** The "CO<sub>2</sub> emissions and energy"

- [Energy and carbon footprint - Policy](#)

The Group's objective with respect to ozone-depleting substances (ODS) is to comply with various local regulations issued following ratification of the Montreal Protocol, an international environmental agreement that went into effect in 1989. This treaty is designed to protect the ozone layer by establishing requirements to phase out ozone-depleting substances.

## Actions

■ In order to protect our atmosphere, Sanofi set many actions by:

- ▼ Reducing VOC emissions
- ▼ Reducing HCFC emissions (R-22 refrigerant)

### Reducing VOC emissions

All our chemical manufacturing sites worldwide comply with local regulations on VOC emissions. The Group routinely adopts the best available technologies (i.e., thermal oxidation, cryogenic capture, etc.).

At our pharmaceutical site in Tours (France), technical teams are designing a new thermal oxidizer to trap VOCs released from a new production line (which will require a large amount of solvents).

### Reducing HCFC emissions (R-22 refrigerant)

Following the ratification of the Montreal Protocol (see above), the European Union committed to phase out CFCs by 2010 and HCFCs by 2015. CFCs, HCFCs and other HydroFluoroCarbons (HFC) are essentially used as refrigerants in chillers.

R-22, which contributes to ozone depletion, has been used as a refrigerant in heat pump and air-conditioning systems for decades. Since 2010, it is no longer possible to produce or import R-22, and today only recycled R-22 may be used.

In 2009 and 2010, Sanofi carried out an inventory of all HCFCs used on our sites, focusing on R-22 in particular. Given the number of French sites and the quantity of R-22 used (slightly above quantities in other European countries), Sanofi decided to contract an external service provider to phase out the Group's R-22 use through the end of 2014.

By early 2011, we had removed 2.7 tons of R-22 from our chillers (of a total of nearly 11 tons). R-22 has been replaced by non-ODS refrigerants, such as R134a. One Group site has completely removed and replaced all R-22. In late 2011, we integrated Merial sites in the retrofit program so that they will also have the opportunity to benefit from this phasing-out program.

This approach helps us to avoid any R-22 shortages and reduces the Group's exposure to risks related to maintaining chillers that have not yet been retrofitted. It also avoids other risks – for example, concerning the continuity of our operations and volatility in R-22 prices.

Definition of HCFC-22 (also known as R-22) has been the refrigerant of choice for residential heat pump and air-conditioning systems for more than four decades. The release of R-22 (i.e., from leaks) contributes to ozone depletion. R-22 is a greenhouse gas and the manufacture of R-22 results in a by-product (HFC-23) that contributes significantly to global warming.

For more information:

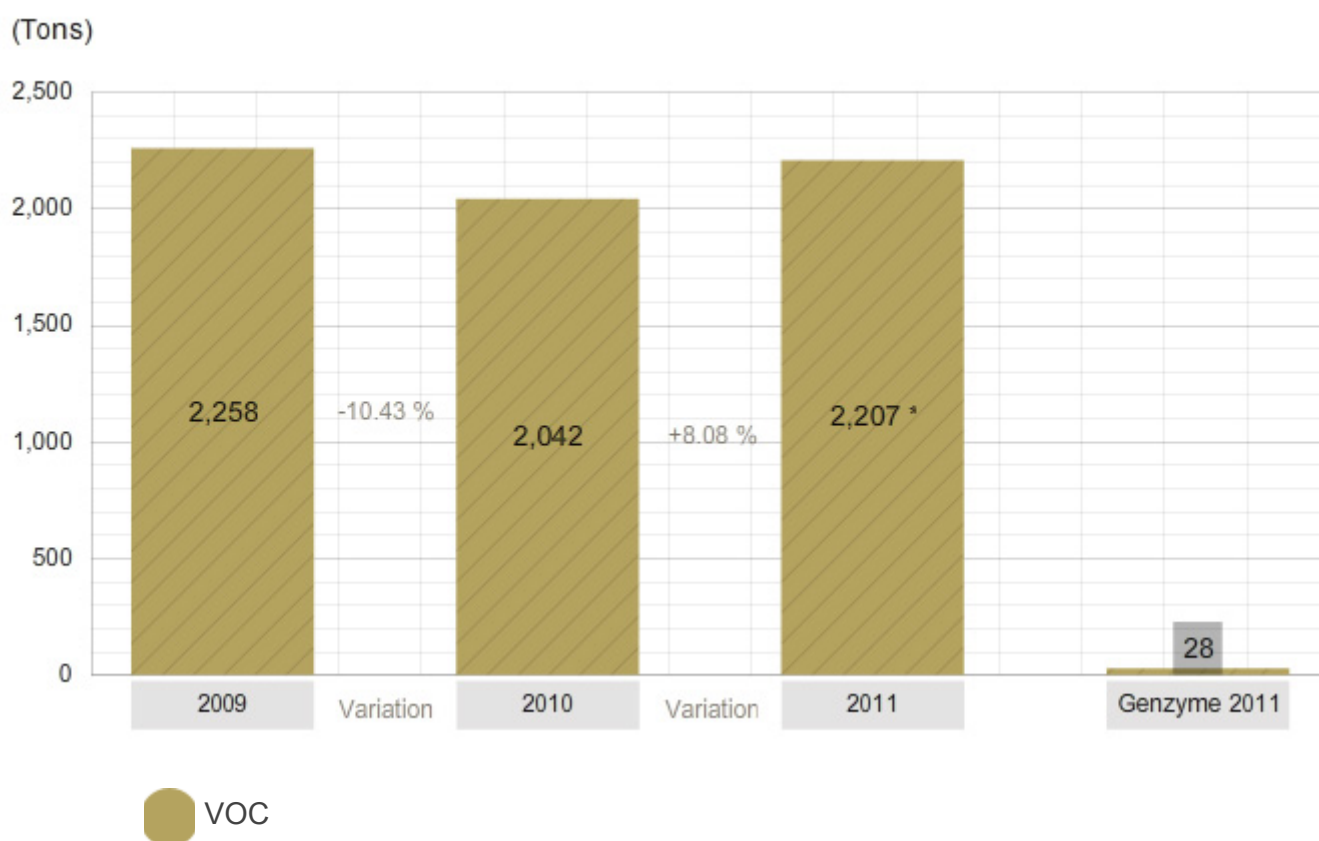
- [www.epa.gov / ozone](http://www.epa.gov/ozone)

## Indicators

- ▼ VOC – Volatile Organic Compounds
- ▼ NOx – Nitrogen oxides
- ▼ SOx – Sulfur oxides
- ▼ ODS – Ozone Depleting Substances

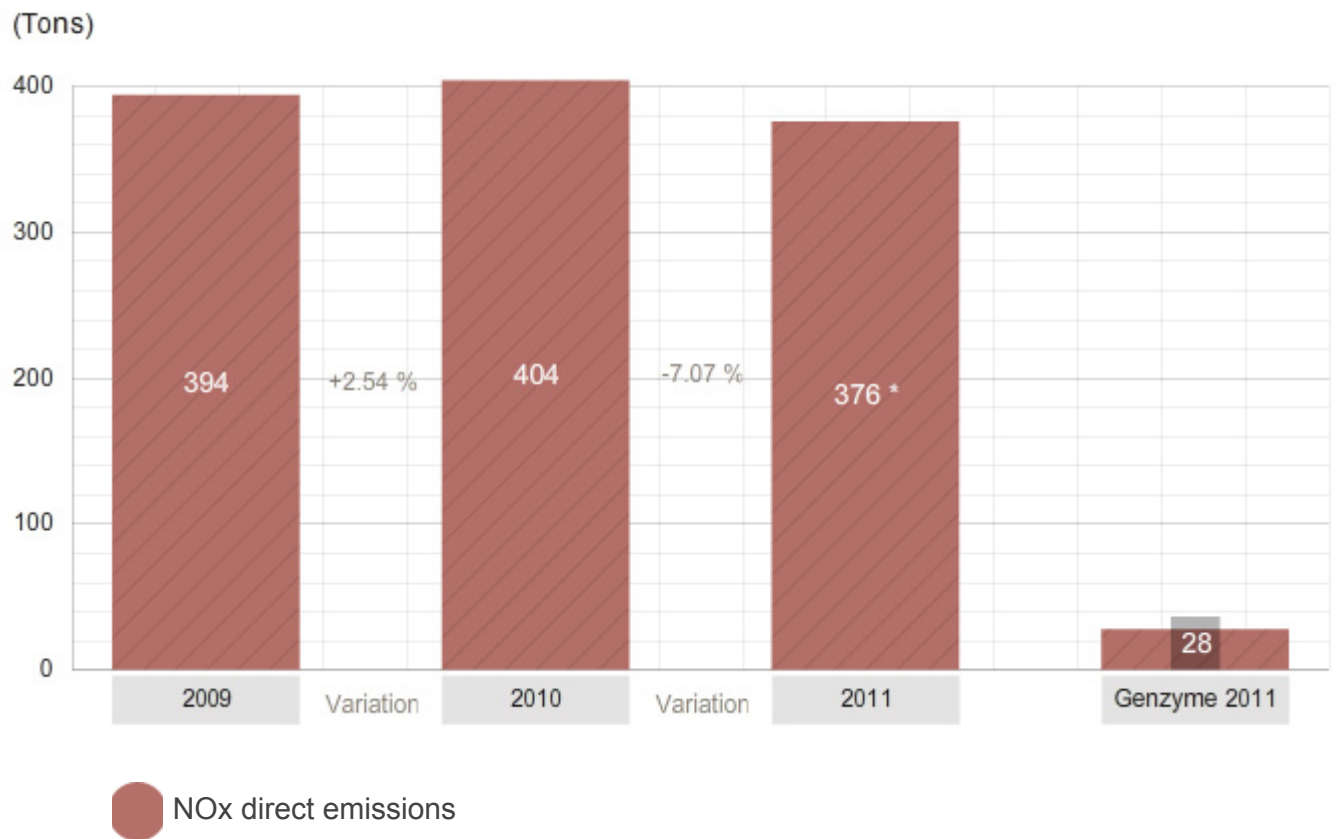
### VOC – Volatile Organic Compounds

In 2011, the Group VOC emissions decreased slightly compared to 2009 thanks to the continuous conversion of chemical sites to biotechnologies activities, these using less solvents.



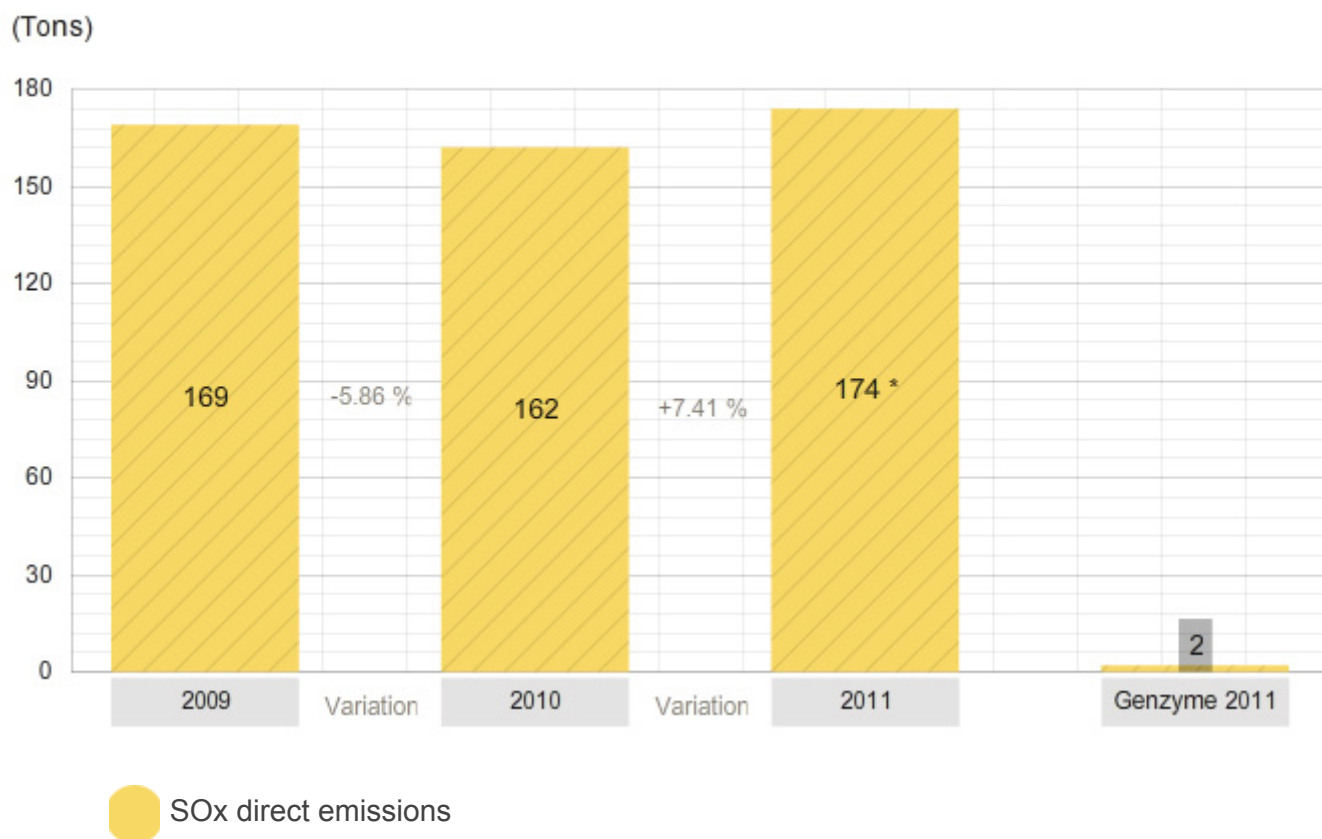
## NOx – Nitrogen oxides

In 2011, NOx emissions remains stable compared to 2009 thanks to the reduction in gas or fuel consumption.



## SOx – Sulfur oxides

SOx emissions increased slightly compared to 2009. This is mainly due to the acquisition in 2011 of an Indian site and to one of our US sites using fuel in its boilers.



## ODS – Ozone Depleting Substances

The amount of ODS emitted do not include Merial's figures. The total ODS emitted in 2011 fell by nearly 90% compared to 2009. In addition, ODS emissions remains very limited over the last 3 years (less than 1%).

(In CFC-11 equivalent Tons)



\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

- [Vision / CSR performance / Statutory auditors' review report](#)



## Packaging

### Background and policy

Pharmaceutical companies use many types of packaging for the medicines and vaccines that they sell.

Packaging is crucial to ensure the quality and integrity of these products throughout the distribution chain. Specific regulations apply to packaging, imposing significant restrictions. Because packaging requires the use of substantial quantities of raw materials, Sanofi has put in place initiatives to reduce the impact of packaging on the environment.

The Group is committed to pursuing our efforts to limit the environmental impact of packaging while taking into account current regulatory constraints by reducing the weight of packaging and limiting packaging waste generated by the transport of temperature-sensitive medicines.

### Actions

#### ▼ Reducing packaging

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#### ▼ Limiting packaging waste

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### Reducing packaging

Hungary: Improving PVC in packaging reduces costs and environmental impact

In 2011, Sanofi's affiliate in Hungary implemented a program to reduce packaging used to ship syringes and ampoules of Lovenox® / Clexane®.

Each year, the Csanyik site was consuming over 330 tons of PVC for this purpose. In March 2011, the affiliate decided to reduce packaging with a two-fold approach that involved standardizing the thickness of PVC films (to have two thicknesses instead of three), while also decreasing the film thickness overall. This led to savings of 6% on average.

After a testing phase, the project was validated and the Csanyik site decided to apply the approach to all relevant packaging in 2012.

In addition to reducing costs, this approach benefits the environment. Using thinner PVC requires less storage space and reduces transportation costs, while also decreasing CO<sub>2</sub> emissions.

Thanks to this program, Sanofi's Hungarian site has lowered its annual PVC consumption by 20 tons. An additional 90 tons of PVC per year could be saved by applying the same approach at four sites in France: the Lovenox® manufacturing sites at Le Trait and Maisons Alfort, and the vaccines sites at Marcy l'Etoile and Val de Reuil.

## Limiting packaging waste

Canada: Protecting the environment by decreasing the use of ice packs and insulated boxes to ship insulin

Just a few years ago, Sanofi's site in Laval (Quebec), Canada, made extensive use of insulated boxes and ice packs to maintain the cold chain for insulin shipments.

One of the materials used for this type of temperature-sensitive shipment is expanded polystyrene (EPS). While it is cost-effective, EPS is not recyclable. Although customers returned empty insulated containers, the need for a more environmentally friendly solution was clear. As a result, the affiliate began working with a transport company that delivers using refrigerated trucks, which can carry products between +2°C and +8°C, thereby reducing the need for insulated boxes and ice packs.

This same solution was adopted in metropolitan France in 2011. The solution was centered around delivering products using temperature-controlled vehicles that can maintain the cold chain and do not require special packaging for products. The goal of the project in France was to share good practices and implement identical solutions for the Group internationally as has been done in Canada.

This solution came at a key time, since the number of units of insulin sold annually was soaring, going from 1,101,233 units in 2009 to 2,002,976 units of projected sales in 2012.

This program has brought valuable benefits by eliminating the use of non-recyclable materials in shipping boxes, leading to the following reductions:

- Expanded polystyrene (EPS): reduced by 13,324 kg / year
- Polymer gel (used in gel packs): reduced by 78,210 kg / year
- Linear low-density polyethylene: reduced by 95,946,240 cm<sup>2</sup> per year

In addition, the number of ice packs used has been cut dramatically (from 174,240 ice packs in 2009 to 94,483 ice packs in 2011), while sales have nearly doubled.

## China: A smarter packaging process for blistered products

To ship blistered products to China, manufacturing teams in France used to pack them into cardboard boxes in small quantities. The receiving sites in China would then open all the boxes and repack blisters according to their own country's packaging requirements.

This process required intensive labor and generated high costs and waste. In a typical year, China would receive some 4.7 million such boxes and spend 8,500 man-hours unpacking them. This became increasingly problematic as markets and product quantities grew.

Aiming to develop a more efficient system, our French and Chinese teams took a look at a "Blister-in-Box" system recently set up at the UK Fawdon Plant. They then successfully implemented a similar approach to deliver specific products to Asia and South America.

As a result, today the French team sends out full batches of blisters in reusable magazines (loading devices), which are adapted to packaging lines in the receiving factories. When they arrive, the blisters can be put into small packaging for the local market. In addition to lowering costs, this new system is expected decrease annual waste by 15 tons.

## France: Using recycled wood pallets for the storage and transport of Sanofi products

Sanofi uses huge quantities of wooden pallets to store and ship our products. Approximately 350,000 pallets are needed annually for the French market and to ship products from France to destinations worldwide.

After an unsuccessful experiment with renting pallets, the Group decided to implemented a system based on recycling wood pallets for France's domestic market (150,000 pallets per year). The Group now works with a firm that delivers new and recycled wood pallets to Sanofi sites and to certain of our sub-contractors.

Recycling consists of collecting, sorting, cleaning, and, when necessary, repairing wood pallets each time they are returned to Sanofi distribution centers. New pallets are also provided as needed.

Thanks to this program, Sanofi spends less on buying pallets and generates less waste from pallet disposal. Less storage space is required because pallets are managed more efficiently, and each Group site has fewer total references to manage and store. In addition to promoting environmental sustainability, the firm that supplies recycled pallets employs workers with disability.

In 2010, the Group reduced spending on the purchase of wood pallets by 15%. In the future, Sanofi Pasteur, Merial and other Group businesses may adopt a similar system to use recycled wood pallets.

Brazil: Recycling and re-using leads to waste reduction

Sanofi's Suzano site in Brazil has implemented local initiatives that have produced promising results. The Group is considering adopting these measures at other sites. They concern:

- Recycling liner (the residue from self-adhesive labels used on bottles), which is expected to result in a reduction of waste sent to the landfill by 6 tons per year
- Re-using shipping boxes, which is expected to result in waste reduction amounting to 174 tons per year.

## BUSINESS CASE



Sanofi's Global Supply Chain function redesigned the boxes in which the Group ships SoloSTAR® disposable pens. By reducing the box size by 36%, this project helped optimize shipping, distribution and storage – in wholesalers' warehouses as well as pharmacists' and physicians' refrigerators.

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- Business case: SoloSTAR

## Business case

Smaller box design for SoloSTAR® pens optimizes transport, storage and waste reduction

### The Challenge

In August 2009, the Sanofi Global Supply Chain decided to implement a comprehensive cost reduction program for the transportation and distribution of SoloSTAR® pens, Sanofi's most important reusable device for administering Lantus®, Apidra® and Insuman® insulins.

The box used most often for shipping this device, designed to contain five SoloSTAR® pens, was large and took up a great deal of space in Sanofi's distribution centers, during transport and in the wholesalers' warehouses, as well as in pharmacies' and physicians' refrigerators.

### Our response

Sanofi therefore decided to develop and design a new, smaller box. The new box, which was 36% smaller than the original box, still contained five SoloSTAR® pens, packed in compliance with the latest quality standards. Furthermore, double stacking for sea shipment, another criterion, was investigated in depth within the scope of this project. This required the development of a new shipping carton for the SoloSTAR® boxes that was strong enough to stack two pallets, one on top of the other.

### Benefits for stakeholders

**For the distribution centers**, using a smaller box led to a significant reduction in the need for warehouse space, especially in cooling areas. In addition, it enabled wholesalers, pharmacies and physicians to store the SoloSTAR® boxes in their refrigerators more easily.

**For carriers**, it is possible to transport much larger volumes. Now, with the reduced box size, 2,000 boxes, each containing five SoloSTAR® pens, can be stored on a single pallet. By comparison, the previous load per pallet was limited to 1,200 boxes. As a result, delivery planning can be optimized and transport efficiency has increased.

**For the environment**, the consumption of paper materials for the new SoloSTAR® box was decreased by approximately one third, leading to a substantial reduction in waste. By reducing the primary packaging weight from 31 grams to 21 grams (including insert) with the new box, a

higher load per pallet is feasible, which contributes to a sustainable reduction of CO2 emissions due to product transport. Moreover, a more efficient utilization of pallets leads to reduced wood consumption.

### Opportunities for the Group

The implementation of the new reduced box size combined with double stacking for sea shipments has made both a financial and an environmental impact, thanks to more efficient transportation and distribution.

### The future

The successful development and implementation process for the new SoloSTAR® box may serve as a general model for the introduction of future boxes. Taking a similar approach for new products supports the optimization of transportation modes and storage in warehouses, as well as a sustainable reduction of CO2 emissions, material consumption and waste produced.

## Waste management

### Background

Waste is divided into two categories: non-hazardous and hazardous, according to local regulations, generally based on UN classifications. Waste must be handled in specialized facilities in compliance with applicable regulations.

In general, waste may be deemed to be hazardous when it represents a risk for health or for the environment.

As a pharmaceutical company, our waste essentially includes:

- Solid and liquid residues from chemical productions and vaccine and drug manufacturing sites, from R&D sites and process development sites, and from cleaning processes in production, which may be categorized, in whole or in part, as hazardous
- Non-hazardous waste from industrial and administrative activities (paper, cardboard, etc.)

**Hazardous waste** generally is waste that poses a risk to health or the environment and requires special treatment. This waste is classified into different categories according to its hazardous properties.

**Non-hazardous** waste generally is waste without any toxic or hazardous nature vis-à-vis the environment or human health.

**Inert waste** is waste that does not undergo any significant physical, chemical or biological transformations. Inert waste does not decompose, does not burn and does not produce any other physical or chemical reaction, is not biodegradable and does not damage other materials with which it comes into contact in a manner likely to cause pollution the environment or harm human health.

**Non-inert** waste is waste which burns and reacts chemically, physically or biologically.

## Policy

Reducing the quantities of waste and managing waste are important objectives for Sanofi. We systematically require waste sorting for re-use or recycling as a first resort, which are key areas of the Group's policy.

Each site manages its waste according to the following principles:

- Eliminate or reduce waste flow at the source
- Reuse, recycle or recover on site or with selected contractors
- Incinerate with energy recovery wherever possible
- Send waste to landfills as a last resort, provided that the landfill is appropriately regulated and controlled as well as audited annually for hazardous waste landfilling, and every three years for non-hazardous landfilling

Our waste management program includes procedures to characterize process streams and to properly identify, organize, collect, sort, treat, store, transport and dispose of each type of waste. In addition, we keep records to ensure the traceability of disposed waste.

Also, prior to engaging a new waste contractor, a purchase agreement is set up and includes a preliminary check concerning the nature of waste to ensure the contractor's qualifications, competence and compliance with regulations for this type of waste.



## Actions

In 2011, The Group has taken initiatives to better manage and to reduce its waste.

For example, primarily due to the continuing process of conversion of a chemical site to biotechnology activities, but also as supported by other efforts by the Group, in 2011, the amount of hazardous waste decreased by 1% compared to 2010 and the amount of non-hazardous waste decreased by 15.4% compared to 2010. In addition, the proportion of hazardous waste landfilled is less than 1%, and this is only the case when appropriate incineration treatment infrastructures are not available locally.

### For more information:

- [Waste management - indicators](#)

In each of our facilities and plants Sanofi provides information and tools to promote the recycling of many kinds of waste: batteries, paper, plastic, ink cartridges, etc. Furthermore, specific actions for waste collection and recycling were organized in 2011

▼ [Managing Infectious Waste](#)

▼ [Responsible collaborations](#)

▼ [Sorting organic waste](#)

▼ [WasteWise Gold Achievement Award](#)

## Managing Infectious Waste

Our activities encompass the production of medicines and/or devices that can be directly used by the patient. For example, we make SoloSTAR® which is a disposable prefilled insulin pen that can be used by a diabetic patient. After use, this disposable pen is considered hazardous waste, and we have to put plans in place to help facilitate proper disposal.

In 2011, in an effort to comply with the French Law related to the treatment of infectious (hazardous) waste from patient's self-treatment, Sanofi has been part of a working-group to set up strategy to collect and treat such waste. This is part of our commitment to reduce hazardous waste as well as endeavoring to promote safety for the entire chain of waste collection as well as for patients and their families because of the public health risk such waste may constitute.

**For more information:** Sanofi's activities to protect patient safety:

- [\*Product risk management\*](#)

**For more information:** Sanofi's activities commitments on Packaging:

- [\*Packaging\*](#)

## Responsible Collaborations

Sanofi Pasteur, is a member of the Global Alliance for Vaccines and Immunization (GAVI Alliance). The primary goal of GAVI is to develop necessary infrastructures enabling access to vaccines to populations in need. In addition they launched a project that started in 2006 in collaboration with WHO (World Health Organization) to adopt a strategy in collecting hazardous waste (i.e. vaccination needles) and setting up incinerators among 68 countries worldwide . 36 countries in Africa, 6 countries in South America, 4 countries in the Middle East, 8 European countries, and 14 Asian countries).

**For more information:** Sanofi's commitment to Packaging:

- [\*Product risk management\*](#)

## Sorting Organic Waste

In 2011, the Ambares production site decided to enhance its organic waste sorting program. The site worked with its cafeteria contractor and set up a working group. Training sessions were organized to raise awareness about what exactly is involved in recycling glass bottles, plastic bottles and cans. Employees learned about the quantities recycled, the impact and the benefits. To make biowaste recycling possible, facilities in the kitchen and cafeteria were renovated to accommodate waste collection. This pro-active initiative results in the recovery of 18 tons of recycled biowaste and 3 tons of compost on an annual basis.

Other Sanofi sites plan to implement similar programs for the collection of biowaste in the coming years.

## WasteWise Gold Achievement Award

In 2011, Genzyme received a WasteWise Gold Achievement Award from the U.S. Environmental Protection Agency (EPA) in the category "Construction and Demolition Material Reduction," recognizing Genzyme's commitment to constructing new buildings using environmentally friendly practices that reduce waste and reuse materials.

## Indicators

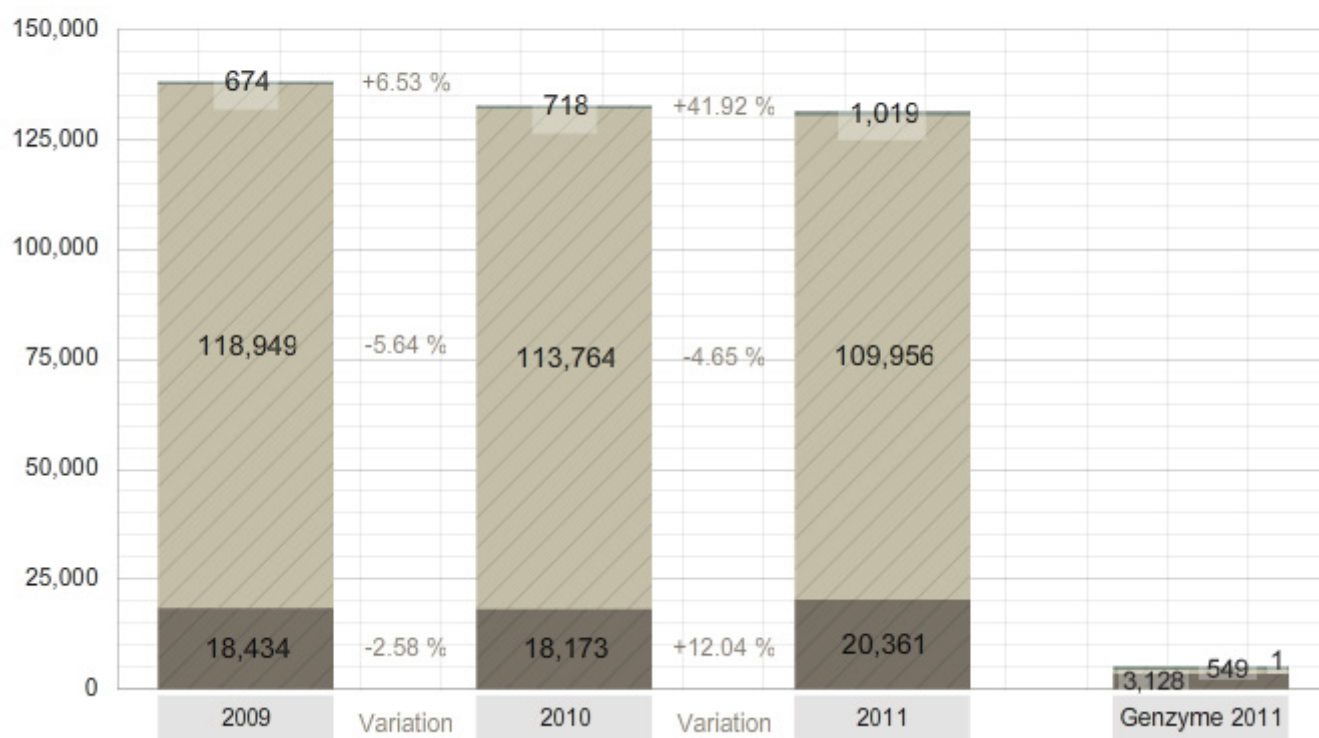
- ▼ Hazardous waste
- ▼ Non-hazardous waste

### Hazardous waste

Although incineration treatment infrastructures are not available locally in some countries, the proportion of hazardous waste landfilled is nevertheless less than 1%. However, in absolute value, the amount of hazardous waste landfilled has increased from 2009 to 2011, mainly due to the sending of contaminated rubble following work at one of our sites.

(Tons)

Total: 138,057 -4.09 % 132,655 -1.01 % 131,336 \* 3,678

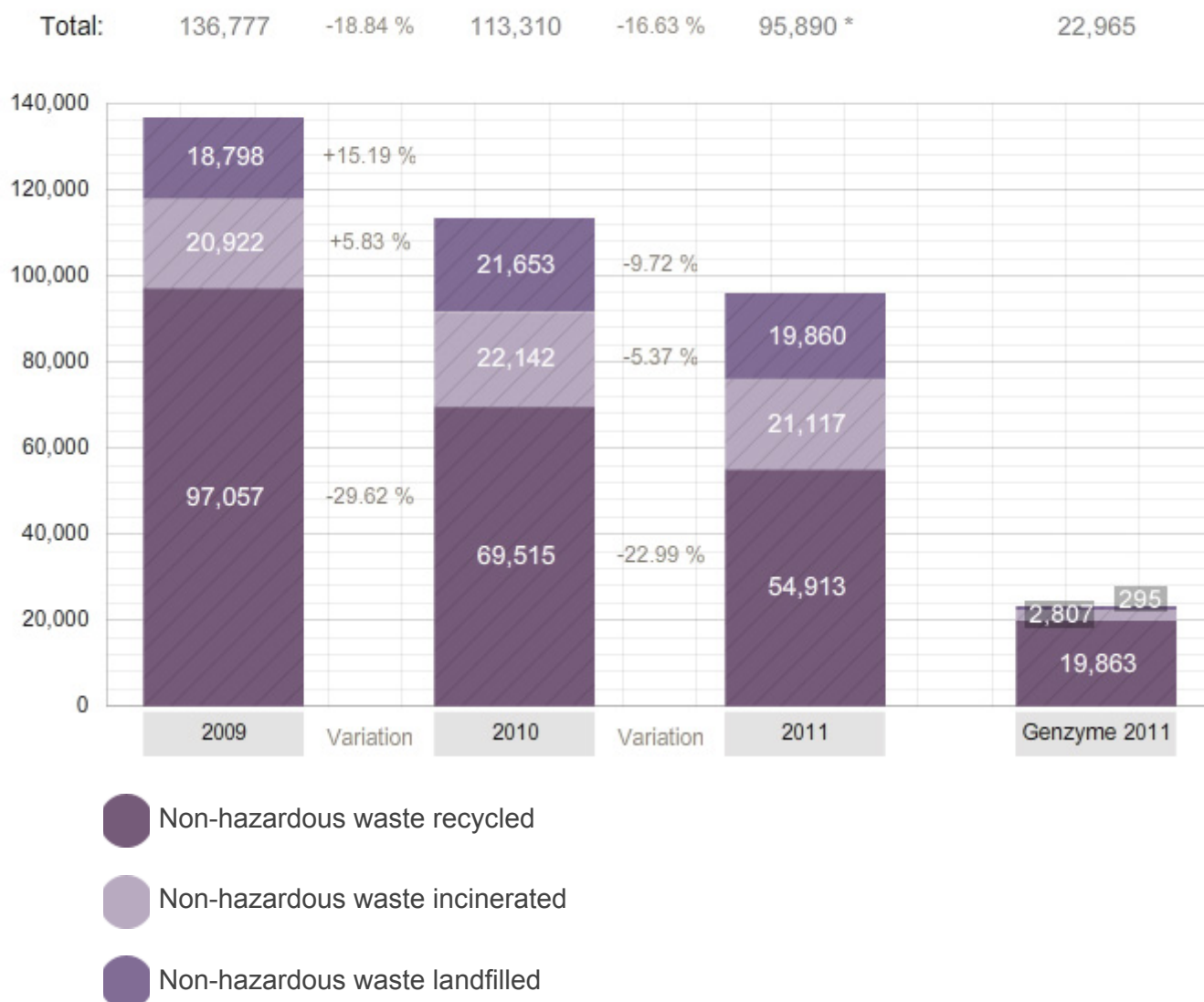


- Hazardous waste recycled
- Hazardous waste incinerated
- Hazardous waste sent to authorized landfills

## Non-hazardous waste

It is noted that non hazardous building waste are not included in the data below even though Sanofi focuses on its recovery after treatment.

(Tons)



\*Indicators identified by an asterisk (\*) were the focus of more in-depth analysis, enabling the Statutory Auditors to express an assurance specifically concerning these data. Their assurance statement, detailing the work they performed as well as their comments and conclusions, appears on this Sanofi CSR Report website, Statutory Auditors' Review Report section:

● [Vision / CSR performance / Statutory auditors' review report](#)

## Soil and groundwater protection

▼ Background

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▼ Policy

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▼ Actions

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### Background

Soil and groundwater protection at Sanofi involves two issues:

- Sites currently operated by the Group that may have an impact on soil and groundwater
- Soil and groundwater contamination that may exist at certain sites as a result of past industrial activities

Whereas today's environmental and technical regulations provide a stringent set of requirements to prevent and control possible sources of soil and groundwater contamination, i.e. spills and releases to soil water and air, it is important to remember that certain sites have very often been operating for many decades, at times when environmental standards were less stringent than today and when knowledge about the environmental impact of industrial contamination was more limited. Where past contamination exists, it may represent an environmental liability that the current site owner must manage.

### Policy

Sanofi's policy addresses the issue of prevention of spills and releases to avoid future soil and groundwater contamination and also addresses remediation of historic soil and groundwater contamination.

In order to avoid future soil and groundwater contamination each site maintains an organization to assess, prevent and control possible spills and releases to air, water and soil. Each industrial and research facility complies with regulatory soil and groundwater contamination prevention principles and good practices as outlined in construction and environmental standards. This includes maintaining the integrity, containment and monitoring of above-ground and underground tanks, vaults, pipelines, loading and storage areas and sewer systems containing materials that may be hazardous to the environment. In addition, spill control kits are in place as part of the emergency spill response program wherever hazardous or potentially polluting liquids are stored or handled.

In terms of already existing historic contamination of soil and groundwater, the objective is to take appropriate steps to ensure that the sites concerned do not pose undue risk for the health of the employees or visitors working at them, and for neighboring communities as well as for the environment.

As a minimum remediation work is carried out in accordance with applicable current legislation and regulations and in concert with local authorities. However, as general principle, Sanofi is pro-active and will take early action to mitigate potential risks resulting from historic contamination also going beyond legal compliance where appropriate. Once work is completed, the remediated property can generally be authorized for industrial or office use. Some remediation projects can be allocated for possible future residential use in concert with the relevant authorities.

## Actions

### Setting up a process for remediation of contaminated sites

Today, industrial engineering standards and modern technical monitoring make it possible to prevent and avoid most risks related to sub-soil and groundwater contamination.

Nevertheless, industrial practices used in the past at certain sites at times when environmental standards were not as stringent as they are today sometimes led to soil or even groundwater contamination when facilities were located near aquifers. Environmental laws and regulations today require Sanofi to implement a remediation process for contaminated sites.

These regulatory requirements concern sites where:

- The Group operates
- The Group (or legal predecessors) operated in the past
- The Group (or legal predecessors) may have stored waste

For this reason, financial provisions are established and adjusted every year to take into account events that may occur as well as updates to environmental assessments.

For more information:



[\*Risk factors, Environmental risks of our industrial activities \(extract from 2011 Form 20-F\)\*](#)

(PDF, 117Kb)

## Assessing the risks and conducting in soil remediation

Sanofi adopts a responsible approach to managing the sites where the Group (or legal predecessors) operates or operated in the past.

The company systematically applies a multi-year soil and groundwater monitoring and evaluation program for the Group's properties, both for those that are currently and formerly owned and operated.

Sanofi relies on detailed risk evaluations of soil and groundwater contamination. These evaluations are carried out, when necessary, at the Group's sites or former sites. Remediation projects are launched either by local authorities or by the Group. Remediation is currently underway at over 20 Sanofi sites worldwide as well as several other sites that have been sold to third parties with guarantees from the Group with respect to environmental liabilities.

For more information:



[\*Risk factors, Environmental risks of our industrial activities \(extract from 2011 Form 20-F\)\*](#)

(PDF, 117Kb)

**€41 million**  
dedicated to soil  
remediation in  
**2011**

In total, remediation costs amounted to €41 million in 2011 (compared to €45 million in 2010).

## Pharmaceuticals in the environment

▼ Background

▼ Policy

### Background

Medicines, as any other chemical substances, can be discharged into the environment as a result of human activities. They have become a focus of attention due to their biological activity and because their presence, even in small amounts, represents a concern for the environment.

In certain countries, public debate has recently focused on reducing the size of packaging for medicines and changing the criteria for establishing products' expiration dates. These issues reflect the public's concern about household waste and pharmaceuticals in the environment.

### Finding pharmaceuticals in the environment

After pharmaceuticals are absorbed or administered, they are partly excreted by patients into the environment either in the same form or as substances called metabolites.

There are also other sources of discharge – effluent from drug production plants and discharge resulting from the inappropriate disposal, of unused medicines (e.g., by an end-user directly discharging unused medicine into a sewage system).

The improvement in analytical methods since the mid-1970s has made it possible to detect an increasing number of pharmaceuticals in the environment. Depending on the substances and the environment in which they are found, they may be present in very low concentrations, measured in nanograms or micrograms per liter.

While the risk to human health appears low in light of such small concentrations based on current information, environmental risks are a genuine concern, particularly for certain classes of pharmaceutical products such as hormonal substances, cytotoxic drugs and antibiotics. Further research on this topic has contributed to public awareness and regulatory changes.

Additional research is needed to increase our understanding of:

- The fate of pharmaceuticals in the environment



- Possible long term effects of low level exposure to pharmaceuticals on human health and the environment
- Possible combined effects of mixtures of pharmaceuticals and other micropollutants found in the environment

## Packaging units and expiration periods

In the debate over the impact of pharmaceuticals in the environment, stakeholders such as environmental groups have raised questions about drug companies' role in determining expiration dates and drug packaging units. They ask whether laboratories contribute to an increase in the consumption of medicines and waste by manufacturing boxes with as many units as possible or by shortening expiration periods. In actual fact, the health authorities in each country establish the rules for the size of drug packaging, taking into account the proper use of medicines, length of treatments, etc. Drug companies then work with the authorities and many other stakeholders to establish expiration dates and to determine the packaging units for their products.

## Expiration dates

The stability of medicines is influenced by intrinsic factors (e.g., raw materials, pharmaceutical formulations and packaging) and extrinsic factors (e.g., temperature, humidity and light). The deterioration of a drug can reduce its therapeutic efficacy and lead to products that create adverse or toxic effects.

Stability testing provides data on how the quality of a drug varies based on different factors. These tests are a key part of obtaining drug-marketing approval, helping ensure the quality of a drug and its safety for use. Based on the results of stability testing, pharmaceutical companies propose expiration dates. Healthcare authorities then evaluate and establish expiration dates.

## Drug packaging

The number of units packaged in each box of medicine also depends on many factors (i.e., whether a drug will be dispensed unit by unit, sold at the local pharmacy, etc.). Health authorities in each region are responsible for establishing the conditions for dispensing drugs, product packaging and the number of units for boxes sold. Pharmaceutical laboratories work with stakeholders (health authorities, healthcare professionals, NGOs, etc.) to define the methods for establishing the packaging units for drugs based on dosages, length of treatment, public health, environmental and other concerns.

## Policy

Sanofi is aware of the growing concern about the issue of pharmaceuticals in the environment (PIE) and has developed a policy encompassing the following key areas:

- Improving the Group's knowledge about the environmental impact of our products – conducting mandatory and voluntary environmental risk assessments on new and marketed products
- Developing general knowledge about the issue of PIE, working in close collaboration with stakeholders
- Analyzing discharge from the Group's production sites, assessing impacts on the environment, if any, and exploring new technologies to remove micropollutants
- Supporting take-back programs for unused medicines where applicable and available

The Group is also committed to complying with expiration dates and local regulations on product packaging, working with all involved players (e.g., health authorities, healthcare professionals, patient organizations and NGOs) in order to define the methods for establishing packaging sizes and expiration periods for medicines that take into both public health and environmental issues.



« The topic of micropollutants in water supply today is an emerging environmental and health issue. Beyond micropollutants, there are increasing concerns over the occurrence of pharmaceutical traces in water, from the scientific community, NGOs, and public authorities, which would probably lead to new regulations. In this context, Sanofi has been engaged in developing scientific and technological knowledge about the environmental impacts of its products. »

**Alain Lamaud,**  
Vice President, Health Safety Environment

## Actions

- ▼ Assessing the Group's products
- ▼ Expanding scientific knowledge
- ▼ Studying discharge from our sites
- ▼ Supporting collection programs for unused medicines
- ▼ Complying with applicable local regulations on product packaging and expiration periods

### Assessing the Group's products

An environmental risk assessment (ERA) is currently required as part of the marketing authorization application dossier for any new pharmaceutical launched on the market in the European Union, the United States and some other countries, for all Sanofi entities. These assessments are a relatively new practice developed over the last few years based on recently acquired knowledge.

While new drugs today are assessed for environmental risks, older drugs that are already on the market may have been studied less thoroughly, since regulatory requirements were not as stringent at the time they were launched.

Beyond regulatory requirements, the Group is committed to improving our knowledge about the potential environmental impact, if any, of Sanofi products already on the market. Since 2005, independent of any regulatory requirement, and through the work of a group of internal experts, the ECOVAL committee, Sanofi has carried out environmental risk assessments of several of the Group's marketed drugs on a voluntary basis.

The environmental risk assessment for each drug, takes into account:

- Predicted environmental concentrations (calculated based on consumption)
- Environmental fate
- Environmental effects, including potential impact, if any, on micro-organisms, plants and animals

A minimal amount of environmental data is required for an environmental risk assessment. Additional studies may also be required when available data are insufficient.

**30** Sanofi compounds have undergone environmental risk assessments.

Counting both regulatory and voluntary environmental risk assessments, some 30 of our major products have thus been analyzed. These evaluations did not show any significant environmental risk at the expected environmental concentration.

In addition, Sanofi participates in the voluntary environmental classification system initiated by the Swedish Association of the Pharmaceutical Industry (LIF).

The Group is committed to continuously improving the Group's environmental risk process by taking into account technological advancements and new practices.

### Expanding scientific knowledge

When patients use medicines, substances may be discharged into the environment in low concentrations. The Group is working with stakeholders in the pharmaceutical sector and the academic world to expand scientific knowledge in this area.

The Group is also acquiring essential information through collaborative projects within the pharmaceutical industry in Europe and the U.S, through membership in trade groups such as PhRMA, EFPIA, LEEM and LIF. The aim of these projects is to assess the potential impact of pharmaceuticals in the environment, including for human health.

In addition, the Group is building alliances in academia. From 2009 to 2011, the Group supported two scientific projects in areas that are considered to be inadequately researched – specifically, the efficacy of water treatment with respect to pharmaceuticals, focusing on oxidative treatments and the fate of pharmaceuticals in coastal waters and their potential to bioaccumulate in marine organisms.

In 2011 we began working with the Israeli NGO Peres Center of Peace on a project addressing the fate of pharmaceuticals in wastewater treatment systems. This program looks at the efficacy of various wastewater treatment technologies, including adsorption and membrane filtration technologies, to remove pharmaceuticals from wastewater. Research teams from an Israeli technical center work with a Palestinian university that has expertise in these research fields. An additional benefit of this project is the opportunity to promote ties between countries in the Middle East.

## Studying discharge from our sites

Manufacturing is generally considered to be a minor source of pharmaceuticals in the environment, compared to pharmaceuticals discharged by patients. However, pharmaceutical sites may constitute point sources that contribute locally to the environmental loading of pharmaceuticals. Some recent publications suggest that the emissions from manufacturing may be significant at a local level and may have an environmental impact.

Further to Sanofi's commitment to minimize our industrial sites' impact on the environment, in particular the aquatic environment, the Group initiated a program to learn more about manufacturing activities' potential contribution to the overall discharge of pharmaceuticals in the environment. Pilot studies have been carried out to research and quantify active ingredients and their degradation products (metabolites) within effluents at several production sites. *Specific analytical methods were developed and applied by an internal environmental laboratory. Discharge from seven sites was studied within the scope of this program in 2010-2011.\**

In addition, we developed a specific strategy addressing the discharge of pharmaceuticals from manufacturing sites in 2011 to be implemented in 2012. Based on a global risk assessment program covering all Sanofi manufacturing sites, this strategy consists of:

- Environmental risk assessment – to use existing data and carry out further assessments of active pharmaceutical ingredients (APIs) handled or manufactured at production sites which can be potentially released into the environment through wastewater effluents
- Micropollutant removal technology assessment – through internal assessments, external partnerships, etc.
- Risk Management – to implement practices and technologies for risk reduction / mitigation
- Communication and prospective actions – to continue our active involvement with trade groups and extend this strategy to third party manufacturers

## Media focus on effluents from the Vertolaye site

The Vertolaye site in France was the focus of media attention in 2011 after endocrine disruption was observed in some fish living in the Dore River, located near Vertolaye. Questions were raised about a potential connection to wastewater from the factory.

Local authorities immediately appointed a technical commission composed of knowledgeable French experts from water agencies, ONEMA, INERIS, ecological associations, etc. Sanofi is a member of the technical commission and takes an active part in its work. The commission's task was to identify compounds that could cause these disturbances in the fish.

The Group is committed to working closely with the authorities and the appointed experts to understand the cause of the observed effects. The Group is also prepared to develop and implement innovative analytical methods to follow the possible presence of substances responsible for the effects observed in the fish.

In cooperation with water treatment companies, Sanofi is testing advanced treatment technologies to remove micropollutants from wastewater effluent. We are checking the efficiency and the scale-up feasibility of these technologies in order to implement them at our site. Initial results have been positive and discussions are on-going.

## Supporting collection programs for unused medicines

Sanofi actively supports local collection programs for unused medicines. These programs are designed to promote the proper disposal of unused and expired medicines through consumer take-back programs in many countries, and through returned goods programs at hospitals, clinics and pharmacies. Very simple but effective steps may contribute to protecting the environment.

"What to do with your unused medicines" is a list of recommendations developed by the Group. An excerpt is provided here.

### What to do with your unused medicines (excerpt)

Sanofi is committed to encouraging proper disposal of unused medicines. Actions to reduce improper disposal of expired or unwanted prescription and non-prescription medicines contribute to protection of our waterways. Although studies have indicated that only a small portion of medicines enter the environment through waste disposal, it is important to reduce our impact from all sources.

Simple steps taken by the consumer will significantly reduce emissions contributing to environmental exposure. For certain types of medicines, for example anticancer drugs, special disposal methods are indicated. The general guidance provided below is for disposal of all medicines in a safe manner and applies to unused household medicines as well as those from long-term healthcare facilities.

- Most importantly, **do not dispose of unused medicines down the drain**. That is, medicines should be neither flushed down the toilet nor poured down the drain.

- **Follow local disposal practices** including community pharmaceutical take-back programs where available. Disposal practices vary by region. In most European nations, unused medicines can be returned to the pharmacy for safe collection and disposal by incineration. In the U.S. and many other nations, local take-back programs may exist through pharmacies or government or community waste treatment programs. Contact your pharmacy or local waste disposal agencies for more information if needed.

Collection of unused medicines for reuse is an acceptable alternative in some communities if authorized programs exist.

- **In the absence of local take-back programs**, dispose of unused medicines in household trash, taking precautions to avoid accidental misuse or possible diversion for drug abuse. Render unused medicine undesirable and unrecognizable (e.g., mix with household waste in non-descript packaging). Mark out or remove any labeling identifying personal prescription information.

Don't forget a simple waste-reduction measure: whenever possible, try to obtain only the quantity of medicine you need. This will minimize having to dispose of expired unused medicines later on.

Local Sanofi sponsored programs to encourage people to bring back unused medicines vary considerably from country to country. Below are a few examples:

## Greece

Athens Green 360 to promote the destruction of unused medicines:



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Greece has been developing a special process for collecting and destroying paper, glass, batteries, etc. for many years now; however, until recently there was no system in place to collect and destroy unused medicines.

Every year over an estimated 50 million boxes of medicine are thrown away by individuals into household trash in Greece (Source: Macedonia newspaper, July 14, 2010).

To counter this trend, a new initiative was launched in 2010: Athens Green 360. This program continued in 2011 with several efforts to increase awareness about the program and also drive participation.

This program, which was developed under the aegis of the PostBank Green Institute, implements an awareness campaign to teach people about the importance of collecting unused medicines (both expired and non-expired) so that they can be destroyed appropriately using incineration.

The campaign consists of information brochures, a special website and TV / radio ads. The campaign brings together all the healthcare players – particularly the pharmaceutical industry and health authorities – to collaborate on this topic.

The information brochures will be available in public and private hospitals, as well as doctors' offices and pharmacies, which will offer operational support by collecting medicines.

In addition to promoting the campaign and raising awareness, the program also plans to place collection containers for unused medicines in major supermarket chains. A specialized company will be responsible for collecting and transporting the returned medicines to incineration plants that are certified for handling this type of process.

Sanofi in Greece supported Athens Green 360 program as the exclusive official sponsor of the program for handling unused medicines.



## Indonesia

In 2011, a program in Indonesia to dispose of unused medicines led to the destruction of 1,446 kg of medicines. A state-approved hazardous waste contractor collects expired, out of spec and unused products for destruction, as well as infectious waste, active pharmaceutical ingredients and excipients.

## Korea

The Green STAR Campaign in Korea was designed to raise awareness of insulin treatment among patients with diabetes while delivering a message of environmental protection by collecting used insulin pens and needles. Collection boxes were placed in 110 hospitals and clinics for collection of used insulin pens and participants were given educational materials about insulin treatment. Working with a total of 15,000 used insulin pens, he created a “wishing tree” to convey a message of hope for people with diabetes.

## India

An awareness program for stakeholders involved in handling the destruction of unused medicines was set up in India. In addition, unused medicines were incinerated by an approved agency recognized by the Pollution Control Board. Over 32,000 kg of unused medicines were destroyed within the scope of this program.

## United States

In the U.S, Sanofi supports PhRMA's efforts to assure the proper disposal of sharps and medical waste including used and unused medications. As a service to patients and to improve awareness about this topic, Sanofi has added guidance for the disposal of sharps and medical waste to the U.S. Corporate Social Responsibility website, published in both the Patient and Planet sections. This guidance is also found on each of our U.S. product websites.

**For more information:** Patient information regarding disposal of sharps and medical waste

- [www.sanofi.us / Patient Information Regarding Disposal of Sharps and Medical Waste](http://www.sanofi.us / Patient Information Regarding Disposal of Sharps and Medical Waste)

## France

### Cyclamed: Collecting and converting unused medicines in France

Cyclamed is a French environmental non-profit organization that brings together various stakeholders within the pharmaceutical sector: dispensing pharmacies, wholesalers / dispatchers and pharmaceutical companies. Its aim is to safely eliminate unused medicines in order to preserve the environment and protect public health.

The organization is responsible for collecting and converting all unused medicines for human use, regardless of whether they are expired or non-expired. Cyclamed collects all tablets, capsules, syrups and ointments that consumers return to pharmacies. The program only accepts waste from households, not waste from hospitals or healthcare professionals.

Cyclamed is financed entirely by drug manufacturers based on the number of boxes they market. As the largest pharmaceutical company on the French market, Sanofi makes the largest financial contribution to the Cyclamed program. In 2011, Sanofi contributed €884,164.55.

When patients have finished their treatment, they must return unused medicines in the original packaging. In accordance with French Law 2007-248, pharmacies are required to take back unused medicines. Special incineration facilities are in charge of destroying unused medicines. The 52 energy incineration units selected by Cyclamed all meet stringent environmental standards.

Sanofi, the number one contributor to Cyclamed, the French collection and energy recovery program for unused medicines: 884,164 Euros in dues paid in 2011

## Complying with applicable local regulations on product packaging and expiration periods

In all the countries where the Group operates, Sanofi is committed to complying with applicable regulations on the size of packaging for medicines and expiration dates.

### Packaging size

The regulatory authorities in each country set out the rules for the size of packaging for medicines. The proper use of medicines, public health issues and economic concerns are all important factors for public authorities when establishing the proper size of packaging for indications, proposed dosages and lengths of treatment.

## France

French regulations on packaging medicines are part of public healthcare legislation, which is covered by the French Social Security Code. This code stipulates that pharmaceutical products must be “presented in appropriate packaging based on therapeutic indications warranting coverage by the public healthcare system, the dosage and the length of treatment.” Over the counter medicines must be on the list of medicines dispensed in pharmacies when “packaging weight, volume or number of doses is adapted to the dosage and the length of treatment recommended on the patient information leaflet.” In addition, a Transparency Commission evaluates the appropriateness of packaging based on therapeutic indications.

**For more information** about the French Social Security Code (in French):

- [www.legifrance.gouv.fr](http://www.legifrance.gouv.fr)

## Germany

In Germany, the Medicinal Products Act establishes that medicinal products can only be marketed using specific packaging sizes and that “the packaging sizes should be established for specific active pharmaceuticals and should take into account the therapeutic indications, the length of treatment and the pharmaceutical formulations.”

**For more information** about the Medicinal Products Act:

- [www.bmg.bund.de/ Medicinal Product Act](http://www.bmg.bund.de/Medicinal_Product_Act)

## Establishing the expiration period of medicines

The stability of medicines depends on intrinsic factors (e.g., raw materials, pharmaceutical formulations and packaging), and extrinsic factors (e.g., temperature, humidity and light). Deterioration of a drug can reduce its therapeutic efficacy and lead to products that create adverse or toxic effects.

Stability testing is used to provide data on how the quality of a drug varies based on the amount of exposure to different factors. Regulated by international guidelines, stability testing is a key step for obtaining drug marketing approval. It helps ensure the quality of the drug and its safety for use.

Shelf life and storage conditions of a drug are defined entirely based on the results of stability studies, in particular real-time data. The expiration period of newly-marketed medicines is

generally limited to two years, based on an extrapolation of real-time data. Beyond two years, only real-time data can be used to extend shelf life.

Based on the results of these studies, pharmaceutical companies propose expiration dates. Healthcare authorities then evaluate and establish expiration dates.

The ICH (International Conference on Harmonization) Q1A guideline provides recommendations to be followed for stability testing to be carried out on active pharmaceuticals and drugs (finished products). These studies are used to determine a drug's shelf life.

**For more information:** On stability testing of new drug substances and products

- [www.ema.europa.eu / Stability Testing of new Drug Substances and Products](http://www.ema.europa.eu / Stability Testing of new Drug Substances and Products)

The conditions for these studies vary depending on the climate zone where a medicine is sold. The length of these studies ranges from six months (accelerated studies) to 24-36 months in general (long-term, real-time studies).

**For more information:**

- [\*Sanofi position paper on Biodiversity & Biopiracy\*](#)

\*The information in italics identified by an asterisk was reviewed by the Statutory Auditors, who expressed an assurance specifically concerning these data. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available in the section:

- [\*Vision / CSR performance / Statutory auditors' review report\*](#)

## Biodiversity

“Biodiversity” or biological diversity, refers to the variety of life on earth. It encompasses three categories: genetic, species and ecosystem diversity. Biodiversity is vital to maintaining the balance of life on our planet.

- **Genetic diversity** refers to the variation of genes within species.
- **Species diversity** refers to the variety of species within a region.
- **Ecosystem diversity** refers to the different communities or habitats found in a given location.

### Biodiversity: A key issue worldwide

The world's natural ecosystems are deteriorating at a rate unprecedented in human history. Preserving biodiversity and ensuring the sustainable and fair use of natural resources stand out as key issues worldwide. Today they are an essential part of any Corporate Social Responsibility policy, and are considered critical topics for the Group.

### The Nagoya Protocol

In October 2010, The Conference of the Parties to the Convention on Biological Diversity (CBD) held their tenth meeting in Nagoya, Japan, drawing up what is referred to as the Nagoya Protocol. It was designed to contribute to the conservation and sustainable use of biodiversity.

This international agreement provides a legal framework to ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources, directly addressing one of the three objectives of the CBD.

The Nagoya Protocol has been at the center of debate in the business world and society at large, and Sanofi takes an active part in these discussions. Questions remain to be answered concerning how the protocol will be implemented, and how companies can prepare themselves to satisfy the new requirements set out in the protocol.

The Nagoya Protocol was open for signature by Parties to the CBD from February 2011 until February 2012 at the UN Headquarters in New York. The Protocol becomes effective no later than October 8th, 2012.

### 2011-2020, Decade on Biodiversity

Following the International Year of Biodiversity in 2010, the UN General Assembly passed a resolution to make 2011-2020 the UN Decade on Biodiversity. One of the objectives of the Decade on Biodiversity is to promote the implementation of the Strategic Plan for Biodiversity (SBN), designed to significantly reduce biodiversity loss. Moreover, the European Union's Biodiversity Strategy to 2020, which is based on meeting six key targets, will also help halt the loss of biodiversity.

## Biodiversity and the pharmaceutical industry

The pharmaceutical industry places a great deal of importance on biodiversity because natural resources are critical for the discovery and development of new drugs.

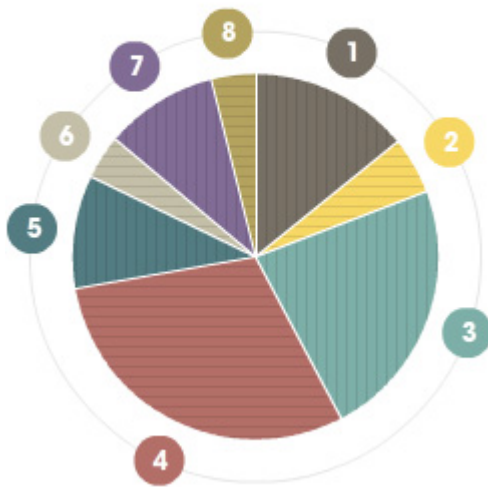
Natural resources offer valuable potential as sources for new chemical substances and active ingredients. Today biologists consider they may very well represent the treasure troves of pharmacopoeia in the 21st century, given the remarkable diversity of their substances and active ingredients.

### Origin of compounds

Over the past 25 years, nearly half of the 1,184 new chemical entities that have been marketed worldwide have come from substances found in nature.

These 1,184 new compounds may be broken down as follows:

All new chemical entities,  
01/1981-06/2006



- Biological (14%)
- NP: Natural product (5%)
- ND: Derived from a natural product and is usually a semisynthetic modification (23%)
- S: Totally synthetic drug, often found by random screening, modification of an existing agent (30%)
- S / Natural product mimic (10%)
- S\*: Made by total synthesis, but the pharmacophore is/was from a natural product (4%)
- S\* / Natural product mimic (10%)

Source: EFPIA – *Good practices and case studies on biodiversity*

References:

Source: David J. Newman and Gordon M. Cragg, "Natural Products as Sources of New Drugs over the Last 25 Years," *Journal of Natural Products*, 2007, Vol.70, p 461-477.

**For more information:** Natural products as sources of new drugs

- [Read the article "Natural Products as Sources of New Drugs over the Last 25 Years"](#)
- [Read the article "Natural Products as Sources of New Drugs over the Period 1981-2002"](#)

## Policy

▼ Adhering to the Convention on Biological Diversity

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▼ Complying with the Group's own guidelines

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▼ Taking action to preserve biodiversity

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Sanofi concentrates on three key issues relating to biodiversity:

- The controlled use of natural plant and wild animal species for research projects to discover new drugs
- Determining the fair distribution and sharing of benefits resulting from the use of this type of resource
- Ensuring to facilitate the preservation of biodiversity surrounding the Group's sites and beyond, particularly in fragile or protected zones

For these three areas, the Group's policy is based on adhering to the Convention on Biological Diversity (CBD) and complying with the Group's own guidelines, summarized in our position paper. In 2010, the Group established a series of commitments focusing on protected species and streamlining research programs for natural substances.

The Natural Product Science (NPS) center – Sanofi's dedicated department located in Frankfurt, Germany – is in charge of natural substances research that provide a potential source for new drug development. The NPS also provides recommendations from the CBD. For several decades now it has pooled the combined expertise of many natural substance specialists.

### Adhering to the Convention on Biological Diversity

Adhering to the Convention on Biological Diversity is the cornerstone of the Group's biodiversity policy. This international convention outlines the principles for obtaining and using natural resources.

Contracts established by the Group with natural product suppliers stipulate that suppliers must comply with the CBD. These contracts set conditions for sharing the benefits arising from the use of these resources.



**For more information:** The Convention on Biological Diversity

- [www.cbd.int](http://www.cbd.int)

## Complying with the Group's own guidelines

Sanofi's biodiversity policy is summarized in the Group's Position Paper. This paper presents an overview of all the principles that the Natural Product Science (NPS) Center, has implemented over many years to preserve biodiversity. It also demonstrates that biodiversity is a key issue for Sanofi, and establishes a clear position on fighting all forms of biopiracy.

**For more information:**

- [\*Sanofi position paper on Biodiversity & Biopiracy\*](#)

These guidelines are consistent with the Group's Human Rights principles, specifically in regards to fair and equitable sharing of the benefits arising from the use of communities' natural resources.

- [\*Human Rights\*](#)

## Taking action to preserve biodiversity

In order to translate our policy into action, in 2011 and 2012 the Group has committed to:

- Verify, prior to placing an order that relevant plant species are not on the lists established by:
  - CITES: The Convention on International Trade in Endangered Species of Wild Fauna and Flora. See [www.cites.org](http://www.cites.org)
  - IUCN: The International Union for Conservation of Nature Red List of Threatened Species. See [www.iucn.org](http://www.iucn.org)
- Ensure that all new contracts are in line with the Convention on Biological Diversity and take into account the Red List criteria
- Ensure that suppliers produce, if necessary, the official authorizations that allow them to collect the plants that have been ordered
- Continue to reduce the weight of powdered plant samples used in research

Sanofi will ensure compliance with applicable local regulations regarding the preservation of diverse areas surrounding Group sites, and, where necessary, will carry out environmental impact assessments.

The pharmaceutical industry will need to address a number of questions arising from the application of the Nagoya Protocol. Once the Protocol goes into effect, Sanofi is committed to updating the Group's positions on key issues, such as the use of influenza strains coming from various locations across the globe, which are essential for the production of Sanofi Pasteur's annual flu vaccine.

The IUCN Red List of Threatened Species is used to identify plant and animal species at risk of extinction. It also aims to provide an updated global index of current changes in biodiversity.

For more information:

- [www.iucn.org](http://www.iucn.org)

Biodiversity: A key commitment for Sanofi

- [\*The Sanofi Position Paper on Biodiversity and Biopiracy\*](#)

Monitoring progress

As part of the French national Corporate Social Responsibility / Sustainable Development program referred to in French as the *Grenelle de l'environnement* program, LEEM (the French Pharmaceutical Companies Association) signed a "Drug Industry Progress Agreement" in 2009 with the French Ministry of Ecology and Sustainable Development. The purpose of the agreement is to monitor CSR commitments within the industry. As part of this agreement, Sanofi now reports biodiversity indicators to LEEM each year.

For more information: on LEEM's Drug Industry Progress Agreement:

- [www.leem.org](http://www.leem.org)

## Position Paper

Sanofi continuously seeks ways to limit and lower the environmental impacts of its business activities in accordance with the Group CSR and HSE policies. In addition, as a Global leader in Healthcare, Sanofi is aware that natural resources (plant, animal, etc.) from ecosystems are sources of potential innovative new medicines that could prevent and cure diseases. Thus, the Group recognizes the necessity to protect and sustain all natural resources that make up biodiversity.

The Group is also aware that unapproved or significant removal of natural resources, as well as polluting production activities, may jeopardize the ecology and economy of the affected countries.

Because Sanofi acknowledges that each country has sovereignty over its natural resources and traditional knowledge for their use, the Group is committed to supporting internal and / or external initiatives against biopiracy.

Sanofi focuses on preventing and managing any of its activities that may have an impact on biodiversity and is implementing processes against biopiracy. This includes:

- Controlling the collection and use of natural resources in research projects to discover new commercial drugs
- Understanding the effects of Group activities and medicines on natural resources
- Implementing a fair process for benefit sharing, with conventional knowledge holders, resulting from the marketing of medicines derived from natural resources
- Conserving habitats and species around Group sites throughout the world
- Sourcing biological materials and related services from suppliers who have appropriate environmental and biodiversity preservation standards (including compliance with international standards on biodiversity)

The Group adheres to several external initiatives that define biodiversity preservation principles:

- The Convention on Biological Diversity, included in the United Nations Environment Programme (UNEP), and agreed to at the Earth Summit in Rio de Janeiro in 1992. It defines

- commitments for maintaining the world's ecological systems including the following three main goals:
  - The preservation of biological diversity
  - The sustainable use of its components
  - Principles with respect to the acquisition and utilization of natural resources, and the fair and equitable sharing of the benefits from their use
- The Human Rights principles regarding the respect of rights for indigenous people to maintain, control, protect and develop their intellectual property over cultural heritage, traditional knowledge and traditional cultural expressions
- The United Nations Global Compact and Millennium Development Goals

In addition, Sanofi is committed to communicating in a transparent manner about the Group's actions and achievements to preserve biodiversity. The Group is also committed to following the G3 Global Reporting Initiative (GRI) guidelines concerning biodiversity to enhance the relevance and transparency of our reporting to local stakeholders.

## Actions

## Natural substances

- ▼ A center specialized in natural substances
- ▼ Limiting the amount of natural substances used
- ▼ Workshop on benefit sharing
- ▼ Establishing contracts that comply with the Convention on Biological Diversity (CBD)

The actions implemented to adhere to the Convention on Biological Diversity and to comply with the Group's position on biodiversity focus on the use of natural substances to develop new drugs. They entail:

- Limiting the quantities of substances used for research
- Identifying protected natural substances (IUCN Red List) and finding alternative solutions
- Establishing contracts with suppliers stipulating that they must comply with international conventions and national legislation on preserving biodiversity
- Conducting Natural Product Science audits of their suppliers to ensure compliance with these obligations
- Adhering to the principle of sharing benefits generated by the Group with countries that give access to their natural resources as well as with local populations having specialized know-how, whenever products made from natural substances are commercialized.

### For more information:

- [\*Biopiracy\*](#)

Between 2003 and 2010, Sanofi studied 647 natural substances derived from 152 plants. Thanks to a new extract screening method, no plant-derived compounds were studied during 2011.

## A center specialized in natural substances

For several decades, Sanofi's NPS center in Frankfurt, Germany, has been specialized in natural substances research. It brings together numerous experts and focuses primarily on investigating natural substances that may provide a source to develop new drugs. The center

also shares knowledge with all the Group's R&D operating units that study natural substances for Sanofi's various therapeutic areas.

This center currently has a collection of some 9,000 plants / plant extracts. Between 2003 and 2010, the Group's experts studied 647 natural substances from 152 plants.

In 2011, following the implementation of a new extract screening method, no plant-derived compounds were studied.

### Limiting the amount of natural substances used

In an effort to preserve the species being used, Sanofi continuously seeks to streamline our R&D programs involving natural substances. Screening operations by the Group involve much smaller quantities than in the past for the 5,500 plant extracts screened recently. In 2000, a few hundred grams were required to study a plant's components, whereas today it only takes a few dozen grams.

### Assessing the species used

Only **1.3%** of the natural species held by Sanofi appear on the 2011 IUCN Red List of Threatened Species™

With an eye to respecting protected species, since 2010 Sanofi has regularly evaluated all the species held by the Group. These evaluations focus on assessing these substances based on the IUCN Red List of Threatened Species criteria. The list is updated annually. Therefore, natural species used by Sanofi that were not protected when preliminary research was carried out may have been added to the list after this research was initiated. It is also important to note that the IUCN Red List is a recent initiative. Sanofi has been compiling our natural

substances database for several decades – before the IUCN list was developed and at a time when the scientific community could not predict the extinction of certain plants.

Results from the most recent evaluation show that only 1.3% of plants held by Sanofi appear on the 2011 IUCN Red List of Threatened Species.

**For more information** on the IUCN Red List of Threatened Species:

- [www.iucnredlist.org / About](http://www.iucnredlist.org / About)

## Workshop on benefit sharing

In 2011, Sanofi took an active role in a Round Table workshop held in Germany about access and benefit sharing in accordance with the Nagoya Protocol. The workshop was organized by the German Ministry of the Environment to make progress in the implementation of the Nagoya Protocol.

## Establishing contracts that comply with the Convention on Biological Diversity (CBD)

Contracts between Sanofi's NPS Division and natural species suppliers (currently based primarily in China and Madagascar) include clauses about preserving biodiversity. Suppliers are required to comply with the CBD and obtain local authorization, where necessary, to collect specimens.

Some contracts go above and beyond respecting these obligations. For example, collaboration between Sanofi and the scientific institution specializing in extraction was set out in a contract that includes:

- A clause for sharing potential benefits if the natural substances studied are used for new drugs.
- A clause for transferring technology related to extracting, purifying and splitting compounds derived from these substances.
- A commitment to train Chinese employees at the Frankfurt site on extraction and purification techniques.

Similarly, the contract between Sanofi and scientific institution includes a clause for sharing benefits if drug compounds are extracted from the supplied plants.

## BUSINESS CASE



Sanofi established a collaborative program to manufacture semisynthetic artemisinin (sweet wormwood), one of the active ingredients in the Group's first-line malaria treatment. This project contributes to the preservation of biodiversity in regions of the world where wormwood is grown.

- *Business case: Artemisinin*



## Preserving biodiversity at our sites and beyond

- ▼ [Initiatives to preserve biodiversity surrounding and beyond our sites](#)
- ▼ [Limiting environmental impact around our sites](#)
- ▼ [Limiting environmental impact beyond our sites](#)

### Initiatives to preserve biodiversity surrounding and beyond our sites

Sanofi understands the importance of biodiversity for the pharmaceutical industry. As a global healthcare partner, we are committed to safeguarding the environment. The Group pursues many initiatives designed to preserve biodiversity at our sites and in the surrounding areas, and beyond.

We endeavor to build on the momentum of the International Year of Biodiversity in 2010, a year-long celebration of the value of biological diversity for the Planet. Through our actions, Sanofi shows support for the new Strategic Plan for Biodiversity, which aims to reduce biodiversity loss. We also plan to play a role in the UN Decade on Biodiversity, 2011-2020.

In addition to complying with the Convention on Biological Diversity, the Group defined its own biodiversity policy in 2010. We want to take tangible steps that make a difference, such as limiting the environmental impact of our activities around our sites worldwide.

- Convention on Biological Diversity: [www.cbd.int](http://www.cbd.int)
- [Position Paper on Biodiversity and Biopiracy](#)

#### 2011-2020, Decade on Biodiversity

Following the International Year of Biodiversity in 2010, the UN General Assembly passed a resolution to make 2011-2020 the UN Decade on Biodiversity. One of the objectives of the Decade on Biodiversity is to promote the implementation of the Strategic Plan for Biodiversity (SBN), designed to significantly reduce biodiversity loss. Moreover, the European Union's Biodiversity Strategy to 2020, which is based on meeting six key targets, will also help halt the loss of biodiversity.

### Limiting environmental impact around our sites

Sanofi sites are implementing a wide range of programs to preserve biodiversity in the areas surrounding their facilities. Here are a few examples.

- ▼ France
- ▼ Pakistan
- ▼ India
- ▼ United States

## France

In 2011, our R&D site at Toulouse, France, initiated an environmental impact assessment. Following an environmental impact assessment, which we have entrusted to a specialized consulting firm (Gaiadomo), we will develop and implement an action plan.

Sanofi's Toulouse site is located in a rich natural setting that is adjacent to ecologically important areas including a bird conservation reserve and sites listed on the Inventory of Natural Areas of Ecological, Faunistic and Floristic Interest (known as ZNIEFF in French). It is also near a Natura 2000 site. Natura 2000 is an ecological network of protected land and marine areas in Europe that are home to rare and endangered wild species of flora and fauna.

Also in close proximity to our R&D site is the Garonne River, one of the principal waterways in France and an important part of the country's river network. Sanofi wishes to determine whether our activities impact species and natural habitats along the river.

This pilot environmental impact assessment project will consist of a comparative study both in situ and ex situ to meet the following goals:

- Establish a baseline
- Identify risks and opportunities related to biodiversity
- Determine environmental challenges at and around the site
- Develop ways to limit the site's environmental impact and better plan its development
- Strengthen and enhance existing environmental approaches
- Recommend specific actions that will make a clear contribution to developing the preservation of biodiversity

This initiative will also improve the Group's in-house expertise in regards to preserving biodiversity, which is a vast and complex field encompassing both animal and plant species.

The findings of this pilot project are expected in July 2012.

## Pakistan

Sanofi's head office is located in Karachi's main industrial area. One of the affiliate's priorities is to ensure that this location contributes to the Group's initiatives to protect biodiversity. The Engineering and HSE Departments work together to keep an updated inventory of plants at this Sanofi site and aim to expand the green belt around the site whenever possible. The head office organized a "Go Green Day" on November 18, 2011, asking each local team to plant a tree on the site. By the end of the year, 100 trees had been planted.

## India

The Group's site in Ankleshwar wished to improve the property surrounding this manufacturing site. They designed a project to create a green belt between the industrial estate and the surrounding residential areas. To date, 5,000 trees of local species have been planted.

## United States

In 2011, the Charles River Conservancy recognized the Genzyme site in Allston, Massachusetts, with the Distinguished Service Member Award for commitment to environmental stewardship. Volunteers from Genzyme have worked with the Charles River Conservancy to prune parkland trees, remove invasive bittersweet and buckthorn, and clear a stretch of Storrow Drive that is popular with joggers and cyclists.

## Limiting environmental impact beyond our sites

### ▼ Mexico

### ▼ Protecting endangered species around the globe

## Mexico

In order to celebrate World Environment Day, observed each year on June 5, Sanofi employees participated in a reforestation operation in the Nevado de Toluca National Park. They planted 400 Moctezuma pines, which are hardy enough to withstand the cold at elevations of 3,000 meters. From 2005 to 2010, a total of 776 hectares of woods and forests were destroyed in Mexico, where 95% of the land is owned by private individuals. This reforestation campaign allowed Group employees' to show that it is up to each of us to make a difference.

## Protecting endangered species around the globe

Sanofi works to protect biodiversity by helping to save endangered species from extinction thanks to Merial vaccines, which are used by governments and wildlife conservation agencies around the world.

**In Southern Spain**, Merial vaccines were administered to the last of the Iberian lynxes, thereby contributing to the preservation of this magnificent medium cat species. Only about 250 individuals remain living in the wild, and they are at grave risk from feline leukemia virus.

**In the Channel Islands** off California, populations of the Catalina Island fox were decimated in 1999 by an outbreak of canine distemper. Wildlife management organizations vaccinated the surviving foxes with a patented Merial canary-pox vector vaccine. The vaccination campaign helped populations of this endangered sub-species to recover.

**In the Himalayas, southern China, and Taiwan and peninsular Malaysia**, clouded leopards are a seriously endangered species. They are hunted for their beautiful fur and are susceptible to feline leukemia. Five Clouded Leopard cubs born to two American zoos were vaccinated with Merial-developed canary-pox vectored vaccines. The zoos hope to help increase the population of this endangered species.

**In Tanzania**, Merial donated rabies and distemper vaccines to a breeding, veterinary and reintroduction program for African hunting dogs, an endangered species. The program aims to breed and vaccinate the dogs and put them back into the wild.

**In South Africa**, Merial donated flea and tick preparations to the De Wildt Cheetah Center. In a study at the center, the project resulted in a significant decrease in tick infestation. Ticks are important vectors for many diseases.

## Safeguarding against biopiracy

Each time the Group investigates a new product isolated from natural sources, a contract is established, stipulating our adherence to the Convention on Biodiversity. This commitment safeguards against biopiracy.

Biopiracy refers to the commercial utilization of endemic resources and local know-how without sharing the profits with the communities or countries that are the source. The Convention on Biological Diversity (CBD) describes the principles governing such utilization, although local laws may vary to a great extent.

Sanofi's Natural Product Science department, located in Frankfurt, Germany, is the Group's research department that performs most investigations of natural products. Each time NPS purchases new natural sources for its research, a contract that must comply with the recommendations of the Convention on Biological Diversity is established. Only after this contract has been drawn up does the research department receive the samples and may proceed with its research project. In particular, the contract may cover pre-existing knowledge and industrial property, the conditions for the use of results, the modalities of the transfer of knowledge, and if it leads to development and market authorization, any consequential royalties and financial profits.

Each new natural source studied (for example, a plant) is registered in a database internal to NPS. Once the natural compounds have been isolated and identified (for example, from a plant), the structures of the pure natural compounds are registered in a Group chemical database. Moreover, when a biological activity is demonstrated for one of these compounds it is also recorded in another Group database – the biological database. Links between the biological and chemical databases make it possible to determine, for each new chemical compound created, whether or not there is a connection with a naturally derived compound.(\*)

Depending on the original contract, it may be possible to file a patent when a new biological activity is demonstrated; compound development is then carried out in compliance with the terms of the original contract, and may lead to royalty payments if the compound is brought to market or key clinical steps are taken. Raw material supplied for production may be provided either by extraction from the original source, or by chemical synthesis (semi-synthesis or total synthesis), which is sometimes competitive from an economic standpoint. In the case of extraction, a feasibility discussion will be carried out with partners depending on the quantities required.

For more information: The Convention on Biological Diversity:

- [www.cbd.int](http://www.cbd.int)

## Business case

Producing semisynthetic artemisinin and contributing to the preservation of biodiversity where wormwood is grown: 2011 update.

## The challenge

Ensuring a stable supply of artemisinin (sweet wormwood), one of the active ingredients in Sanofi's first-line malaria treatment, while contributing to the preservation of biodiversity in areas where it is grown. It is especially important to avoid a situation where artemisinin is grown to the detriment of food crops.

## Our Response

Artemisinin is extracted from the leaves of the sweet wormwood plant, which has traditionally been grown in China and Vietnam and, more recently, in Madagascar, East Africa and Southern Africa.

Artemisinin is at times in short supply. Fluctuations in demand and raw material shortages may create tensions among growers. Sanofi uses artemisinin to manufacture the antimalarial drug Coarsucam™/Artesunate Amodiaquine Winthrop® (ASAQ). To avoid situations where farmers choose to grow artemisinin instead of food crops, it was important to determine a way to produce this plant on an industrial scale to supplement agricultural production and stabilize prices.

A method to produce semisynthetic artemisinin was developed through collaboration between Sanofi and the Institute for OneWorld Health (IOWH). The Bill and Melinda Gates Foundation awarded IOWH a \$42.6 million grant for this project, while Sanofi contributed the Group's expertise in fermentation, chemical development techniques and industrial process optimization. This project led to increased yields of yeast strains that produce artemisinin and the development of a new chemical process.

In 2011, Sanofi tested and validated a pilot method to manufacture semisynthetic artemisinin on a small scale. The method was then scaled up for production of large quantities of artemisinin, which required additional validation steps to ensure that the quality of the drug produced on a larger scale remained optimal. Sanofi has installed and tested large-scale facilities and is currently producing the first batches of artemisinin for industrial validation. The validation phase is expected to continue through mid-2012.

## Benefits for stakeholders

### For patients:

The industrial production of semisynthetic artemisinin benefits patients because it means consistent, high-quality raw material as well as shorter production times and stable prices.

### For local communities:

Producing semisynthetic artemisinin prevents pricing speculation and ensures that producers of sweet wormwood will receive proper compensation. This project is carried out in a transparent manner with natural artemisinin growers and extractors. Sanofi has taken part in numerous meetings with farmers and extractors from various countries, presenting the project and explaining its benefits.

### For the WHO, governments, NGOs and other pharmaceutical companies:

This approach seeks to guarantee a constant raw material supply for the reliable production of quality medicines at a stable price. It is expected to also contribute to slowing the emergence of resistance to malaria resistant drugs.

## Opportunities for the Group

Producing semisynthetic artemisinin thanks to collaboration with the abovementioned stakeholders is consistent with Sanofi's Access to Medicines strategy. It allows the Group to make a difference in one of its areas of expertise – malaria; it helps meet patients' needs with an affordable drug. In addition, this project helps the Group be equipped to respond to growing demand for the raw material used to make ASAQ®.

The project strengthens the Group's image by promoting a program that has a positive impact on biodiversity, contributes to developing a cutting-edge biological process and responds to a pressing public health challenge.

## The future

The next step will consist of submitting the dossier to obtain regulatory validation for the manufacture of the first batches of semisynthetic artemisinin, which are expected in late 2012 / early 2013. Sanofi's goal is to produce 40 tons of artemisinin in 2013.



For more information:  
[www.sanofi.com](http://www.sanofi.com) - [www.sanofi.tv](http://www.sanofi.tv) - <http://reportingrse.sanofi.com>



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