

2012 REPORT

# CORPORATE SOCIAL RESPONSIBILITY



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Our 2012 CSR report offers a close look at Sanofi's Corporate Social Responsibility (CSR) priorities and practices. As a key component in our CSR communications suite, it describes the challenges we face, the strategic approaches we use to address them, and our progress toward meeting our goals. For each challenge, we also highlight initiatives that illustrate CSR in action in our day-to-day work.

The sections of this report reflect our pillars of Patient, Ethics, People, and Planet. Within each of these key areas, we present three or four emblematic CSR issues as a means to focus on the most critical CSR challenges today, for us as a global healthcare company and for our stakeholders.

For all Sanofi CSR topics, initiatives and positions, visit our Download Center at <http://csr.sanofi.com/downloadcenter>.

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## OUR CSR PERFORMANCE

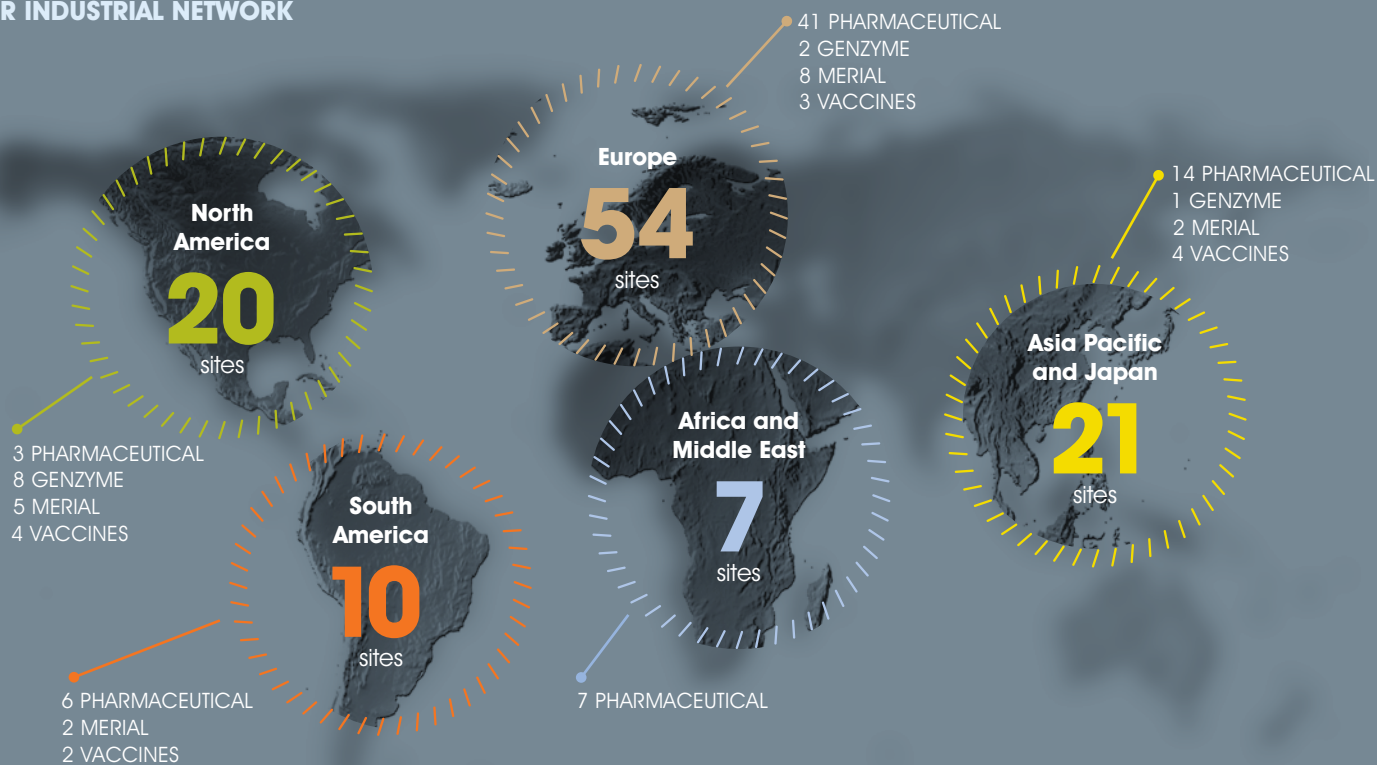
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# GROUP PROFILE

Sanofi, a global and integrated healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs.

## OUR INDUSTRIAL NETWORK



**MORE THAN  
110,000**

**EMPLOYEES  
IN 100 COUNTRIES**

- 25% FRANCE
- 25% EUROPE (excluding France)
- 17% NORTH AMERICA
- 33% REST OF WORLD



**TOTAL SALES  
€34.9bn  
2012**

- 31% USA
- 24% WESTERN EUROPE
- 32% EMERGING MARKETS<sup>1</sup>
- 13% REST OF WORLD



**18  
R&D SITES  
WORLDWIDE**

- 10 EUROPE
- 7 NORTH AMERICA
- 1 ASIA



**112  
INDUSTRIAL  
SITES  
IN 40  
COUNTRIES**



**18  
NEW  
POTENTIAL  
LAUNCHES  
2012-2015**



**WATER  
CONSUMPTION  
49.7  
MILLION m<sup>3</sup>**



**CO<sub>2</sub>  
EMISSIONS  
1,137,029  
TON<sup>2</sup>**



<sup>1</sup> World excluding North America (USA, Canada), Western Europe (Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK), Japan, Australia, and New Zealand.

<sup>2</sup> Direct and indirect CO<sub>2</sub> emissions.

## SENIOR MANAGEMENT INTERVIEW



**Christopher A. Viehbacher**  
Chief Executive Officer

**Gilles Lhernould**  
Senior Vice President of Corporate  
Social Responsibility

**You are, respectively, the CEO and the Senior Vice President of CSR at one of the world's leading healthcare companies. Please share your perspective on the key CSR challenges facing Sanofi.**

**C. Viehbacher:** We operate in over 100 countries and in hundreds of thousands of communities. Societies place a huge amount of trust in us and our solutions and Corporate Social Responsibility, as a result, is an integral part of our DNA. It is not an activity that is separate and stand alone. It is who we are.

We decided to focus on areas where we can make a real difference and have the most impact. For me, this is access to quality healthcare. Today, approximately one third of the population has no access to essential healthcare. That's over two billion people. The issues are many – lack of infrastructure, medical professionals to diagnose and treat, education and awareness of diseases, supply chain, transport/storage and, of course, funding.

As a result of our resources, our decades of experience and accumulated expertise, and our size and geographic presence, we can go beyond donation of medications to really help develop multiple responses to these healthcare challenges.

As part of our response, we have a dedicated Access to Medicines Department which focuses on working with partners to assess the needs and find the response together. For example, we have been working in Neglected Tropical Diseases, and in particular

sleeping sickness, since 2001. We have managed to screen nearly 200,000 people and reduce new cases from over 30,000 in 2001 to less than 7,200 in 2010. The key to success is that the program goes way beyond drug donation. It consists of disease awareness, screening, diagnosis and then the complicated treatment. I visited one of the programs in Chad last year. It was extremely impressive and very moving to see what we are accomplishing with our partners. We continue to work on improving the program. Even though we are on track to eliminate the disease by 2020, we are currently working on an oral treatment. This will make a huge difference in people's lives as they will not have to travel the long distances to the hospital a number of times to receive long infusions. At the moment, it often means the whole family travels for a number of days to the hospital and camps outside during the treatment phase.

Another example in terms of access is our program in Russia. We realized that hospitals only had enough budget to treat some women for cancer with chemotherapy, but not all. So our team looked at what to do and decided that we could reduce the cost, but then the savings may be spent elsewhere. So we came to an agreement with hospitals. If they agreed to treat all the women, we would provide half the medicine free of charge.

Of course CSR is also about helping all communities in which we operate. It is a natural reaction to what is happening around us. Through our Foundation Sanofi Espoir and in all our

## SENIOR MANAGEMENT INTERVIEW

affiliates, we work on reducing health inequalities through both international and locally adapted programs and when needed, respond to unexpected disasters as they happen.

As a global healthcare leader, with over 110,000 people, I am convinced we have not only the ability, but also a responsibility to make a difference.

**G. Lhernould:** At the same time, we are humble enough to recognize that meeting our ambitious goal – to improve the health of all seven billion people on the planet – is not something we can accomplish alone! We rely on the cooperation of many different stakeholders, whose know-how and abilities complement our own. This is why we've made an explicit commitment to act as solid partner to international institutions, NGOs, health professionals and authorities, and we work with patient associations across the globe.

Similarly, upholding our CSR commitments would not be possible without the talent of our workforce. Our employees are the real drivers of our performance, and one of our top CSR priorities is to ensure their health, safety and well-being. Our injury rate is below average for major pharmaceutical companies and went down by 14% from 2010 to 2012. We've also sought to constantly improve our workforce development processes, for example, by allowing employees to acquire new skills as we migrate research and industrial facilities to biotechnology. While we provide training opportunities in skills specific to the pharmaceutical sector, we also want to empower our employees to develop their professional potential.

I like to think of our multicultural workforce as a mirror: it reflects the broad diversity of the patients and consumers who use our products. Our diversity helps us understand our customers. Thanks to their insights and skills, we develop novel solutions for patients that fit their lifestyles and needs. For example, we've added QR codes on the packaging of certain insulin products in Israel. After scanning the code with a smartphone, patients can see a video presentation on how to inject insulin.

### Can you cite some examples of accomplishments in 2012 that especially impressed you?

**GL:** The launch of AllStar™ insulin pen in India is an excellent example of how we develop innovative solutions for patients. The number of people living with diabetes is growing exponentially, and India is especially hard hit. The AllStar™ is the first re-usable insulin pen to be manufactured locally by a global company – illustrating our commitment to build production plants located close to patients and their needs. This pen is technologically innovative, yet easy to use and even more affordable.

Another source of pride is the recognition the Group received by our new ranking on the Access to Medicine index – we moved up to third place, thanks to significant progress in our approach.

**CV:** One of our 2012 milestones was signing the London Declaration on Neglected Tropical Diseases (NTDs) together with the Bill & Melinda Gates Foundation, other pharmaceutical companies, governments, the World Bank, representatives of NTD-endemic countries, and other stakeholders.

It is the largest coordinated effort to date to combat NTDs and ten diseases have been identified as priority. We are working on five of them (sleeping sickness, Buruli ulcer, Chagas, Leishmaniasis and Lymphatic Filariasis) and have committed to sustain and expand drug donation programs in addition to sharing expertise and compounds to accelerate R&D to reach the goals set out.

As part of this agreement, we initiated a new partnership with Eisai and the Bill & Melinda Gates Foundation to support the World Health Organization's (WHO's) Global Program to Eliminate Lymphatic Filariasis by 2020. This consortium, the first of its kind, will donate 120 million tablets of DEC (diethylcarbamazine), allowing the WHO to provide treatment for 30 million people. By the end of 2012, we had already delivered 60 million tablets.

This is just one part of our ongoing collaboration with the WHO to combat NTDs, which we started in 2001 and have renewed through to 2016. For Sanofi, it represents an investment of approximately U.S.\$75 million, or U.S.\$5 million annually, over 15 years.

### Where do you plan to concentrate your energies in the future?

**CV:** We will continue to work on the five Neglected Tropical Diseases we agreed under the London Declaration. We have also identified a number of key programmes through the Sanofi Espoir Foundation, one of which is a partnership with the Stand up for African Mothers campaign. The objective is to achieve a 25% reduction in maternal mortality by 2015, by training 15,000 midwives in 15 countries.

The fight against counterfeit medicines is another area we will concentrate on. Fake medicines are a genuine danger to health and can cause life and death. Our central anti-counterfeit laboratory cooperates with police and other enforcement authorities and we have initiated training programmes with them. We will continue to work with police officers, customs officials, health authorities and other pharmaceutical companies to seize potentially harmful medicines and shut down illegal websites that sell counterfeit drugs.



## SENIOR MANAGEMENT INTERVIEW

Another area where we can have a real impact is in chronic disease. The steady rise in chronic diseases like Type 2 diabetes and cancer is one of the greatest health challenges of the future. No longer diseases of the west, prevalence is increasing at an alarming pace in the developing world. We have huge experience in chronic disease and we can be part of the solution. We want to work with countries and stakeholders to help establish healthcare systems that will help prevent these diseases, rather than adapt the archaic healthcare systems of the Western world today. The developing economies have an opportunity to learn from our mistakes and prepare for a better healthcare future.

**GL:** In addition, we'll build on our recent success and remain focused on further limiting the environmental impact of our business by optimizing energy consumption and reducing our carbon footprint in all our production and distribution activities.

We are aware that climate change is a fundamental issue for the healthcare of the world's population. As more CO<sub>2</sub> and other greenhouse gases are released into the atmosphere, global warming levels will increase, leading to the proliferation of many fatal diseases including ones that Sanofi currently combats, such as malaria and dengue fever.

When it comes to CO<sub>2</sub> emissions, our objective is to achieve a 20% reduction by 2020 at our industrial and R&D sites. To reach this goal, we recently signed a collaboration agreement with Schneider Electric to improve the energy performance of our manufacturing sites worldwide. As a leader in energy management, Schneider Electric will help us become more energy efficient through practical support measures – such as forecasting, performance monitoring, on-site diagnostics and efficiency improvement plans.

We also continue to improve our knowledge and monitoring of pharmaceuticals in the environment while promoting take-back programs for the collection of unused medicines.

I think it is important to keep in mind that all these CSR initiatives and progress are anchored in our determination to act ethically and responsibly in every aspect of our business – for the planet in the examples above, but ultimately for patients and healthcare professionals, our shareholders, our employees, and many other stakeholders.

We provide medicines and vaccines to consumers and patients all over the world, and our conduct must be above reproach. Ethics is one of the four pillars in our CSR approach because it is essential to all aspects of our business: clinical trials, relations with patient organizations, transparency about our marketing and lobbying activities, etc.

Going forward, we aspire to build on our accomplishments and do even better.

# ABOUT CSR AT SANOFI

Sanofi’s ambition is to improve the health of the seven billion people around the world.

A majority of the world’s population continues to have little or no access to the most basic medicines and vaccines. We believe that improving access to healthcare for as many people as possible, regardless of where they live or their ability to pay for medicines, is a critical global challenge where we can make a difference. We have the expertise and the resources to do so, and our vast range of initiatives in this field speaks for itself.

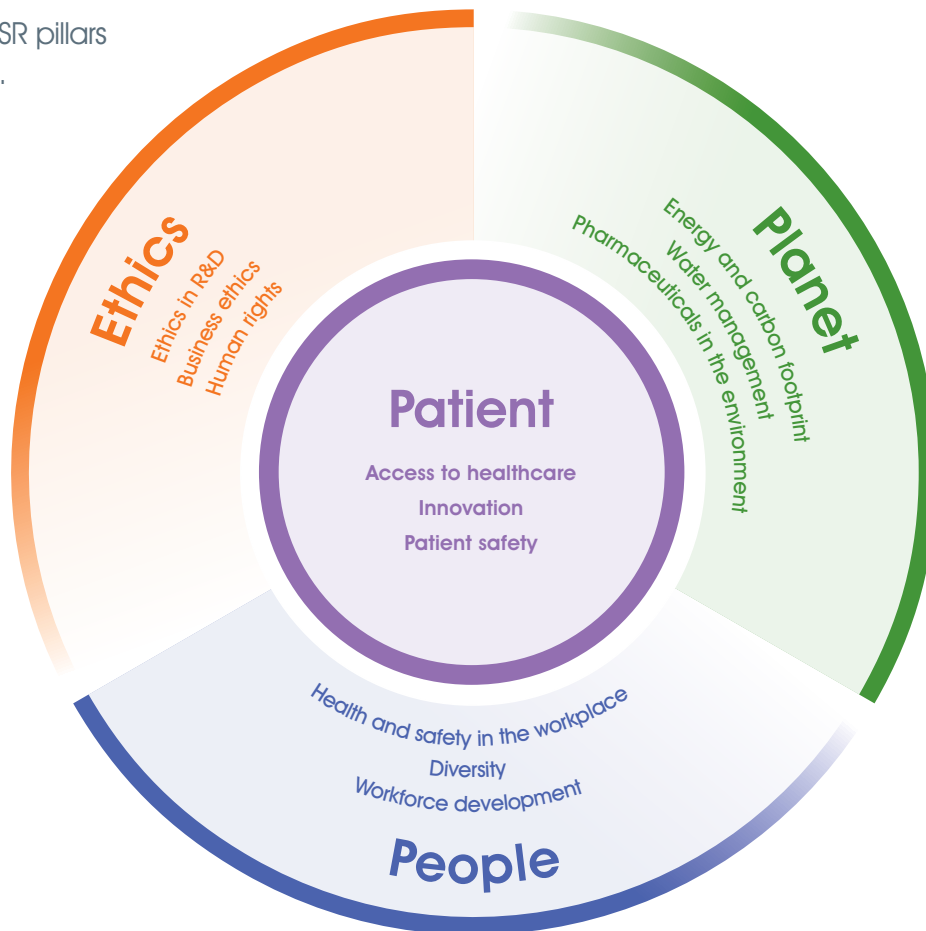
We cannot meet our CSR goals alone. We work closely, every day, with a broad range of stakeholders: patients, healthcare professionals, NGOs, public health authorities, employees, investors, and many others.

In addition to improving access to healthcare, the value of our CSR-based strategy in addressing the challenges before us is manifested, for example, in how we devise innovative solutions for patients, respect ethics in clinical trials and the promotion of our

medicines, and monitor our suppliers’ human rights performance. We protect our employees’ health and safety while supporting their professional development, and we promote diversity among our workforce as a driver of our business performance. Preserving the planet is essential to protect the health of people everywhere, which is why we limit our carbon footprint and use energy responsibly, and monitor pharmaceuticals in the environment.

Each time we respond to a challenge, we also try to seize a business opportunity and mitigate risks to ultimately find solutions that improve our overall performance as a responsible corporate citizen. This approach brings benefits for us, for patients, and for many other stakeholders. As we develop pragmatic and innovative responses to the CSR challenges facing us – very often through teamwork and pooling valuable expertise within the Group – we are convinced that we also improve our business.

We have four CSR pillars and 12 priorities.



# OUR MATERIAL ISSUES

Sanofi is committed to addressing numerous CSR challenges with a particular focus on the 12 key priorities across our pillars for action: Patient, Ethics, People, and Planet.

## Determining critical CSR issues: the materiality review

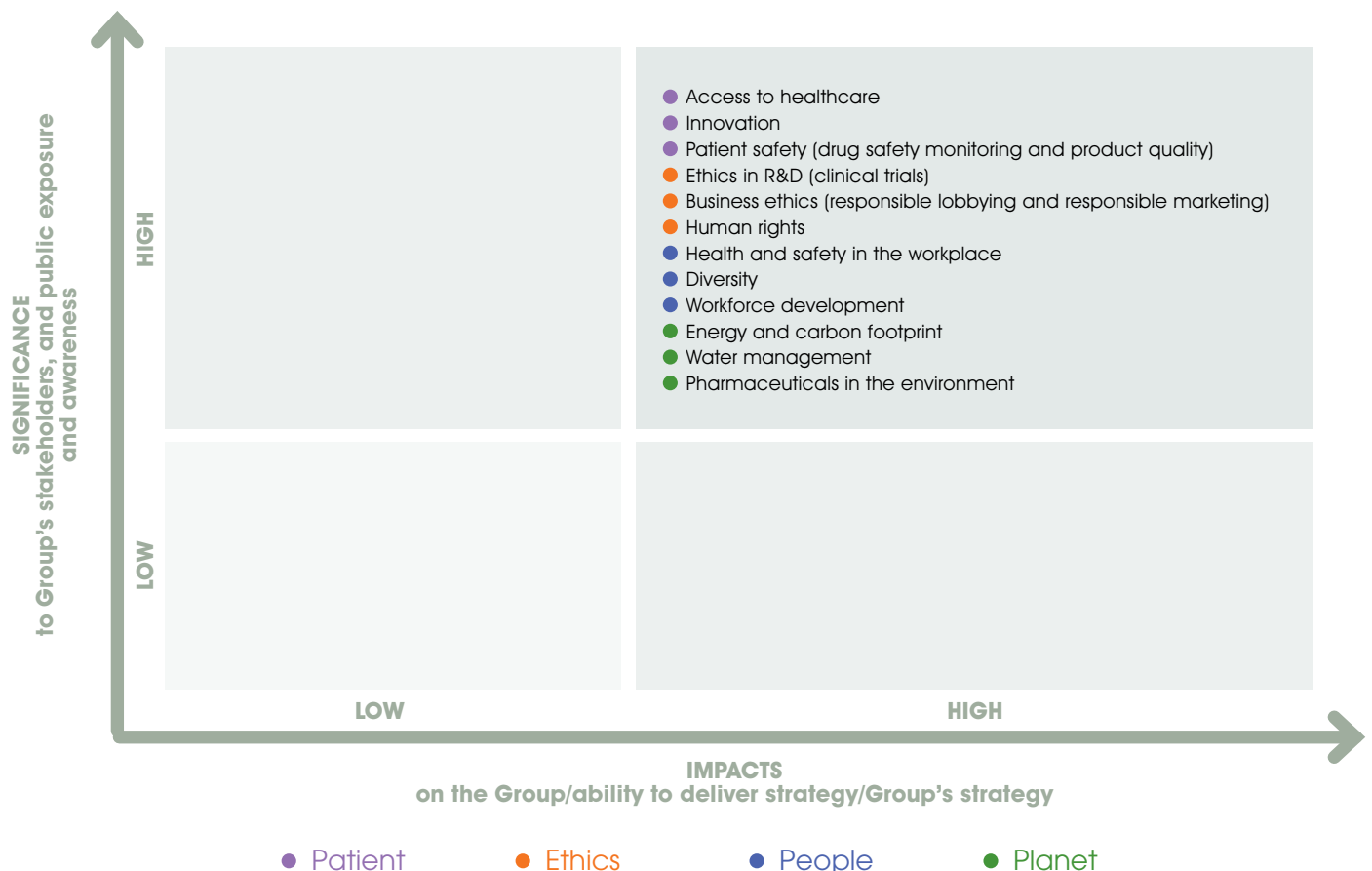
To align our CSR strategy with meeting our business goals and the expectations of stakeholders, we regularly review the issues that are most material to us. Material issues are those that may have a critical impact on the business if they are not actively managed, or those that our stakeholders consider to be of utmost importance. To help us identify such issues and focus our efforts, we rely on the materiality test. The CSR report describes the principal CSR challenges facing us today. For issues that are less material, more information may be found online in the documents located in the Download Center ([en.sanofi.com/csr/download\\_center/download\\_center.aspx](http://en.sanofi.com/csr/download_center/download_center.aspx)).

Thanks to this approach, as we organize initiatives and allocate resources, we concentrate on the issues that have the potential to impact Sanofi's business and reputation, either positively or negatively. At the same time, they provide an opportunity to create value and drive innovation, and it is up to us to successfully tap this potential.

In 2010, we undertook an in-depth materiality test, assessing CSR challenges based on their level of importance for stakeholders and their relevance to Sanofi's overall strategy. This careful analytical review allowed us to establish 12 key priorities for action over the next three years.

Since then, we have updated the materiality review each year by consulting our stakeholders, benchmarking CSR practices among international groups, and analyzing external questionnaires from non-financial rating agencies, investors, etc. We follow the method recommended by the Global Reporting Initiative Guidelines (GRI G3.1) and the AccountAbility Principles standard (AA1000).

Working with our stakeholders during this exercise allows us to realign our priorities as needed, to ensure they match stakeholders' expectations as closely as possible. Furthermore, their feedback enables us to identify new and increasingly important CSR issues that we must pay attention to.





# STAKEHOLDER RELATIONS

## Engaging our stakeholders

We are committed to responding to the needs and expectations of a wide range of stakeholders, particularly those in the healthcare field. Each day, representatives from all areas of Sanofi's business interact with stakeholders from many different walks of life. Our R&D and industrial activities, corporate functions, and marketing teams engage them for myriad projects through dedicated Sanofi organizations.

Very often, they ask us to provide appropriate information about the proper use of medicines as well as factual data, such as financial and extra-financial information. For example, we work with them to form collaborations in the healthcare industry and in academia, to support patient associations, and to provide humanitarian assistance. They also participate in formal discussion groups and advisory bodies: CSR committees, environmental protection groups, and local communities. We strive to constantly listen to our stakeholders, and this mutually beneficial interaction provides us with a great deal of knowledge and learning.

## Stakeholder dialogue within our affiliates worldwide

Many Sanofi affiliates around the world organize their own stakeholder consultation initiatives, which provide valuable insights from different perspectives and geographical locations. They contribute to shaping a global, concerted vision of our CSR challenges. For example, with our affiliates in Algeria, Brazil, Russia, and Turkey, Sanofi recently organized the analysis of materiality reviews so that we may adapt our global CSR strategy to local realities.

## Stakeholder Panel in France

*CSR Stakeholder Panel was set up in France in late 2011. Two meetings were held in 2012. The first aimed to identify external stakeholders' expectations regarding the CSR issues to be addressed, while the second focused on discussing the solutions implemented by Sanofi in connection with selected issues identified by the Committee.\**

The Stakeholder Panel will continue to meet on a regular basis in 2013.



### Related content online

[Download center](#)

- Stakeholder Engagement factsheet

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

# CSR GOVERNANCE

## CSR governance and management

The CSR Direction is responsible for managing and integrating our CSR approach at every level of the Group – locally, regionally, and globally. It coordinates major initiatives in connection with Sanofi's economic, social, and environmental responsibility across all our entities.

As a source of expertise, the CSR Direction proposes Sanofi's CSR strategy to the CEO. We organize initiatives, implement CSR practices worldwide, and promote awareness of key CSR issues both inside and outside of our business. We engage in ongoing dialogue with our stakeholders and develop action plans to address Sanofi's CSR challenges.

## Two CSR networks, 100 correspondents worldwide

We rely on two distinct and complementary networks to reach all Sanofi entities and affiliates worldwide. Together, the regional and functional networks cascade our approach and gather feedback from our sites.

- The **CSR Functional Network** represents all functions, including Industrial Affairs, R&D, Commercial Operations, HSE, Compliance, Human Resources, the Legal Department, etc. It coordinates the integration of our global CSR strategy across all Sanofi's business activities.
- The **CSR Regional Network** is made up of 60 correspondents from regions and countries where we operate. It implements, adapts, and develops our global strategy locally and regionally.

## Awareness among our workforce

To embed CSR understanding among our employees, we rely on in-house communication tools, training, and rewards and recognition. We also develop the CSR blog, our annual CSR brochure, videos, and the Sanofi CSR intranet to reach all employees. A specially designed e-learning tool allows them to master the fundamentals of CSR at their own pace.

In 2012, the CSR Direction organized the CSR Awards to recognize the most innovative projects, which were submitted from every level of our organization worldwide. High-ranking company leaders lend their support to this innovative project, which provides tangible examples of how CSR is lived out each day by our teams, and illustrates the very real benefits it brings to Sanofi and to our stakeholders. We received over 100 entries for the inaugural 2012 CSR Awards, and preparations are already underway for the 2014 event.

We organized our second convention for the CSR correspondents in June 2012. This annual meeting has rapidly become a tradition. Not only does it strengthen our CSR networks, but it also provides a forum where regional and functional correspondents can exchange information and learn from one another.



SANOFI  
CSR Awards

2012 CSR AWARDS

**9 WINNING PROJECTS**

**2 WINNING TEAMS PER  
CSR PILLAR: PATIENT,  
ETHICS, PEOPLE, PLANET**

**1 GRAND PRIX**

### Related content online

#### Download center

- 2012 Internal Sanofi CSR Awards factsheet
- CSR Approach and Governance factsheet
- Corporate Governance factsheet

# POLICIES AND MANAGEMENT SYSTEMS

Our CSR approach relies on internal policies and tailored management systems that make it possible to integrate the approach across all Sanofi entities.

## Policies

Sanofi has developed codes, charters, directives, and guidelines to support and structure our work. While they integrate external standards and legislation that apply to our activities, they are often designed to exceed compliance with regulatory and other requirements by setting even higher standards for ourselves.

As an essential component of our CSR approach, transparency contributes to building trust with our stakeholders and, most importantly, with patients. Our Transparency Policy, introduced in late 2011 and rolled out worldwide in 2012, covers the disclosure of payments to healthcare professionals and organizations, the disclosure of donations to patient associations in specific regions, and access to our clinical trials and publications data. It is one of several transparency initiatives within Sanofi.

## Management systems

We adopt specific procedures to ensure that all Sanofi employees uphold the policies we have committed to follow. We rely on solid management systems to establish a framework for monitoring the full integration of policies and standards at every level of the Group.

Because managing risks to our reputation is also essential to the viability of our business activity, we have created a dedicated team to address this need. The Sanofi Risk Management team reports to the Senior Vice President of CSR, who is also Co-Chairman of the Group Risk Committee. Its role is to assist Sanofi's Executive Committee in fulfilling its responsibility with respect to risk management and implementing an enterprise risk management framework.

**Our CSR-related management systems govern six areas that are critical to the viability of our business.**

Management system	Role
Quality	Protect patient safety by implementing a quality management system designed to guarantee the quality of all Sanofi products and oversee compliance with pharmaceutical regulatory requirements across all R&D programs and for our affiliates' promotional activities
HSE	Protect health and safety of each employee, develop and utilize safe industrial processes, and limit the environmental impact of the Group's activities
Compliance	Develop processes to instill ethical values and clear standards of compliant behavior
Drug safety monitoring (pharmacovigilance)	Ensure patient safety by constantly evaluating and monitoring risks associated with the use of our products and seeking to optimize the benefit/risk profile of our medicines and vaccines during their entire life cycle
Internal audit and control	Provide reasonable assurance to Sanofi's senior management on the level of control over operations, seeking to optimize operational efficiency and compliance with internal and external standards and requirements
Risk	Identify, assess and proactively manage risks in our activities

## Related content online

### Download center

- Code of Ethics
- Anti-Bribery Policy
- Health Safety and Environmental Management System factsheet
- Quality Management System factsheet
- Compliance factsheet
- Internal Audit and Control factsheet
- Risk Management factsheet
- Position on CSR Topics factsheet

**THE SANOFI CODE OF ETHICS  
HAS BEEN TRANSLATED INTO  
30 LANGUAGES.**

BY THE END OF 2012,  
MORE THAN **85,000** EMPLOYEES  
IN OVER **80** COUNTRIES HAD  
RECEIVED TRAINING ON OUR  
CODE OF ETHICS.

# EXTERNAL RECOGNITION

## External recognition for Sanofi's performance

In recognition of our CSR and sustainability performance, we were included on the most recognized global CSR indices in 2012.



Sanofi was listed on the DJSI (Dow Jones Sustainability World Index) for the sixth consecutive year.



We have been listed on the FTSE4Good and Ethibel Sustainability Excellence Indices for several years.



We have been included on the newly launched Vigeo Europe 120 and Vigeo France 20 Indices.



We are one of the top three companies listed by the 2012 Access to Medicine Index.

[www.accesstomedicineindex.org](http://www.accesstomedicineindex.org)



Sanofi reached a 93B score (93/100 for disclosure and B (A–E) for performance).

Sanofi is listed in the France SBF250 Carbon Disclosure Leadership Index.

In addition to these global listings, Sanofi received 25 awards in 15 countries from local organizations. The list of these awards is available in the Download center.

### Related content online

#### [Download center](#)

- 2012 External CSR Awards Received factsheet
- Memberships and Collaborations factsheet



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SANOFI'S CONTRIBUTION TO WHO PARTNERSHIP TO FIGHT NEGLECTED TROPICAL DISEASES:

**U.S. \$75 MILLION** FROM 2001 TO 2016

**€9 MILLION** INVESTED IN R&D TO FIGHT MALARIA, TUBERCULOSIS AND LEISHMANIASIS IN 2012

OVER **230** ACCESS TO HEALTHCARE PROGRAMS BENEFITTED **270 MILLION** PEOPLE WORLDWIDE IN 2012

Marco, Patient, Venezuela.

# PATIENT

As we seek to improve the health of all seven billion people around the world, we focus on patients and their needs. We rely on innovation to increase access to healthcare, ensure patient safety and anticipate tomorrow's challenges.



# ACCESS TO HEALTHCARE

## CHALLENGE

Ensuring healthcare for all is one of the most pressing challenges facing society today, especially considering that approximately one-third of the global population does not have access to essential medicines and vaccines.

Yet access to healthcare is a complex issue, one the pharmaceutical industry cannot tackle alone, which requires the participation and cooperation of numerous and diverse stakeholders with complementary responsibilities and capabilities.

### Facilitating access to healthcare involves addressing many challenges

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

When access to healthcare is limited by the cost of treatment or the lack of available appropriate treatments, then pharmaceutical companies can be more directly involved by:

- developing solutions that are better suited to patients' needs;
- adapting the company's commercial offerings to economic conditions;
- supporting the production of generic versions of its own products, including by manufacturing them; and
- contributing to innovative strategies and programs that improve health outcomes beyond access to medicines, such as access to prevention, diagnosis and follow-up, especially when it comes to chronic diseases (e.g., cancer, diabetes, mental illnesses).



## ACCESS TO HEALTHCARE

**STRATEGIC APPROACH**

Sanofi believes that enabling individuals to assert their right to health means facilitating access to quality medicines and vaccines to benefit as many patients as possible, whether they live in developing, emerging or developed countries.

We consider 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 benefit from disease prevention and to receive comprehensive care, from diagnosis to treatment.

**Our perspective**

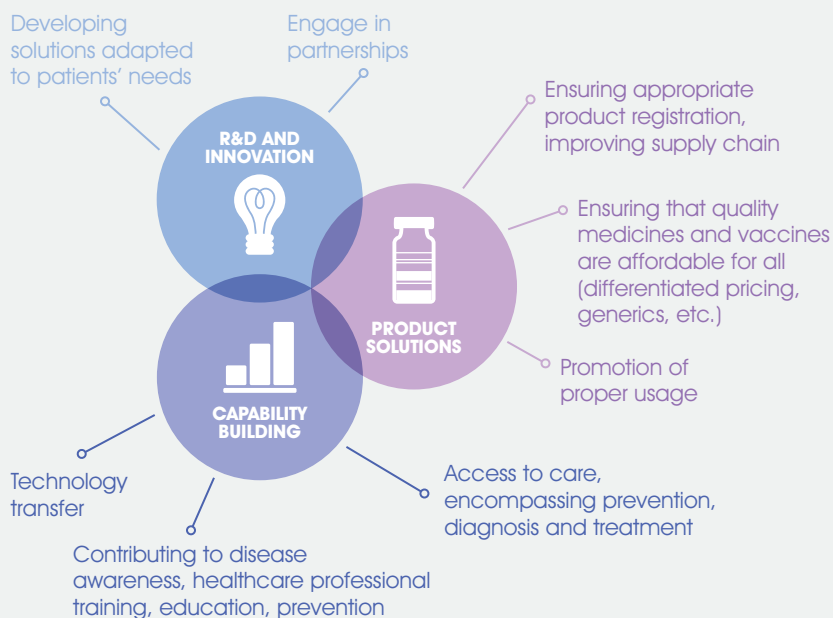
We are committed to doing everything in our power to support governments and other stakeholders' efforts to reduce the barriers to access to healthcare for all. For this reason, we design initiatives to address major public health priorities, while supporting an economically viable business model that places patients and their needs at the center of our concerns.

In response to today's challenges, we develop three types of programs:

- R&D and innovation;
- product solutions; and
- capability building.

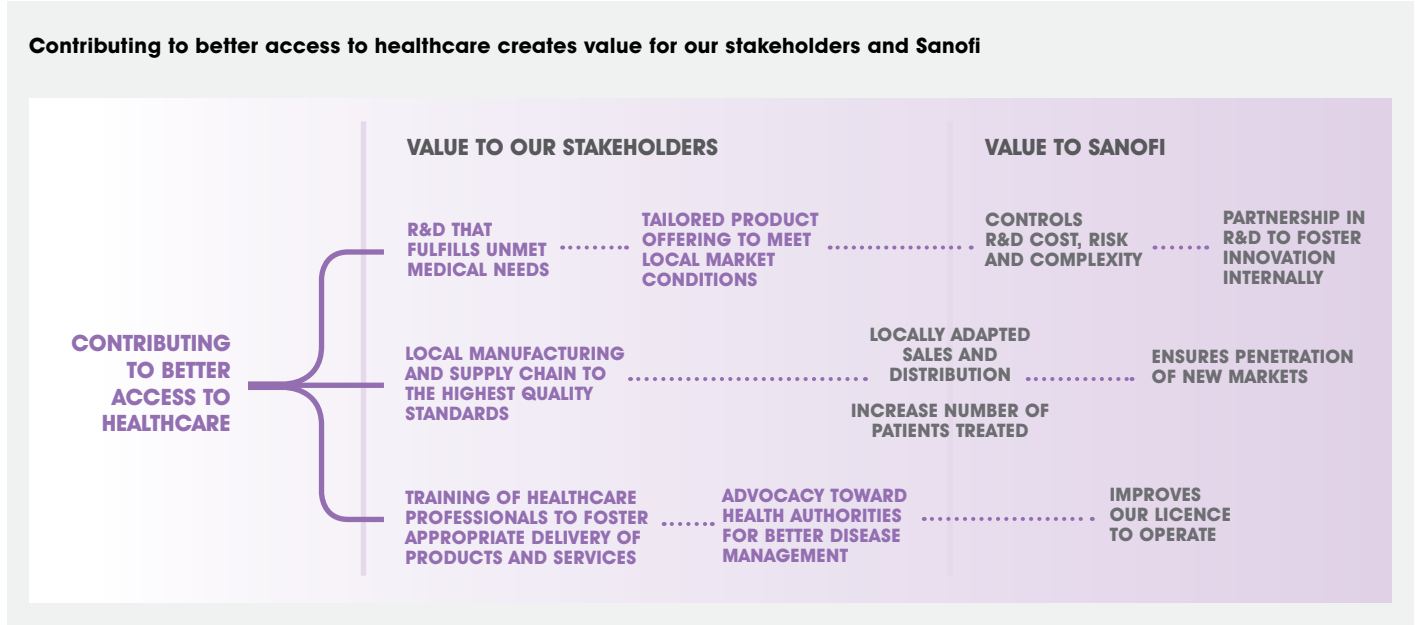
**Related content online**[Download center](#)

- [Access to Healthcare and Innovation Position Paper](#)
- [Collaborative Efforts to Promote Access to Healthcare factsheet](#)

**Our three types of programs**

# ACCESS TO HEALTHCARE

## Business rationale



The most effective way we, in the healthcare industry, can have an impact is by finding means to achieve the combined goals of improving access to medicines and improving access to quality healthcare. At the same time, we need to build a sustainable business to be able to invest in delivering innovative solutions for those in need.”

Christopher A. Viehbacher, CEO

Visit by Christopher A. Viehbacher to Chad, April, 2012. Care of sleeping sickness.

## ACCESS TO HEALTHCARE

## Our response

We resolutely believe that when it comes to ensuring access to healthcare, one size does not fit all, which is why our response to this challenge takes many forms.

## For the most disadvantaged patients

**A dedicated Access to Medicines Department**

To promote access to healthcare for the neediest patients in resource-poor countries, Sanofi has created a dedicated department called Access to Medicines (ATM). ATM focuses on disease areas where we have decades of experience based on our portfolio of medicines: malaria, tuberculosis, Neglected Tropical Diseases (sleeping sickness, leishmaniasis, Chagas disease, Buruli ulcer), epilepsy and mental disorders.

Our ATM Department has developed a holistic approach to disease management that encompasses:

- **Tiered pricing to help ensure medicines are affordable for all.** Medicines are sold at market prices in developed countries and to the private sector in developing countries. For the public sector and non-governmental organizations, they are sold using tiered pricing schemes, which may reach “no profit – no loss” levels.
- **Information and education programs for all links in the health chain.** We provide tools to help train healthcare professionals, inform communities and educate patients on prevention, diagnosis, and treatment. Through our partnerships, these tools are available to governments and organizations that are active in the field.
- **R&D designed to meet future needs.** Sanofi R&D's dedicated infectious diseases unit conducts research on multi-resistant bacterial infections as well as on malaria, tuberculosis and Neglected Tropical Diseases.
- **Partnerships and collaborations for success in the field.** To respond to public health challenges in developing countries, we increase our chances of success by soliciting valuable expertise to complement our own.

**The Sanofi Espoir Foundation**

The Sanofi Espoir Foundation was created in 2010 with the ambition of bolstering Sanofi's commitment to international solidarity, and bringing it to the fore as an integral part of our CSR strategy. With a budget of €33.7 million over five years, the Foundation has a clear-cut agenda aimed at reducing healthcare inequalities among the world's poorest communities by building sustainable partnerships and collaborations to meet the basic needs of prevention, training, and access to care in three key areas:

- the fight against childhood cancer;
- the fight against maternal and neonatal mortality; and
- facilitating access to healthcare to the most vulnerable patients.

**Related content online**[Download center](#)

- Access to Medicines Brochure
- Malaria factsheet
- Neglected Tropical Disease factsheet
- Tuberculosis factsheet
- Epilepsy and Mental Illness factsheet
- List of Access to Medicines Direction Programs-2012 factsheet
- Employee Volunteering factsheet

[Sanofi Espoir Foundation Website](#)[Sanofi Espoir activity Reports](#)

FONDATION  
**SANOFI**ESPOIR

Mother waiting to have her child vaccinated by a health worker – Ethiopia.

## ACCESS TO HEALTHCARE

## Providing solutions for patients

**Sanofi's approach to chronic diseases and conditions**

Based on the health needs of each country, Sanofi's diversified portfolio includes over 400 products to address infectious and chronic diseases and conditions.

Diabetes, cancer, and heart disease are on their way to becoming the leading causes of death and disability worldwide due to multiple factors: the aging of the population, increased urbanization, and globalization of the Western lifestyle. In light of this trend, Sanofi considers access to healthcare for chronic diseases and conditions a key priority today. This is because, first, patients' needs in this area are growing, and second, chronic diseases may represent an even greater obstacle to global development than do infectious diseases. Patients who live with a chronic condition must receive treatment for their entire lifetime, and they require sustainable access to healthcare, from prevention to treatment.

Through Sanofi's specialized business units devoted to oncology, diabetes, cardiovascular diseases and multiple sclerosis, we organize a number of initiatives to address a broad range of access to healthcare issues in the field of chronic diseases and conditions. We seek to provide solutions for both general and specific needs at the global, regional, and local level.

We believe that appropriate intellectual property protection is critical for innovation and does not represent a major obstacle to access to our products. Indeed, only about 10% of our products are protected by patent rights which, if effectively enforced, would prevent other companies from manufacturing, using and/or selling generic versions of these products.

Our chronic disease initiatives focus on:

- R&D programs designed to provide effective and adapted solutions for all patients;
- information and education programs to help train healthcare professionals, inform communities and educate patients, from prevention to treatment;
- adapted pricing schemes and access programs in partnership with local healthcare communities and authorities; and
- innovative programs to improve health outcomes.

**Related content online**
[Download center](#)

- List of Access to Healthcare Programs developed by our Affiliates-2012 factsheet

**Related content online**


Worldwide, more than 366 million people are currently living with diabetes. Building upon its century-long history in this field, Sanofi is committed to improving global diabetes management through its integrated offering of treatments, medical devices and services.



## ACCESS TO HEALTHCARE

**Access to our vaccines**

Vaccines save millions of lives each year. However, at least two million children under age five still die each year due to diseases that vaccines can prevent.\* The vision of Sanofi Pasteur, our vaccines branch, is a world in which no one suffers or dies from a vaccine-preventable disease. We play a critical role in improving public health by contributing to making vaccines accessible to as many people as possible.

Sanofi Pasteur takes a comprehensive approach encompassing:

- **Participation in one of the most ambitious public health projects.** Sanofi Pasteur is a longstanding corporate partner of the Global Polio Eradication Initiative (GPEI), launched in 1988 and spearheaded by the WHO, UNICEF, Rotary International, and the U.S. Centers for Disease Control and Prevention.
- **A differentiated pricing policy for vaccines.** Sanofi Pasteur has been a partner in the Global Alliance for Vaccination and Immunization (GAVI) since it was launched in 2000 by the Bill & Melinda Gates Foundation, the World Bank, the WHO, UNICEF, and vaccine manufacturers.
- **Training and information adapted to all stakeholders in the healthcare pyramid.** We promote vaccination specifically targeting the needs of the poorest populations through the development of immunization-capacity building at local level.
- **Ongoing research to develop vaccines that are suited to patients' needs.**

**Expanding our offer of quality and affordable products via generics**

Generic drugs are a vital part of establishing a balance in healthcare systems, from a financial standpoint and to promote access to care. For several years, Sanofi has adopted an approach based on the development of our generic portfolio (including auto-generics) and strategic acquisitions to reinforce our presence in the generics market as we continuously expand our activity through targeted regional approaches.

- We have further strengthened our European platform under the Zentiva affiliate, which conducts Sanofi's generics activity for France, Germany, Italy, Switzerland, Portugal, and the UK, as well as Russia and Turkey.
- Sanofi has registered and launched many generics in various markets through the Zentiva affiliate.
- In May 2012, we entered into an agreement with Medreich India Ltd., under which Sanofi is to acquire the rights to a line of that company's generic products. Medreich products are well established and will allow Sanofi to expand in Nigeria and other sub-Saharan countries our portfolio of quality generic products at affordable prices in key therapeutic areas such as anti-infectives, pain and anti-inflammatory, anti-malarial, and vitamin products.
- In October 2012, Sanofi signed an agreement to acquire Genfar S.A., a Colombian pharmaceutical company that is a major player in Colombia and other countries in Latin America. Genfar is the second-largest generics manufacturer in Colombia by sales, and the leader by volumes sold. Together with the previous acquisition of Medley, a leading generics company in Brazil, this reinforces our position in Latin America.

**Related content online**

[Download center](#)

- [Access to Vaccines factsheet](#)



Polio vaccination in Africa.

\* World Health Organization. *50 Facts: Global health situation and trends 1955–2025.*

## ACCESS TO HEALTHCARE

**Genzyme: specialized in rare diseases**

Through Genzyme, a Sanofi company, we are able to address the unique needs of patients living with rare diseases in both developed and developing countries. Rare diseases are increasingly recognized by health authorities as a public health concern given the lack of awareness and treatment options. They are often very serious, chronic, and in many instances may be life threatening. Nearly 7,000 such diseases have been reported worldwide, and new ones are reported on a regular basis. Some 80% of these are inherited diseases.\*

Rare diseases can have a devastating effect on patients and families alike. The medicines used to treat such diseases are known as orphan drugs. They are a critical part of the Sanofi portfolio for both existing products and new product development.

Genzyme focuses its approach on:

- educating physicians, payers, and other stakeholders on rare diseases to help accelerate the proper diagnosis and encourage early treatment;
- providing treatment to patients who meet serious medical criteria where coverage is not available;
- helping countries establish sustainable healthcare systems; and
- working with national health services and private insurers to establish coverage for products.

**Partnering with patient associations, supporting patients and their families**

One of the ways that Sanofi translates this commitment toward access to healthcare into reality is by partnering with patient associations all over the world on mutual priorities that benefit patients. We are committed to foster an open dialogue, to listen, to learn and to act to meet patients' needs in order 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; and
- help advocates work together and voice their opinions to ensure patients' interests and appropriate access remain at the forefront of our healthcare systems.



Maryze, Patient, Netherlands.

**Related content online**
[Download center](#)

- [Discovering and Treating Rare Diseases factsheet](#)
- [Partnering with Patient Associations factsheet](#)
- [List of Patient Associations Supported by Sanofi factsheets](#)

\* Cambridge Medicine Journal, 2012

## ACCESS TO HEALTHCARE

### ACHIEVEMENTS

#### Over 230 access to healthcare programs in 2012

Sanofi conducted more than 230 Access to Healthcare programs worldwide in 2012. Including international programs that are vast in scope as well as modest initiatives designed to meet very specific local needs. Across our organization, we take an adaptable, highly integrated approach to improving access to healthcare.

Breakdown of our programs:

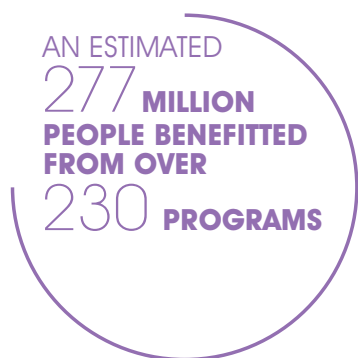
- 43% were developed by our dedicated Access to Medicines Department, the Sanofi Espoir Foundation, and Sanofi corporate teams including Sanofi Pasteur (1); and
- 57% were developed at country level by our affiliates (2).

Our programs were organized in more than 65 countries across the globe, primarily in developing countries but also in developed countries, where not all communities have access to healthcare.

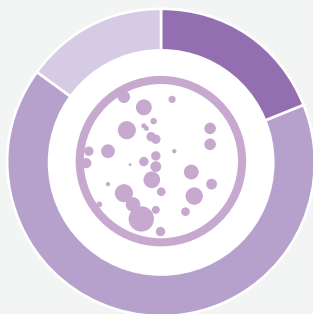
#### Related content online

##### Download center

- (1) List of Access to Medicines Direction Programs-2012 factsheet
- (1) Collaborative Efforts to Promote Access to Healthcare factsheet
- (1) Access to Vaccines factsheet
- (2) List of Access to Healthcare Programs developed by our Affiliates-2012 factsheet
- (1) [Sanofi Espoir Foundation Website](#)



#### Distribution of our programs



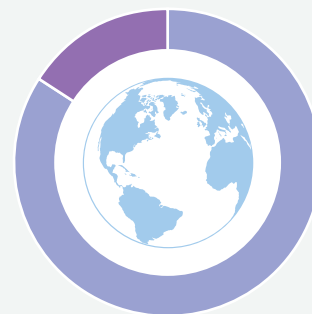
##### By type of disease

- **19%** INFECTIOUS
- **66%** CHRONIC DISEASES AND CONDITIONS
- **15%** OTHER (including both infectious and chronic, and child and maternal health)



##### By type of program

- **14%** R&D AND PRODUCT SOLUTIONS
- **75%** CAPABILITY BUILDING
- **11%** COMBINED



##### By geographic location

- **16%** EUROPE AND NORTH AMERICA (U.S. and Canada)
- **84%** OTHER REGIONS (Asia Pacific, Latin America, Africa, Middle East, Japan)

## ACCESS TO HEALTHCARE

**ABOUT €9 MILLION**  
INVESTED IN RESEARCH AND DEVELOPMENT TO  
FIGHT MALARIA, TUBERCULOSIS AND LEISHMANIASIS

### Investments and major partnerships

In 2012, as in 2011, about €6 million were invested in programs coordinated by our dedicated ATM Department.

Thanks to our tiered pricing policy, through which our anti-malarial drug Coarsucam/Artesunate-Amodiaquine Winthrop (ASAQ Winthrop®) is made available in malaria endemic countries at differentiated prices, 73 million units of ASAQ were sold in 2012, over 95% on a “no profit – no loss” basis (compared to 51.4 million units in 2011).

**73 MILLION MALARIA ATTACKS**  
TREATED IN 2012

### An interactive diabetes training program for African healthcare professionals

In 2012, more than 1,500 African healthcare professionals in 23 countries were trained each month in primary care for diabetic patients thanks to the e-Diabete program, which aims to improve diabetes diagnosis and treatment in Africa. Participants watch monthly interactive courses taught in French and English by international diabetes experts, and they can download free courses via the website [www.e-diabete.org](http://www.e-diabete.org).



### Our partnerships and collaborations

In 2011, we renewed our partnership with the WHO to fight NTDs. For the period 2001–2016, we committed to invest U.S.\$75 million, or U.S.\$5 million annually.

On January 30, 2012, we signed the **London Declaration on NTDs** alongside public and private partners with the explicit goal of **eliminating ten NTDs by 2020**. We also joined a partnership to help eliminate **lymphatic filariasis**, committing to provide 120 million Sanofi-produced DEC (diethylcarbamazine citrate) tablets to the WHO free of charge over a two-year period through 2014, which represents treatment for 30 million people.

Since we launched our collaboration with the WHO in 2001 to combat **sleeping sickness**, over 20 million people have undergone screening and over 170,000 patients have been treated for this disease, which is fatal if untreated. Reported new cases fell from 30,000 in 2001 to under 7,200 in 2010.

Sanofi is one of the founding members of the **WIPO Re:Search** (World Intellectual Property Organization) alongside partners in the private and public sectors. In its first year of existence, the consortium's membership more than doubled, going from 30 to 61. Already it has led to 11 research collaborations, with many others in the works. Through these partnerships we share valuable intellectual property and expertise to enable faster development of more effective treatments in NTDs.

Our CEO, Christopher A. Viehbacher, is the **Co-Chairman of the Gates CEO Round Table**, and the **Chairman of the CEO Round Table on Cancer**. Sanofi is a member of the Healthy Living Charter of the World Economic Forum ([www.weforum.org/issues/healthy-living](http://www.weforum.org/issues/healthy-living)) and a supporter of the NCD alliance ([www.ncdalliance.org/](http://www.ncdalliance.org/)).

**PROVIDING 120 MILLION TABLETS**  
TO TREAT **30 MILLION** PEOPLE, HELPING TO  
ELIMINATE LYMPHATIC FILARIASIS

#### Related content online

[Download center](#)

- Collaborative Efforts to Promote Access to Healthcare factsheet

## ACCESS TO HEALTHCARE

**Sanofi Espoir Foundation**

€33.7 million over five years allocated to responding to humanitarian emergencies and to developing more long-term access to healthcare programs.

In 2012, the Foundation helped coordinate 60 development aid programs in 40 beneficiary countries. In addition, humanitarian emergency actions were implemented in eight countries (Haiti, Syria, Chad, Niger, Mali, Cameroon, Senegal and Burkina Faso).

 **Related content online**

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- Employee Volunteering factsheet



Fighting leishmaniasis in Brazil with the Oswaldo Cruz Foundation.

**Donations**

212,000 boxes of drugs and more than 645,000 doses of vaccine were donated in 2012, for an estimated value of €12 million. These donations have supported the medical care of 2.2 million people in 31 countries, including 26 emerging or developing countries. In addition, in 2012, a total of 66,400 boxes of drugs were donated through Genzyme programs on rare diseases, for an estimated value of €59.3 million.

**FOR THE FUTURE**

- Continue to include more beneficiaries in our many and diverse Access to Healthcare programs.
- Enhance the country coverage of our programs worldwide.
- Strengthen our presence in emerging markets by responding to local health needs through sales of our products.



## ACCESS TO HEALTHCARE

## HIGHLIGHTS

## Mental health programs

Epilepsy and mental disorders affect the same proportion of people in industrialized countries and in resource-poor countries\*. Although effective and affordable drugs exist, most patients in developing countries do not receive appropriate healthcare, due largely to stigmatization and prejudices that prevent them from seeking appropriate assistance. Sanofi's ATM Department has developed programs designed to inform primary healthcare providers about epilepsy and mental disorders, fight stigma through community organizations, and facilitate access to adapted and affordable medicines.

## 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 program 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. We have also implemented a differentiated pricing policy in an effort to help make affordable anti-psychotics available to patients. Since the start of this program, 452 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 (i.e., the number of people who need treatment but do not receive it) has gone from 93% in May 2009 to 48% in December 2012 – an improvement of 48% in 3.5 years. Following these results, the program was extended to other provinces of Mauritania and now includes other major mental disorders and epilepsy, in addition to schizophrenia.



**MAURITANIA**  
TREATMENT GAP  
REDUCED BY  
**48%**  
IN 3.5 YEARS

## AllStar™: a state-of-the-art insulin pen for patients in emerging markets



To meet the needs of patients in emerging markets and improve access to innovative yet affordable devices, in 2012, Sanofi India Limited launched the first re-usable insulin pen manufactured at one of our manufacturing sites in India.

The AllStar™ re-usable pen is indicated for patients already using products in Sanofi's insulin portfolio as well as those who are starting to take insulin for the first time. It supports physicians in early initiation of insulin therapy for better glycemic control and enhanced therapeutic outcomes. Featuring a sleek design and easy-to-use yet sophisticated technology, AllStar™ combines convenience and affordability. It conforms to the International Organization for Standardization (ISO) standards and is equipped with new features.

Close to 63 million people in India have diabetes. This made-in-India re-usable insulin pen is the result of three years of exemplary teamwork to develop a device to match needs in India as well as other emerging markets where we plan to make AllStar™ available.

Sanofi has long been at the forefront of diabetes research and development. The AllStar™ pen demonstrates our focus on innovation in diabetes and our commitment to help provide access to healthcare in emerging markets by taking a regionalized approach to finding solutions that are adapted to local market needs.

\* Santé mentale: (WHO source, media center factsheet no 220, September 2010 – Epilepsie) (WHO source, media center factsheet no 999, October 2012).

## ACCESS TO HEALTHCARE

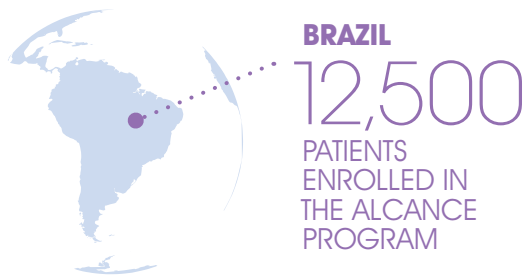
**The Alcance program in Brazil**

The Alcance program aims to provide educational services and expand access to diabetes treatment primarily for the middle/low tier of patients, which make up 29.3% and 14% of Brazil's population, respectively. The initiative was developed to address a situation where access to medicines is directly tied to purchasing power, since Brazil is an out-of-pocket market and patients have to cover their own treatment expenses.

Through an in-depth analysis of the local diabetes market, we determined that a one-off discount on our products does not increase patients' access, as the total cost of diabetes treatment would still remain too high to bear individually. Patients require more than just insulin; their medical expenses may also include monitoring devices, strips, needles, anti-diabetic oral drugs and other medicines to control cholesterol and hypertension. Designed to meet this challenge, Alcance addresses the full range of products and services for diabetes therapy.

The Alcance program was developed through collaboration between Sanofi and a chain of accredited pharmacies and other companies, which offer special conditions for a broad range of products and services. This program was launched nationwide in November 2010 and currently has more than 12,500 active patients enrolled, representing almost 50% of all new patients starting on Lantus in 2012.

Much more than a tiered pricing program, Alcance illustrates the importance of taking into account the full treatment environment and establishing solid relationships with multiple stakeholders to help provide sustainable and long-term access to healthcare for patients.

**Giving Life a Chance program for breast cancer patients in Russia****RUSSIA**

**GIVING LIFE A CHANCE  
RECOGNIZED AS THE  
BEST SOCIAL PROJECT  
IN RUSSIA**

Of all cancers affecting women in Russia, breast cancer has the highest mortality rate. The survival rate of women with breast cancer is far below that 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 takes part in awareness campaigns and support programs for breast cancer patients in cooperation with leading Russian cancer institutes and clinics. Traditional communication channels and social media are used to spread the word, with high-impact messages such as "Each day in Russia, 47 children lose their mothers to breast cancer."

Sanofi is a member of a non-profit partnership that cooperates with Avon's charity walk. At the Together Against Breast Cancer event in May 2012, 700 women were screened and 120 were identified as requiring further examinations. Also in 2012, over 3,000 breast cancer patients from 67 Russian cities gained access to quality treatment meeting international standards. The project's goal for 2013 is to increase the number of newly treated patients to 3,500.

In December 2012, the Giving Life a Chance campaign was recognized as the best social project in Russia by two Russian ministries and several international organizations.



## ACCESS TO HEALTHCARE

**Sanofi Patient Connection™ in the U.S.**

Sanofi U.S. has embarked on a cutting edge program that includes not only reimbursement support and patient assistance, but also provides patients with access to additional services and resources. An integration of several once separate programs, Sanofi Patient Connection™ was launched in January 2012 to provide tailored access solutions to patients. It also gives patients the ability to find alternative resources to help them better deal with their illnesses. In 2012, the new platform assisted over 203,000 patients and supported over 71,000 healthcare providers.

Sanofi Patient Connection™ provides three main types of patient support:

- *Reimbursement Connection* – helps patients to determine if they qualify for a benefit with reimbursement services.
- *Patient Assistance Connection* – through company product donations to the Sanofi Foundation for North America, provides free prescription drugs to patients who meet established eligibility criteria.
- *Resource Connection* – helping patients to identify additional resources and support such as co-pay assistance, support groups, transportation, etc.

Sanofi Patient Connection™ currently supports over 25 products across all Sanofi businesses in the U.S.

**OVER  
U.S. \$300 MILLION**  
TOTAL INVESTMENT IN  
THE SANOFI PATIENT  
CONNECTION™  
PROGRAM

**Related content online**

In this video, Sue describes how she benefitted from the U.S. Patient Connection program.



**UNITED STATES**  
OVER  
**203,000**  
PATIENTS  
ASSISTED IN 2012

# INNOVATION

## CHALLENGE

The pharmaceutical industry is one of the business sectors most impacted by rapid changes in an ever more global world – with new demographic trends, growing healthcare reforms, and increasing demands for a strong discovery and R&D platform. Sanofi relies on innovation as the best way to address these many areas of change while continuing to develop safe and effective medicines designed to improve the lives of patients everywhere.

## STRATEGIC APPROACH

Innovation is a powerful way to reach our goal of providing patients with solutions for unmet therapeutic needs. In addition to driving drug discovery and development, it brings numerous benefits to Sanofi so that we can:

- take advantage of recent advances in medical and scientific research through collaborations between our own R&D teams, top-notch scientists and cutting-edge research organizations;
- optimize skills within networks of scientific excellence;
- develop new solutions for patients – for example, to improve adherence to treatment regimens;
- seize opportunities to promote health awareness and educate the public about diseases and conditions; and
- adjust to new reimbursement policies that impact the affordability of medicines for patients.

At the same time, innovation is essential to other aspects of Sanofi's business, such as finding ways to continuously improve our manufacturing processes, adapt to the needs of emerging markets, and better serve an aging population of individuals who are living longer and healthier lives. We seek to address the needs of our customers in emerging countries as well as more mature markets.

## Organizing innovation

To channel the impetus provided by innovation into an organized approach, we have dedicated management structures within R&D, Industrial Affairs and our commercial operations. Across all our management structures, our goal is to provide solutions for patients with a benefit demonstrated through outcomes and to go beyond simply delivering products.

In R&D, our "open innovation" strategy is based on business decentralization. Our drivers are medical value, operational effectiveness and top-quality science as we concentrate on:

- creating an efficient global R&D organization by maximizing synergies and convergence around a hub model, leveraging economies of scale, and improving our R&D cost structure;
- focusing on high-value projects, including through early-stage portfolio prioritization based on medical value and translational medicine, which aims to match compounds to the patients they will benefit most by putting human disease at the forefront of drug discovery; and

## INNOVATION

- establishing new models of innovation outside the Company by optimizing external opportunities and partnerships while developing creative and adapted models with collaborators across the healthcare ecosystem.

Sanofi's Industrial Development and Innovation Department acts as interface between R&D and industrial processes to improve the dynamics of product life cycle management thanks to process and technology innovations for medicines and medical devices.

Our patient-centered solution network designs initiatives that encourage the development of solutions to improve patients' day-to-day lives and the care they receive.

## ACHIEVEMENTS

## In R&amp;D

## In our portfolio

**64 New Molecular Entity (NME) projects and vaccine candidates** in clinical development

**17 NME projects or vaccine candidates** are in Phase III studies or have been submitted to the health authorities for potential marketing approval

**31 NME projects** are being developed in collaborations

## SANOFI'S EXPENSES IN R&amp;D AMOUNTED TO

**€4,922 MILLION** IN 2012  
THE R&D/SALES RATIO WAS **14.1%** IN 2012

## Key regulatory achievements in the last 12 months as of February 2013

Nine regulatory approvals	Six new drugs and vaccines submitted
Zaltrap® (U.S. and EU) <sup>1</sup>	Aubagio® (EU)
Aubagio® (U.S.)	Lyxumia® (U.S.) <sup>2</sup>
Lyxumia® (EU) <sup>2</sup>	Lemtrada™ (U.S. and EU)
AUVI-Q™ (U.S.)	Fluzone® Quadrivalent IM (U.S.)
Kynamro™ (U.S.) <sup>3</sup>	Hexavalent paediatric vaccine (EU)
IMOVAX® POLIO (JP)	
Lantus® paediatric use (EU)	
Plavix® for PAD and STEMI (JP)	

<sup>1</sup> Zaltrap® was approved in EU on Feb 1, 2013.

<sup>2</sup> Lyxumia® was approved in EU on Feb 1, 2013 and FDA file acceptance is expected in Q1 2013.

<sup>3</sup> Kynamro™ was approved in the U.S. on Jan 29, 2013.

Zaltrap® is developed in collaboration with Regeneron – Lyxumia® is in-licensed from Zealand Pharma.

Sanofi U.S. licensed the North American commercialization rights to AUVI-Q™ from Intelliject Inc.

Lemtrada™ is the registered trade name for alemtuzumab submitted to health authorities.



## INNOVATION

**In industrial affairs****Fostering a culture of innovation**

Sanofi's Industrial Affairs Innovation Awards celebrate our most promising projects each year. In 2012, the industrial activities of Genzyme and Merial joined the competition alongside Sanofi and Sanofi Pasteur. A total of 396 applications were received from teams in 36 countries. The jury selected the 30 best projects and one award winner was chosen in each of six categories: enhancing patient centricity, accurate industrial performance, improving our industrial efficiency, high-tech challenges, replicating good ideas, and entrepreneurship. Some examples of winning ideas included a project focused on reducing production time and boosting industrial agility; one aimed at optimizing the manufacturing processes of Lovenox®; and using dronedarone (Multaq® active ingredient) to tackle leishmaniasis. During the awards ceremony, posters were presented featuring the 30 short-listed projects. As a follow-up to the awards, Sanofi is organizing road shows in many countries, starting with Brazil, the U.S., and China in 2012. These events provide a forum to share good ideas and strengthen our industrial performance.

**Science and Technology Prize**

Sanofi received the Pierre Potier Science and Technology Prize in 2012 in the sustainability category. This award recognizes an innovative artemisinin production process that helps to preserve biodiversity. Artemisinin is an active ingredient in a Sanofi malaria drug.

**Related content online**

[Download center](#)

- Malaria factsheet

**Innovative solutions for the patient**

Sanofi's wide range of solutions for the patient has been designed to meet different needs:

- **Educating patients to better understand their disease**, such as a website for teenagers with Type 1 diabetes, [www.t1dstars.com](http://www.t1dstars.com).
- **Raising awareness about the importance of treatment and prevention**, such as an easy-to-use web-based solution assisting healthcare providers in improving vaccine compliance in the United States.
- **Increasing patient benefit through improved compliance and helping to ensure the proper use of medicines**, such as an application for smartphones and computers developed to support the proper use of Multaq®.
- **Bringing comfort and assurance to patients' daily lives**, such as AllStar™, a state-of-the-art reusable insulin pen that combines ease of use and affordability. AllStar™ was launched in October 2012 in India, and by the end of the year more than 8,000 patients had initiated insulin treatment with this device.
- **Developing sustainable collaborations with healthcare professionals**, such as the Care Companion for patients with breast, prostate and colorectal cancer. This personalized online tool empowers patient/physician interactions by streamlining communication and information between hospital teams, physicians and patients.

**Related content online**

[Download center](#)

- Innovative Solutions for Patients factsheet

**FOR THE FUTURE**

- Pursue our "open innovation" strategy in R&D with an emphasis on translational medicine and constantly seeking new sources of innovation.
- Continue to focus on developing innovative industrial processes designed to benefit both the patient and our economic performance.
- Motivate all our teams to adopt an innovation mindset to devise new solutions aimed at facilitating the everyday lives of patients and their families.

## INNOVATION

## HIGHLIGHTS

**An example of translational medicine: anti-PCSK9 monoclonal antibody in development**

The discovery of PCSK9 protein's involvement in hypercholesterolemia (an excess of cholesterol in the blood) perfectly illustrates the transfer of knowledge from the patient's bedside to the lab bench, leading to the development of a new treatment.

In 2003, a patient at Necker Hospital in Paris was diagnosed with severe hypercholesterolemia, and a genetic analysis revealed he had a hyperactive PCSK9 gene. The same year, in Dallas, Texas (U.S.), a genetic study of 300 patients with very low serum cholesterol levels showed a PCSK9 protein deficiency. PCSK9 was thus identified as a novel pathway to potentially achieve lower cholesterol levels.

Keeping cholesterol levels under control is one of the keys to preventing heart attacks and lowering the risk of cardiovascular disease, a leading cause of death worldwide.

Sanofi's anti-PCSK9 antibody, Alirocumab, may address an unmet medical need among certain people with high cholesterol since, despite available therapies, many patients are still not able to reduce their cholesterol to target levels. The anti-PCSK9 monoclonal antibody under development, which utilizes Regeneron's VelocImmune® innovative technology, is a novel, fully human, subcutaneously administered monoclonal antibody. Sanofi has set up a Phase 3 clinical program called ODYSSEY that has enrolled 22,000 patients receiving anti-PCSK9 antibody.

**A doubly smart label added to insulin product packaging**

Sanofi has added a label (QR code) on packaging of our Lantus® and Apidra® insulin products, which leads patients and caregivers to an educational video showing how to inject insulin using the Solostar® pen. After scanning the code via a smartphone (eliminating the need to type a URL into a computer or call a number), patients reach the video presentation of injection instructions. The video gives visual and audio, step-by-step instructions in Arabic, English, Hebrew, and Russian.

This high-tech solution, provided free of charge, enables patients to easily acquire knowledge designed to help them to use our product safely and confidently. We believe this new label may generate cost savings because we anticipate that fewer pens will be damaged due to inappropriate use, and patients will be more relaxed and confident about using our insulin Solostar® pen.

**Connecting nurses and a new innovation award**

Nurses today are the backbone of most healthcare systems and they are highly trained to provide the best possible care for their patients. In 2011, Sanofi joined the Connecting Nurses collaboration with four of the leading international nurse associations to provide a forum for nurses from around the world to share their ideas, advice, and innovations. The platform allows nurses to access, download and adapt information about patient support, education and disease awareness, and best practices. Since its inception, the website has grown in popularity, with over 40,000 connections by users in 130 countries.

Patients benefit from nurses' patient education skills and the time they devote to sharing knowledge about diseases and treatments. The Connecting Nurses community also shares useful education

web links with their patients through the Information Shareapy platform, a professional resource community coordinated in collaboration with nursing organizations.

Building on this success, Sanofi created the first Nurse Practice Innovation Award, receiving over 100 submissions in 2012. An independent jury of nurses selected the 20 most promising initiatives for patients and nurses. Some of the winning ideas included home care nursing, care for orphans with HIV in Africa, podcasts on disease awareness and tele-health programs for the elderly in Asia, programs on advanced nurse practice in Europe, and projects to support pregnant teenagers in the U.S. The Connecting Nurses project received the Sanofi CSR Patient Award in 2012.

## PATIENT SAFETY – Drug safety monitoring

### CHALLENGE

All medicines have potential risks as well as benefits. As a healthcare company, it is our responsibility to identify, evaluate, and mitigate safety concerns as well as to guarantee that the overall benefits of our products outweigh the risks. In addition, Sanofi teams in charge of drug safety monitoring seek to optimize the benefit/risk profile of our medicines and vaccines during their entire life cycle.

### STRATEGIC APPROACH

The Sanofi Global Pharmacovigilance & Epidemiology (GPE) Department is our center of medical and clinical expertise for drug safety monitoring. It detects, evaluates, and monitors risks related to the use of all products from Sanofi Pharma, Genzyme, Fovea, and Sanofi Pasteur, as well as products from our generic medicines and consumer health (OTC) divisions. This responsibility never ceases for a product's full life cycle, from development to marketing. The GPE works closely with healthcare professionals, health authorities, and the patient community to reduce safety risks and prevent adverse events for patients. It also makes recommendations designed to ensure the safest possible use of medicines.

The GPE moreover coordinates the flow of drug safety information and facilitates decision making, from signal detection – regardless of the source – to risk prevention. This allows us to provide customer-oriented outputs and solutions.

Sanofi's drug safety monitoring approach is based on:

- meeting the most demanding regulatory and legal requirements, as well as companywide standards;
- performing systematic and continuous medical analyses called "signal detection" for marketed products as well as products under development to optimize product safety;
- employee training and awareness initiatives in medical safety analysis and benefit/risk optimization;
- a product alert management process, ensuring that any alert challenging the benefit/risk of a medical product is taken into consideration and managed appropriately. If needed, a crisis management process is initiated under the leadership of the CEO; and
- performing in-house audits to monitor compliance with our operational standards and policies for all Sanofi employees, subcontractors and partners working in drug safety monitoring.

## PATIENT SAFETY – Drug safety monitoring

**The purpose of drug safety monitoring is threefold:**

To detect, evaluate, and monitor risks related to the use of all Sanofi medicines, devices and vaccines

To make recommendations for the safest possible use of medicines, devices, and vaccines

To seek and implement measures designed to reduce safety risks and prevent adverse events

**These efforts make it possible to:**

Optimize the risk/benefit ratio of drug, device or vaccine use

Determine the best treatment for a specific patient

Inform physicians about potential risks associated with a product

Propose adequate market conditions for a product

**ACHIEVEMENTS****2012 milestones**

Continuous enhancement of ongoing benefit/risk analysis of company products with the introduction of new periodic safety reports that, in addition to summarizing safety data, provide a critical analysis of the benefit/risk profile of a medicinal product.

Finalization of the integration of safety data for Zentiva and Fovea in Sanofi's global safety database; data for Sanofi Pasteur and Genzyme will be fully integrated in 2013.

Successful launch of the yearly global pharmacovigilance awareness campaign across all affiliates: currently, 45 of 84 affiliates have finalized materials for use at local level.

Enhancement of our processes for the integration of safety data: in line with Sanofi's increased presence in the social media, we strengthened processes designed to recognize safety data from social media, transmit it to the Pharmacovigilance Department, and integrate it into our safety surveillance systems.

## PATIENT SAFETY – Drug safety monitoring

## HIGHLIGHTS

## Alignment with new European pharmaceutical legislation

The new European pharmaceutical legislation defines the benefit/risk balance of a medicinal product as the evaluation of the product's positive therapeutic effects in relation to any risk relating to its quality, safety, or efficacy as regards patients' health or public health.

To meet the deliverables imposed by the new legislation and translate the requirements into smart and sustainable processes within our organization, Sanofi set up a cross-functional expert task force to perform an in-depth review of all drug safety-related processes (pharmacovigilance, regulatory, medical affairs, and quality). This task force implemented the integration of the main outcomes of the new legislation, including:

- the development of sound risk management strategies during the entire life cycle of all products;
- an enhanced safety governance model; and
- improved interactions with the Pharmacovigilance Risk Assessment Committee of European Medicines Agency.

## Developing drug monitoring capacity in malaria-endemic countries

Drug safety and efficacy monitoring systems are limited in most African countries. In close collaboration with national ministries of health, Sanofi and the Drugs for Neglected Diseases initiative (DNDi) have set up a field-monitoring program to gather quality information about the safety and efficacy of our anti-malarial combination, ASAQ Winthrop. This innovative program, supported by Medicines for Malaria Venture, was formalized as a risk management plan and submitted to the World Health Organization. With more than 20,000 malaria treatment episodes expected to be recorded in more than 12 countries, this is the most ambitious drug monitoring program ever launched in Africa. Through the involvement of numerous partners, the program will not only provide high-quality information, but it will also contribute to developing local expertise on pharmacovigilance in line with the needs and resources of African countries.

## Protecting patients: a harmonized process for managing product alerts

Ensuring the safety of those who use our products is an absolute priority for Sanofi. As part of meeting this priority, the Group may issue a product alert whenever a medical, safety, quality, or regulatory issue related to a Sanofi product poses a substantial risk, or even a potential risk, to patients, consumers, or clinical trial participants.

The Group recently introduced an improved product alert system based on enhanced coordination and transparency. Today a single, standardized process is followed to manage any product alert, regardless of its nature or cause. From start to closure, a dedicated operational team with relevant experience and expertise is in charge of overseeing each alert.

A Global Quality Directive outlining the process that all product alerts must follow is applied across all Sanofi entities, for all personnel and products. The product alert system is managed at the corporate level by a coordination team and a decision-making committee. Sanofi's Chief Quality Officer and Chief Medical Officer introduced this standardized process to simplify and facilitate the management of all product alerts, with the goal of continuously improving patient safety.





## PATIENT SAFETY – Product quality

### CHALLENGE

As we seek to satisfy global demand for Sanofi's medicines and vaccines, we never lose sight of the need to ensure patients' safety by guaranteeing the quality of our products.

To meet this challenge, we rely on our drug safety monitoring and quality teams and we comply with the industry standards. In addition, we take steps to maintain business continuity designed to help our supply chain continue to deliver our medicines and vaccines to the market at all times, without interruption. To reduce the risk of fraud and combat the phenomenon of counterfeit drugs, we make use of cutting-edge technology designed to safeguard the integrity and traceability of our products.

### STRATEGIC APPROACH

Sanofi is committed to providing safe and effective products worldwide that are developed, manufactured, distributed, and marketed in compliance with statutory and regulatory requirements and our corporate values. To ensure patients' safety and satisfy stakeholders' expectations, we uphold the same standards of quality across the globe.

Our commitment to patient safety and product quality appears in Sanofi's Global Quality Policy, which has been translated into 11 languages and distributed to employees in all countries where we operate. We implement guidelines designed to ensure quality, safety, and continuous improvement at each phase of the product life cycle – from development to marketing – as well as for the services associated with our products.

Our quality systems are organized to encompass all processes related to the development, manufacturing, and distribution of our products, including third parties. From the earliest phases of research, our quality systems are followed in compliance with our internal rules of Good Research Practices.

This approach applies to our entire product portfolio: prescription medicines, over-the-counter products, animal health products, vaccines, and generics.

To keep pace with the pharmaceutical industry's increasingly regulated environment, Sanofi complies with Good Manufacturing Practices and Good Distribution Practices. Each of our divisions monitors the effectiveness of our quality systems by setting objectives and developing performance indicators. Reviews are carried out on a regular basis, with the participation of senior management and internal partners. They serve a dual purpose: ensuring continuous improvement of our processes and the prevention of potential incidents.

### Quality audits and preparedness for inspections by regulatory authorities

Sanofi created a Global Quality Audit program for periodic self-assessments by all our internal and external pharmaceutical sites. Our goal is to instill a sustainable compliance culture and adherence to all regulatory requirements. Preparedness for inspections by regulatory authorities is one of the pillars of our quality system.

#### Related content online

##### [Download center](#)

- Continuity of Activities and Supplies factsheet
- Fighting Corruption factsheet
- Anti-Bribery Policy



Injectables production at Suzano's production site – Brazil.

## PATIENT SAFETY – Product quality

### Quality risk management

Quality risk management contributes to Sanofi's business continuity by ensuring proactive management of any quality-related risks. In 2012, Sanofi initiated a company-wide process to manage alerts related to product quality or safety. In-house teams with extensive experience and expertise oversee each alert. Starting in 2013, a dedicated team will coordinate the management of emerging risks related to quality. Our quality risk management organization facilitates better decision-making and contributes to increase public authorities' confidence in our ability to address potential issues.

### Quality compliance among our suppliers

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 and products manufactured by our suppliers, as well as the services provided by third parties. All materials, equipment, and services (including transport) that may have an impact on product quality are purchased from approved sources according to predefined criteria, and they are further tested upon reception at our plants as appropriate. We also perform audits of our suppliers on a regular basis.

*The quality system makes it possible to ensure strict application worldwide of the Good Manufacturing Practices set forth by legislation and with Sanofi quality assurance directives, and to ensure that subcontractors meet equivalent levels of quality.*

*Implementation of the quality system involves the following steps:*

- *for each product batch, quality controls are performed and documented at every step of production, prior to release;*
- *each year, product quality reviews are conducted for each product on the market in order to assess the validity of the manufacturing process and ensure continuous improvement;*
- *a system for monitoring product quality defects reported by patients and healthcare professionals allows for a quick analysis of complaints and the implementation of corrective and preventive actions; and*
- *an audit strategy has been developed and put in place for operations involved in the production of Group products, related systems and any subcontractors that may be involved in these types of operations.\**

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, **which addresses the French Grenelle II law requirement**. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## PATIENT SAFETY – Product quality

## ACHIEVEMENTS

## Key quality figures

In 2012, Sanofi continued to strengthen our manufacturing operations and quality systems in line with health authority requirements. As part of our goal to continuously instill a sustainable compliance culture in line with regulatory requirements and to prepare for regulatory inspections, we performed 238 internal audits.

In addition, over 460 external audits were conducted to monitor the quality of ingredients manufactured by our suppliers and services provided by subcontractors at every step of the supply chain.

	2012
<b>Number of regulatory inspections</b>	<b>262<sup>1</sup></b>
Pharmacovigilance	11
Clinical research (Good Clinical Practices)	77
Pre-clinical research (Good Laboratory Practices)	3
Manufacturing and distribution sites (Good Manufacturing Practices/Good Development Practices)	171
<b>Number of inspections resulting in regulatory action from health authorities</b>	<b>4<sup>2</sup></b>
<b>Number of audits of manufacturers or suppliers</b>	<b>466</b>
Suppliers of active pharmaceutical ingredients (API)	242 <sup>3</sup>
Contract Manufacturing Organization (CMO)	197 <sup>4</sup>
Contract Research Organization (CRO) and Clinical Medical Quality Operations (CMQO)	27 <sup>5</sup>
<b>Number of internal audits</b>	<b>238</b>
<b>Number of class 1 recalls<sup>7</sup></b>	<b>1<sup>6</sup></b>
<b>Number of class 2 recalls<sup>8</sup></b>	<b>21</b>
<b>% of customer complaints treated in due time (45 calendar days maximum to close a complaint)<sup>9</sup>:</b>	<b>63.6%</b>

1 Nearly 50% of inspections took place in Europe and 30% in Asia Pacific and Japan.

2 On July 12, 2012, Sanofi Pasteur received a warning letter from the FDA following routine inspections conducted during 2012 at its facilities in Toronto (Canada) and Marcy l'Etoile (France). The warning letter contains observations about products intended for the U.S. market, and the premises in which they are produced. Sanofi Pasteur takes these observations extremely seriously, and is working actively with the FDA to implement a series of immediate and ongoing measures to address the issues raised in the warning letter and to further strengthen its production tools and quality systems.

A global Quality Enhancement Program (QEP) was established to ensure a systematic approach to developing remediation and to align efforts by Sanofi Pasteur to achieve sustainable compliance and quality systems improvement. The QEP is managed as a global transversal initiative.

3 Including 120 audits in Asia Pacific and Japan and 96 audits in Europe, where most of our active pharmaceutical ingredient (API) suppliers are located.

4 Including 121 audits in Europe, where most of our CMOs are located.

5 Ten audits in Asia Pacific and Japan, ten audits in North America, six audits in Europe and one audit in the Africa Middle East region\*.

6 In June 2012, Sanofi Pasteur voluntarily recalled the Bacille Calmette-Guérin (BCG) vaccine produced in its Canadian facility due to manufacturing issues. This withdrawal is expected to last several months while the renovation of the building is completed.

7 Class 1 recall: defects that are potentially life threatening or could cause risk to health – EMA definition.

8 Class 2 recall: defects that could cause illness or mistreatment, but are not Class 1 – EMA definition.

9 On the scope of Sanofi Pharma and Genzyme.

\* **Definition of regions**

**Europe:** Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Republic of Moldova.

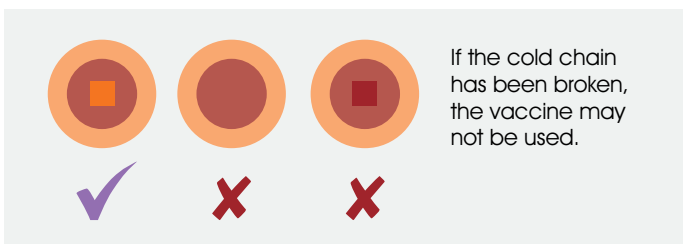
**North America:** United States, Canada, Puerto Rico, Bermuda.

## PATIENT SAFETY – Product quality

## HIGHLIGHTS

## Temperature monitor helps to guarantee the quality of vaccines

The HEATmarker® project was developed by Sanofi's South African affiliate to provide enhanced security for customers in the private vaccine market. Biological vaccines, such as the flu vaccine, are heat-sensitive; from the time of manufacture to the moment they are used, they must constantly be stored and handled at temperatures of 2 to 8°C.



The HEATmarker® is a miniaturized, self-adhesive temperature indicator affixed to vaccine packaging at the time of manufacture. It provides an easy tool to identify whether a vaccine has been exposed to heat damage. Without such a system, consumers have no means of ascertaining whether the vaccine they will receive has been properly stored and handled before it is administered.

The cold chain must be respected at all times to preserve the quality of biological vaccines. If it is broken, the HEATmarker® indicator changes color, becoming darker.

This monitoring tool is particularly valuable in remote areas and other settings where the cold chain is most vulnerable.

As a leading vaccine manufacturer at the cutting edge of vaccine quality and safety, Sanofi Pasteur is currently working on the deployment of the HEATmarker® to other vaccines to build trust among customers who are increasingly safety conscious.

 **Related content online**

[Download center](#)

• Quality Management System factsheet

## Data Matrix code: a cutting-edge tool designed to ensure traceability and product quality

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. According to the EU Directive on falsified medicines, the code is designed to contain a unique serial number on each box (2017). Data Matrix codes will be read when drugs are dispensed. Not only are they extremely valuable to ensure traceability, they also enable the automatic detection of falsified or expired products and facilitate batch recalls.

Sanofi actively supports the 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, mass serialization, and systematic controls at the time of dispensing by pharmacies and hospitals.

In Turkey, Sanofi has used a Data Matrix code on all secondary packaging since January 2010, in line with Turkish laws. In addition, an aggregation process of all logistic units (packs, bundles, cases, and pallets) has been implemented in Sanofi Turkish's production and distribution sites to allow additional product verification and traceability by wholesalers.

In 2013, Sanofi will continue to expand its policy of identifying our medicines based on Data Matrix technology and industry-recommended international standards, in compliance with applicable national legislation and regulation in the countries where we operate.



IN THIS SECTION

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**85,822**

EMPLOYEES TRAINED IN THE CODE OF ETHICS

OVER **350**

SUPPLIERS SELECTED TO UNDERGO CSR EVALUATIONS

**271**

AUDITS OF CLINICAL TRIAL ACTIVITIES, RELATED SYSTEMS, AND SUPPLIERS

Amy Niambo, Director Business Development at Sanofi, Dakar.

# ETHICS

We are committed to acting ethically and responsibly in all our activities, from R&D to production and marketing. Respecting the rules of ethics in relation to Sanofi employees, patients, customers, suppliers, and other stakeholders is one of the pillars of our CSR approach.



# ETHICS IN R&D – Clinical trials

## CHALLENGE

Respect for ethics in clinical trials, one of Sanofi's primary focuses, is based on providing solid and reliable data, ensuring the welfare of trial participants, and helping build trust in the pharmaceutical industry.

We are committed to conducting exemplary clinical trials worldwide by applying the most stringent quality standards and making a particular effort to protect trial subjects who may be vulnerable for any reason.

## STRATEGIC APPROACH

Clinical trials are essential to ensure that new treatments are effective and well tolerated by patients. Health authorities require such studies as a mandatory part of the approval process for any new drug or medicinal product. They also may be carried out after the marketing of drugs, in particular for the development of new indications.

### Guaranteeing ethics in clinical trials

#### Independent ethics committee review

Information about a clinical trial is submitted on an ongoing basis to local health authorities and an independent ethics committee (at least one per country where the trial is conducted), which carefully examines the trial protocol and procedures. Sanofi will only initiate clinical trials that have received a favorable assessment by the ethics committee and by health authorities. The ethics committee monitors the trial on a regular basis to ensure that participants' safety and welfare are protected. In addition, this committee, trial investigators, and participants are kept informed of any significant study-related event or issues that arise during the course of the trial. In countries without ethics committees, a French committee that includes stakeholders from the country in question must review the trial protocol and procedures before Sanofi initiates the trial.

#### Free and informed consent

Regardless of a trial's objective, it must be designed to protect the safety of participating subjects and guarantee that they give their consent based on clear, complete information that is written in an understandable, non-technical style. Sanofi assures that all subjects (or their legal representatives) enrolled in any clinical trial we conduct have given their free and informed consent to participate in the trial. Such consent must be obtained prior to any procedure or change in the procedure required by the study protocol and before any data is collected.

#### Related content online

##### [Download center](#)

- Laboratory Animals factsheet
- Sanofi Position on Biodiversity and Biopiracy factsheet
- Clinical Trials FAQs
- Clinical Trials factsheet

## ETHICS IN R&amp;D – Clinical trials

**Compliance with international standards**

Our worldwide approach to clinical research helps make it possible for us to address a wide variety of medical conditions. All our clinical trials are conducted with the aim of collecting relevant and reliable data according to strict international standards and local legislation. Everywhere in the world, we are subject to inspections by the health authorities, and we perform internal audits of trials to ensure compliance with rules of ethics and legislation. Employees working on clinical trials receive training on a regular basis about adhering to international standards and regulations.

**Internal audits**

Also on a worldwide basis, we conduct internal audits of our clinical trials, associated systems and subcontractors to ensure continuous improvement and compliance with our quality standards. Another factor in our audit strategy is readiness in the event of an inspection by health authorities. We determine our audit program based on an evaluation of potential risks associated with clinical research activities.

Within the scope of worldwide trials, we may outsource clinical operations to clinical research organizations (CRO), whose compliance with Good Clinical Practices is overseen and monitored by our own teams. In the event of non-compliance, we rapidly notify the relevant managers, regulatory authorities and ethics committees, as appropriate, and we participate in related risk mitigation plans when necessary.

**Clinical trials in resource-poor settings**

When we conduct clinical trials in resource-poor settings, we assess the vulnerability of subjects prior to their enrollment, paying particular attention to ethical issues. Regardless of the country where studies are conducted, Sanofi provides training to local healthcare professionals in international standards and regulations, new technology, the use of new medicines, etc. We seek to ensure that infrastructure established for a clinical study will bring lasting benefits to all members of the patient and healthcare community, whether or not they take part in the trial.

**Addressing the risk of clinical investigator misconduct**

To limit the risk of potential misconduct by a clinical investigator, we utilize central data surveillance and on-site trial site monitoring, which allow early detection of signals that indicate potential deviations so that we can take prompt corrective and preventive actions. As a result, we have set up systems to detect, prioritize, assess, and mitigate potential risks caused by deviations.

In the event of a serious deviation (e.g., data fabrication, scientific misconduct or serious non-compliance at investigator sites), various steps may be taken, depending on the severity of the situation. They may include an in-depth investigation by a cross-disciplinary panel or termination of the trial for that particular investigator site, and notification of the ethics committees and the health authorities.

**Transparency**

We believe that patients, healthcare professionals and other stakeholders have a legitimate interest in clinical trials sponsored by Sanofi. We are committed to publicly disclosing appropriate information about our clinical study protocols and results ([clinicaltrials.gov](http://clinicaltrials.gov)).

**SANOFI BIOETHICS COMMITTEE**

The Sanofi Bioethics Committee, which was created in 2010, studies emerging ethical issues brought about by advances in biology and medicine. The committee develops our position on bioethics, which lays the foundation for our research strategy.



Sanofi assures that all subjects (or their legal representatives) enrolled in any clinical trial we conduct have given their free and informed consent to participate in the trial.

ETHICS IN R&D – Clinical trials

**ACHIEVEMENTS**

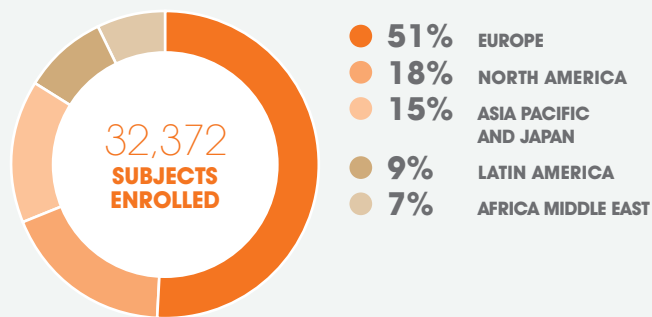
**Overview of 2012 clinical trials**

In 2012, we obtained the following approvals: Aubagio®, monotherapy for multiple sclerosis in the U.S. and Australia; Zaltrap® (collaboration agreement with Regeneron), second line treatment for metastatic colorectal cancer in the U.S.; Jevtana®, hormonal refractory treatment for metastatic cancer in South Africa, Trinidad, Tobago, and Ecuador.

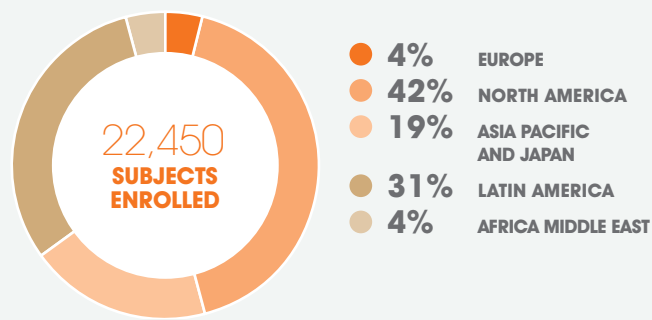
As part of the development of our dengue fever vaccine, many participants were enrolled in South America (31.5%) and Asia (19.2%). The number of participants in clinical studies has significantly increased within the scope of this program.

In the U.S., the proportion of participants (42%) may be explained by the flu immunization program conducted by Sanofi Pasteur at the request of the American government. Patients were also recruited for the Clostridium difficile toxoid vaccine research program, as healthcare associated infections are becoming pandemic in the U.S. (as is true in many other countries). In Europe, vaccine campaigns are organized under the leadership of Sanofi Pasteur MSD, a joint venture between Merck and Sanofi.

**Sanofi Pharma and Genzyme clinical trials 2012 by region**  
(number of subjects enrolled)<sup>1, 3</sup>



**Sanofi Pasteur vaccines clinical trials 2012 by region**  
(number of subjects enrolled)<sup>2, 3</sup>



**Monitoring clinical trial investigators for potential misconduct**

For Sanofi-sponsored clinical trials in 2012:

- 28 situations required in-depth investigations, of which 6 stemmed from allegations of scientific misconduct and/or malpractice;
- 22 of 28 cases were related to potential serious non-compliance;
- 5 of 28 cases led to agency notifications (fewer than in prior years); and
- 2 cases prompted involvement by Sanofi's Global Risk management committee; corrective and preventive actions were taken rapidly to avoid critical impact.

403  
**CLINICAL TRIALS**  
CONDUCTED IN 2012

**268** SANOFI PHARMA  
AND GENZYME

**135** SANOFI PASTEUR

<sup>1</sup> Geographic breakdown of subjects enrolled in clinical trials in 2012 for Sanofi Pharma and Genzyme: Phase I, II, III and Life Cycle Management trials to develop pharmaceuticals.

<sup>2</sup> Sanofi Pasteur (Vaccines): Phase I, II, III, IV and epidemiology exploratory trials to develop vaccines.

<sup>3</sup> Definition of regions

**Europe:** Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Republic of Moldova.  
**North America:** United States, Canada, Puerto Rico, Bermuda.

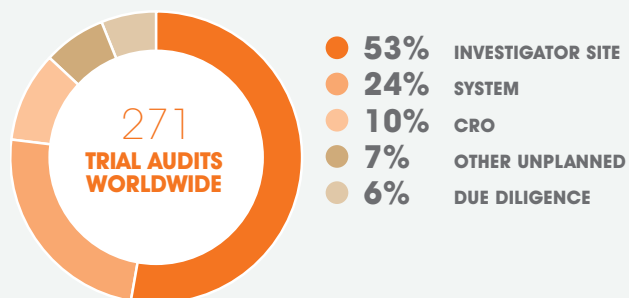
## ETHICS IN R&D – Clinical trials

### Overview of 2012 clinical trial audits

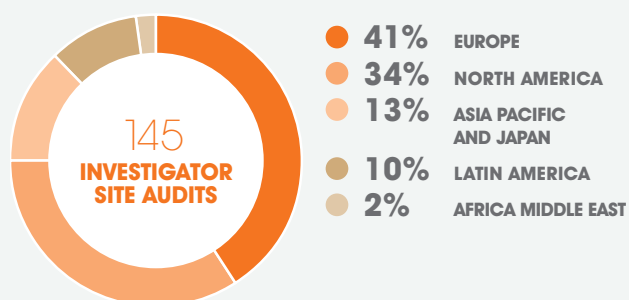
In 2012, Sanofi conducted 271 audits for our clinical trial activities and related systems and suppliers. The proportion of system and process audits (e.g., audits of country affiliate operations, research units or local and global pharmacovigilance units) remained stable at 24% compared to 2011, reflecting a strong focus on global quality standards and systems. A significant portion of audit resources (10%) was also devoted to oversight of subcontractors (CRO: Clinical Research Organizations).

In 2012, Sanofi conducted 145 investigator site audits. Approximately 25% took place in developing countries or emerging markets. This is in line with the geographic distribution of our clinical trials.

**2012 clinical trial audits by category<sup>1</sup>**  
(percent)



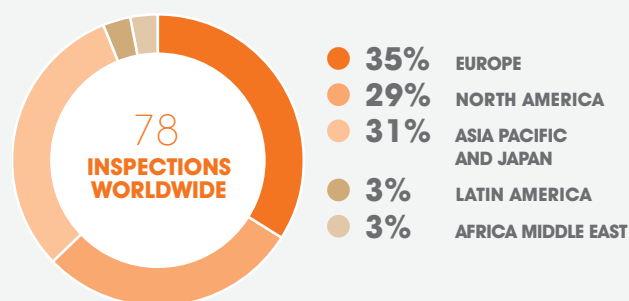
**2012 investigator site audits<sup>1</sup> by region<sup>2</sup>**  
(number of trial audits)



### Inspections<sup>1</sup>

On the perimeter of R&D/Pharma, Genzyme and Fovea (excluding Sanofi Pasteur), none of the inspections in 2012 had critical outcomes resulting in regulatory action from health authorities (such as a warning letter, significant disruption of product supply or registration submission, or impact on marketing authorization approval status).

**2012 inspections by regulatory health authorities<sup>1</sup> by region<sup>2</sup>**  
(number of inspections)



### FOR THE FUTURE

- Continue to ensure that we meet the highest ethical standards of conduct in our clinical trials.
- Participate in international debate on ethics in clinical trials and put forward suggestions and recommendations for ongoing progress and improved practices.

<sup>1</sup> Sanofi Pharma and Genzyme, excluding Sanofi Pasteur.

<sup>2</sup> Definition of regions

**Europe:** Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Republic of Moldova.  
**North America:** United States, Canada, Puerto Rico, Bermuda.

## ETHICS IN R&amp;D – Clinical trials

**HIGHLIGHTS****Helping people decide whether to take part in a clinical trial – initiatives in France and Brazil**

Clinical research trials of a drug or medical device require that participation be voluntary and based on informed consent. For volunteers, making this decision is not always easy.

As part of our ongoing efforts to develop more effective ways of communicating with patients, Sanofi's French Affiliate recently contributed to the production of a film for people who are considering whether to take part in a clinical trial.

This film provides information and support by explaining the rules of informed consent, trial-related information delivered orally, and the documents that must be delivered to patients. It looks at special cases (such as pediatric clinical trials), choices, restrictions, risks, and the importance of taking one's time to decide.

The film may be seen on a dedicated website created by the French National Center for the Management of Trials on Healthcare Products (Centre national de gestion des essais de santé). The [www.notre-recherche-clinique.fr](http://www.notre-recherche-clinique.fr) website was designed to inform and educate the public about clinical research.

**In Brazil, using a comic book format to explain free and informed consent**

Based on the worldwide initiative to make consent terms more informative and better adapted to the needs of the participants, Sanofi's Brazilian affiliate has developed a document about free and informed consent using a comic book format. By presenting information visually, this format is designed to help people understand what clinical studies involve, and to decide whether or not they wish to participate. The document was approved in 2012 by the Brazilian Ethics Authorities (Institutional Ethics Committee) and the National Committee of Ethics in Research (CONEP) and will be distributed to health centers in 2013.

**Related content online**

Learn more about informed consent in medical research, see the film (in French) [\*I consent, but to what?\*](#).



In Brazil, Sanofi has developed a comic book about free and informed consent.



# BUSINESS ETHICS – Responsible lobbying

## CHALLENGE

Lobbying practices are the focus of much debate in today's business and political world, with demands from the public for greater transparency. The public wants multinational companies like Sanofi to show that we take a responsible approach to lobbying. Concerns have been voiced about the pharmaceutical industry's ties with politicians, health authorities, medical experts, and other decision makers, feeding a growing climate of mistrust.

Sanofi participates in lobbying activities that aim to help protect the interests of patients and communities while preserving our reputation and the interests of our shareholders. In light of current events and public perception, we must be even more strongly committed to transparency and continue to implement strict rules to avoid corruption and conflicts of interest in our relations with third parties.

## STRATEGIC APPROACH

Because our business model is highly dependent on regulations and decisions by administrative and government authorities, Sanofi wishes to be involved in policy debate about public health issues that will affect our business, to the extent appropriate and consistent with applicable law.

The Group aims to establish sustainable interactions with legislators and other stakeholders to work toward the common goal of improving access to the best medicines and healthcare products while preserving incentives for research and innovation.

We lay the framework to interact responsibly and ethically with such stakeholders by establishing clear rules to avoid conflicts of interest, and ensuring they are enforced across our organization.

Sanofi's lobbying activities are conducted in compliance with the Group's Code of Ethics as well as lobbying and advocacy laws and regulations where we do business. We seek to act conservatively within the scope of legal requirements by additionally complying with the OECD's Ten Principles for Transparency and Integrity in Lobbying. Our recently adopted Responsible Lobbying Directive reflects our commitment to the UN Global Compact, which addresses responsible lobbying as a key component in the fight against corruption (Principle No 10).

To prevent corruption, we have established mandatory policies and training programs for employees.

*The corruption prevention program at Sanofi is based on two reference texts: the Code of Ethics, on which more than 85,000 employees have received training, and Sanofi's anti-corruption policy, which can be accessed by all employees via Sanofi's intranet, and sets out the Group's expectations regarding the prevention of and fight against corruption.\**

### Related content online

#### [Download center](#)

- Fighting Corruption factsheet
- Prevention Conflicts of Interest factsheet
- Anti-Competitive Behaviour factsheet
- Anti-Bribery Policy

### Related content in this report

p50 [Human Rights](#)

p44 [Code of Ethics](#)

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## BUSINESS ETHICS – Responsible lobbying

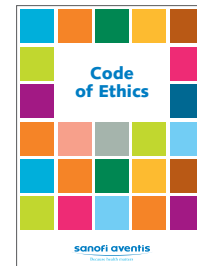
Only personnel who are registered lobbyists or who have received prior approval from our management may engage in lobbying activities on behalf of Sanofi. We ensure that employees who may be involved in lobbying have a sound understanding of the conduct to adopt by communicating about responsible lobbying, providing training, and maintaining an alert system. Our International Public Affairs Coordination (IPAC) also supports this goal.

To supplement the Responsible Lobbying Directive and Sanofi Code of Ethics, we have additional in-house standards that structure and set clear compliance rules for our interactions with key experts, health authorities, public officials, and other stakeholders who may potentially be involved in legislation and decision making in the health field.

*To increase vigilance about compliance with internal practices in the Group's Code of Ethics, in 2006, a warning system was established to facilitate reporting for internal controls in the areas of finance, accounting, banking, and fighting corruption and anti-competitive practices.\**

 **Related content online**
[Download center](#)

- Position on CSR Topics factsheet
- Code of Ethics



The Sanofi Code of Ethics is available in more than 30 languages.

**ACHIEVEMENTS****Hospitality rules updated in 2012**

Our internal rules on hospitality (i.e., travel and lodging) for healthcare professionals, which have been in force for several years, were updated in 2012. They comply with all international healthcare industry standards and codes (EFPIA, IFPMA, etc.).

Third parties with whom Sanofi does business or interacts must also be able to make objective and fair decisions. It is important that business courtesies never compromise, or even appear to compromise, this ability. For this reason, in 2012 our senior management approved a policy concerning invitations to third parties. It provides a framework for all employees worldwide by setting clear limits on invitations, especially regarding public or government officials.

**Taking part in drafting an industry guide to responsible lobbying**

At Sanofi's impetus, the French Pharmaceutical Companies Association (LEEM) created a working group to develop a Responsible Lobbying Guide in 2013, marking the first time an initiative of this type has been undertaken within the pharmaceutical industry.

**A new policy on grants, donations, and charitable contributions**

In 2012, our policy on grants, donations, and charitable contributions was endorsed by the Executive Compliance Committee. This policy establishes rules concerning any form of contribution to charitable or non-profit organizations on behalf of Sanofi. No grant, donation, or charitable contribution may be made for the benefit of individuals, whether directly or indirectly.

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## BUSINESS ETHICS – Responsible lobbying

**Sanofi's International Public Affairs Coordination (IPAC)**

IPAC's role is to build a strong, pro-active network to provide clear messages in today's turbulent international business environment. It enables the Group to speak with one voice. IPAC facilitates communication between Sanofi's offices and divisions, ensures alignment between local messaging and global activities, and contributes to promoting good practices. Its work also supports decision-making by senior management.

IPAC's achievements in 2012:

- contributing to the development of our Responsible Lobbying Policy;
- providing guidance to employees who participate in lobbying activities;
- interfacing with Sanofi's Global Compliance Organization to ensure ethical compliance; and
- optimizing interactions among all Sanofi public affairs offices worldwide and bringing together our different entities with a focus on key issues in business ethics.

**FOR THE FUTURE**

- Implement the communications strategy and develop employee training materials about the Responsible Lobbying Directive and related internal rules; make use of various tools such as e-training via the Group's intranet, Q&A, net meetings, etc.
- Continue to build in-house awareness about responsible lobbying best practices through Public Affairs representatives, Sanofi executives, and affiliates' communications teams.

85,000  
**EMPLOYEES**  
TRAINED IN THE  
CODE OF ETHICS

**HIGHLIGHTS****Sanofi's 2012 Responsible Lobbying Directive**

In 2012, the Sanofi Responsible Lobbying Directive was endorsed by our Executive Compliance Committee on behalf of the CEO. Designed to provide a global framework for all the Group's lobbying activities at the international, regional, federal, national and local levels, this directive complements the Sanofi Code of Ethics and our Anti-Bribery Policy. Together, these three documents constitute the foundation for ethical business conduct across the Group.

In addition to a foundation of compliance with lobbying and advocacy laws and applicable regulations where Sanofi operates, the key principles of the directive include, but are not limited to, standards of quality in information communicated by Sanofi and support for initiatives that aim to increase transparency in public and business life.

As a direct consequence of the new directive, we launched training sessions at a meeting of Sanofi Public Affairs – Europe held in Brussels in September 2012 and we organized regional campaigns to build awareness about responsible lobbying across the Group.

In line with our commitment to transparency and our responsible lobbying approach, Sanofi discloses information about major financial contributions to organizations.

**Related content online**

[Download center](#)

- Responsible Lobbying factsheet

## BUSINESS ETHICS – Responsible marketing

### CHALLENGE

We strongly believe that fair competition and transparent, ethical conduct are an essential part of patients' access to healthcare. We know that the promotional practices of our industry are increasingly in the public eye, with concerns being expressed about the completeness, fairness and reliability of the information that pharmaceutical firms provide to healthcare professionals and organizations. Concerns also have been expressed that medical sales representatives may seek to influence prescribers for the sole benefit of drug companies, to the detriment of patients and their safety.

We are committed to respecting the highest ethical standards in the promotion of our products. We also believe it is important to respond to calls from patient organizations and consumer advocacy groups for concerted action by pharmaceutical companies, governments and institutions to work together to ensure that the development of promotional materials, the distribution of samples, and the organization of conferences and physicians' meetings are all conducted in compliance with ethical standards.

### STRATEGIC APPROACH

As a global company, Sanofi adheres to the codes governing our industry in Europe (EFPIA), the United States (PhRMA), and worldwide (IFPMA). Sanofi's internal codes designed to oversee our 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, legislation, and regulations that may vary from one country to another.

In addition, the Sanofi Global Medical Affairs Department has established procedures and directives that comply with international standards:

- 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.; and
- for websites: Sanofi publishes many different kinds of information on numerous websites. Our Internet Committee has established a validation procedure for all websites developed by the Group.



A pharmacy in Buenos Aires, Argentina.

## BUSINESS ETHICS – Responsible marketing

To uphold ethical standards in all our marketing practices, we are committed to:

- providing ongoing training for medical sales representatives and evaluating pharmaceutical sales visit presentations;
- applying the highest ethical standards to promotional materials;
- providing up-to-date, accurate, objective and scientific information so that our sales representatives are knowledgeable in their interactions with healthcare professionals and consistent with applicable legal requirements and standards;
- distributing materials that allow the proper assessment of the quality of a product and 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; and
- conducting internal audits to ensure affiliates' compliance with the approval procedures for promotional materials, as well as adherence to Sanofi codes and applicable law concerning authorized promotional material content.

When evaluating pharmaceutical sales visit presentations, Sanofi is responsible for ensuring that the message conveyed by medical sales representatives is scientific, balanced, accurate, and not misleading in any way (including information about the proper use of the product and related tolerance data). The information provided by representatives must be fair and ethical, and it must comply with applicable statutory and regulatory requirements and in-house conduct standards concerning the promotion of medicines. As part of ongoing training, Sanofi consistently evaluates practices during pharmaceutical sales visits and the approaches taken by our medical sales representatives, including when they are assigned new products.



We are committed to ensuring that all promotional materials and product information are based on scientifically proven results.

**FOR THE FUTURE**

- Initiate implementation of improved medical information system for handling medical inquiries.
- Launch the new IS tool for review and approval of promotional materials.
- Revise operational quality standards on hospitality rules for healthcare professionals to include a global quality document concerning the organization of scientific events.



## BUSINESS ETHICS – Responsible marketing

**ACHIEVEMENTS****Responsible marketing 2012 milestones**

- Our internal directive on good practices with respect to scientific information and marketing was updated in line with the revised IFPMA Code of Practice (2012). The revised directive also takes into account the specific requirements of consumer healthcare promotion.
- As a consequence of the updated directive, new standard operating procedures were published for corporate-level approval of promotional materials and for the management of complaints in connection with Sanofi's promotional activities.
- Employee training initiatives included face-to-face sessions, such as a joint workshop medical information compliance/medical for diabetes teams, as well as the release of e-learning materials about educational and promotional items.
- A new policy and process for the management and validation of scientific publications was introduced to ensure a single, streamlined process across Sanofi's different entities.
- Since July 5, 2011, the scientific information activity of Sanofi in France has voluntarily sought and received ISO 9001 certification for the "dissemination of quality scientific information in response to healthcare professional requests."
- We also updated procedures to clarify the definition and requirements of Patient Support Programs and further describe how pharmacovigilance (PV) data is to be reported.
- For the management of medical inquiries, in 2012 Sanofi established a new medical information services model to be implemented in the coming years by all Group entities, including Sanofi Pasteur, Genzyme, etc. It will enhance the consistency of our responses to medical inquiries all over the world.

**Promotional materials: number of reviews prior to use in 2012**

Promotional/non-promotional materials	1,492
Digital projects	156 (161 in 2011)
Communication materials	178
Scientific events reviewed	19 scientific congresses and 8 events

**Audits of affiliates**

In 2012, Sanofi conducted 23 internal audits of our affiliates' compliance with the approval procedures for promotional materials (PM). Audit result analysis shows a downward trend in the number of observations related to promotional material management compared to the past two years. In 2012, there were no critical findings and 20% of findings were rated as major. Our primary action plans have focused on:

- PM review and approval process documentation;
- local quality documents explaining the PM management process; and
- management of company websites.

**Evaluating pharmaceutical sales visit presentations**

In France, a total of 1,113 oral presentations by medical sales representatives were evaluated in 2012 (compared to 1,090 in 2011), with the following results:

- compliant as is: 768, representing 69% of the presentations evaluated; and
- compliant with revisions: 345, representing 31% of the presentations evaluated.

Since the Group began validating presentations in 2006 in France, no presentations have received a "non-compliant" rating.

## BUSINESS ETHICS – Responsible marketing

**Monitoring promotional activities**

In 2012, as part of an internal productivity enhancement program, the Group introduced an optimized review and approval process worldwide that will be supported by a new IS tool, currently under development. All materials produced by any affiliate, worldwide, are and have been approved by the appropriate personnel at the affiliate prior to use.

**Interaction with healthcare professionals**

In 2012, our rules about hospitality to healthcare professionals were updated in line with our Transparency Policy. They establish limits for the organization of international events and set maximum cost levels. In our interactions with external experts, we adopted a new methodology and established fee grids. We also endorsed a new policy covering grants and partnerships with healthcare organizations and medical or scientific associations.

**HIGHLIGHTS****Updated rules for compensation of external experts**

Sanofi engages healthcare professionals for a variety of reasons – from leading training programs to providing expertise about how our products will be received by patients. In our dealings with healthcare professionals, we comply with applicable laws and regulations, including but not limited to anti-corruption laws.

Sanofi recently updated our hospitality rules governing interactions with healthcare professionals and developed a new quality document defining Sanofi's standards for engagement with external experts. These improvements are designed to ensure consistency across the Group in how we select and compensate healthcare professionals for their expertise and the service rendered.

Specifically with regard to compensation, and in anticipation of public disclosure of our financial interactions with healthcare professionals, the Group has adopted a harmonized methodology to be used by each country to determine local fee grids, which are available on the Sanofi intranet. The fee grids are designed to ensure that compensation is based on fair market value in the country where experts practice. Sanofi's hospitality rules also set limits on travel and lodging when healthcare professionals attend international events.

# HUMAN RIGHTS

## CHALLENGE

Pharmaceutical companies must address the human rights issues facing all businesses, such as labor conditions, fair compensation, employee safety, and the abolition of forced labor and child labor. At the same time, they must speak to issues that are specific to the pharmaceutical industry, such as improving access to healthcare, respecting rules of ethics during clinical trials, and monitoring the impact of pharmaceuticals in the environment.

For Sanofi, it is essential to ensure that respect for human rights is integrated into our business activity everywhere we operate, including in countries considered to be at risk of human rights violations.

## STRATEGIC APPROACH

We are convinced that the principles of human rights apply to people, to nations and, by extension, to businesses, and this is why ensuring respect for human rights is one of the cornerstones of our CSR strategy.

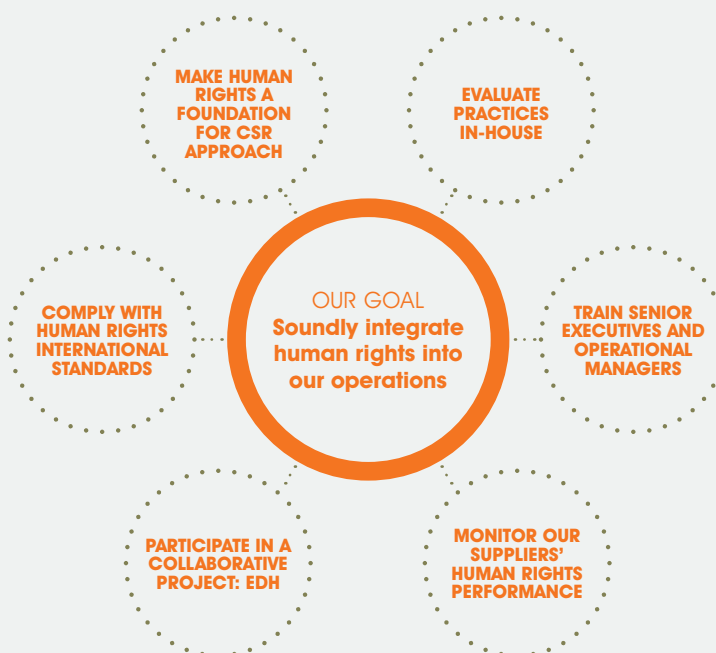
We furthermore wish to respond to the expectations of stakeholders, who expect companies to comply with international standards and provide transparent information about their human rights practices.

Our approach to human rights complies with the Guiding Principles on Business and Human Rights endorsed by the United Nations (UN) in 2011. In addition, in keeping with our commitment to the UN Global Compact, which we joined in 2003, each year Sanofi issues a Communication on Progress signed by our CEO, Christopher A. Viehbacher. This report to the UN Secretary-General outlines our human rights progress in the areas of human rights, labor rights, environmental protection, and fighting corruption.



Sanofi is a member of the UN Global Compact.

### Our approach to human rights



### Related content online

[Download center](#)

- Human Rights factsheet
- Protection of Personal Data factsheet
- Code of Ethics
- Sanofi Suppliers Code of Conduct
- Sanofi Social Charter

### Related content in this report

p13 [Access to healthcare](#)

p38 [Ethics in R&D clinical trials](#)

p81 [Pharmaceuticals in the environment](#)

## HUMAN RIGHTS

Three of our most fundamental references – Sanofi’s Code of Ethics, Suppliers’ Code of Conduct, and Social Charter – are designed to uphold the human rights principles defined in international standards. In our Code of Ethics, we support each person’s right to health, as defined in the International Covenant on Economic, Social and Cultural Rights.

Sanofi’s commitment to incorporating human rights principles into all our activities is part of a long-term learning process that creates value for the Group. In addition, it motivates employees, contributes to building the public’s trust, and makes us an attractive employer on the job market. Thanks to our participation in the debate on human rights and our pro-active initiatives to raise employee awareness, Sanofi is one of the leaders in this field.

We have adopted an ambitious and holistic approach based on initiatives to progress towards a single goal: to ensure that human rights are soundly integrated throughout all the Group’s operations.

### Self-assessment of internal practices

We encourage and enable the Group’s different functions to evaluate the impact of their own activities, with a particular focus on identifying any potential human rights concerns.

At the corporate level, we use an internationally recognized matrix, developed by the Business Leaders Initiative for Human Rights, to establish an inventory of Group practices and identify areas for improvement.

At the local level, self-assessments are organized in countries considered to be at risk of human rights violations, using an assessment tool created specifically for pharmaceutical companies by the Danish Institute for Human Rights.

Self-assessments cover human rights issues including the abolition of child labor and forced labor, non-discrimination, freedom of association, access to healthcare, the respect of ethics rules during clinical trials, patient safety, etc.

### Human rights training

Senior executives from a range of functions and countries participate in training sessions tailored specifically to the pharmaceutical industry, based on materials developed with *Entreprises pour les Droits de l’Homme*.

*In-house human rights training sessions are organized with the support of outside experts. These experts help prepare the training program, which includes “case study” workshops relating to the human rights issues that Sanofi addresses. The training sessions also provide an opportunity to regularly discuss and share best practices.*

*In order to bring human rights issues to the attention of as many employees as possible, in 2012, Sanofi began developing a guide containing specific examples of best practices implemented by the Group.\**



Sanofi’s operations in India were the first part of the Group to perform the human rights self-assessment and are currently implementing the resulting action plan.

### ENTREPRISES POUR LES DROITS DE L’HOMME (EDH)

Sanofi is proud to be a founding member of EDH, alongside seven other French international groups and CAC 40 companies, which together represent over one million employees. This initiative aims to unite highly motivated businesses that seek to improve respect for human rights through their activities.

#### Related content online

[Download center](#)

• Overview of EDH factsheet

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## HUMAN RIGHTS

**Monitoring our suppliers' human rights performance**

Sanofi is committed to applying CSR principles in our procurement activities by selecting goods and services that are produced and provided in compliance with high environmental, social, and ethical standards. We work closely with our suppliers to promote social responsibility in the sourcing and use of materials and services.

The Suppliers' Code of Conduct was developed to ensure that all suppliers are aware of the Group's CSR principles. Based on the Global Compact, International Labour Organization conventions and our own Code of Ethics, it sets out the standards to apply with respect to human rights and labor practices, health and safety, the environment, and ethics.

In 2012, we designed a specific risk methodology to identify suppliers that should receive priority attention for CSR evaluation and monitoring. We analyze CSR risk factors through risk mapping by procurement category (looking at environmental, social, and ethical risks and highlighting 34 categories considered to present the greatest risk) and risk exposure mapping by country.

*In late 2011, Sanofi overhauled its policy in an effort to enhance its analytical capacity and further integrate its policy into the Group's procurement risk management model and processes.*

*Rolled out over the course of 2012, the policy aims to satisfy the Group's requirements, and implement a process of continuous improvement. With our suppliers, the new approach is based on a comprehensive, multi-criteria CSR risk analysis (procurement strategies, types of goods and services, and countries of operation) and the recognized expertise of an external partner that has developed a collaborative platform for evaluating and analyzing the CSR performance of Sanofi's supplier base.\**

**Related content online**[Download center](#)

- Human Rights factsheet
- Responsible Procurement factsheet

**FOR THE FUTURE**

- Complete and distribute to employees the Sanofi in-house guide to human rights, with examples of best practices.
- Meet target of 150 buyers to be trained on the Responsible Procurement Platform.

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## HUMAN RIGHTS

## ACHIEVEMENTS

## Training indicators

Since the launch of the Human Rights annual program, a total of 76 employees representing more than 25 functions have received one full day of training.

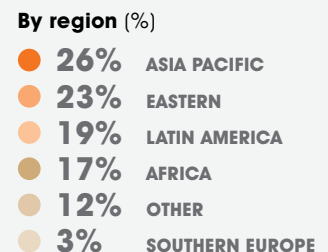
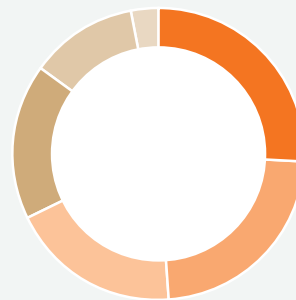
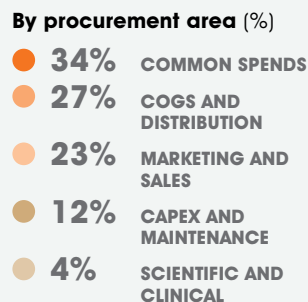
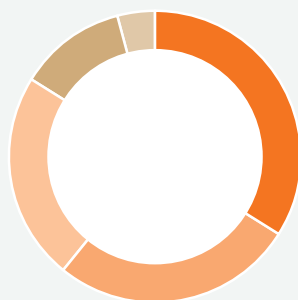
India was the first country to perform the human rights self-assessment and is currently implementing the resulting action plan. In this context, 17 Indian employees were trained (out of 76 Sanofi employees receiving training).



## Supplier evaluations in 2012

In 2012, over 350 suppliers were selected to undergo CSR evaluations. Sanofi's purchases from these suppliers account for over 20% of our total expenditure for the 34 procurement categories identified as having the highest CSR risk.

## Distribution of suppliers enrolled in the 2012 supplier evaluation campaign



**Common Spends:** Fleet and Travels, Energy and Waste, IT, Real Estate and Site services, Consulting, HR and Insurance

**Cost of Goods Sold (COGS) and Distribution:** Raw Materials, Packaging and Devices, Subcontracting, Licenses and Supply Chain

**Marketing and Sales:** Communication agencies, Events and Media, Market Research, Promotional Items

**Manufacturing Capital Expenditure (CAPEX) and Maintenance:** Civil Works, Manufacturing equipment, Spare Parts and Industrial Maintenance

**Scientific and Clinical:** Clinical, Laboratory equipment, Research materials and Subcontracting

**Asia Pacific:** Bangladesh, China, India, Indonesia, Philippines, Pakistan, Thailand, Vietnam

**Eastern:** Belarus, Bulgaria, Iran, Kazakhstan, Lebanon, Romania, Russia, Saudi Arabia, Ukraine

**Latin America:** Argentina, Brazil, Colombia, Dominican Republic, Ecuador, Guatemala, Mexico, Panama, Paraguay, Peru, Venezuela

**Africa:** Algeria, Egypt, Maroc, Senegal, Tunisia

**Southern Europe:** Bosnia, Serbia, Greece

## Key Performance Indicators measures

2012

Number of people having access to the Responsible Procurement Platform	150
Number of buyers involved in the new methodology and suppliers selection process (awareness)	200
Number of countries where implementation of the Responsible Procurement Platform is mandatory	36
Number of suppliers identified in 2012 to undergo CSR evaluation	354
• Number of supplier evaluations completed	161
– Number of suppliers evaluated that met our CSR requirements	96
– Number of suppliers that must initiate corrective action plans in 2013	65
• Number of suppliers for which evaluation is ongoing	193

## HUMAN RIGHTS

**HIGHLIGHTS****Supplier evaluations**

The Procurement Function has set up a sourcing program for educational items and aids for the patient (i.e., nurse demo caddy, injection dome), as well promotional materials such as pens and USB flash drives in areas where such items may be distributed consistent with applicable law and standards. This initiative is important for several reasons. It contributes to:

- avoiding human rights violations with respect to working conditions and wages, since labor conditions may be extremely poor for the manufacturing of this type of product (due to component toxicity, poor safety controls, illegal overtime, etc.);
- avoiding the use of “in between” suppliers (i.e., producers, re-sellers, wholesalers), thereby helping to safeguard our supply chain management;
- endeavoring to guarantee that sourcing origins comply with our CSR standards and allow us to trace production while preserving product quality and safety; and
- standardizing the materials we use.



On-site audits were conducted in the local language to monitor our suppliers' compliance with labor, social, and environmental requirements, with the support of an independent, specialized third party on behalf of Sanofi. They included visits to factories, workshops, dormitory buildings, and other facilities, as well as face-to-face interviews with employees. In 2012, seven suppliers underwent on-site audits: five in China and two in Russia.

**Due diligence**

As a member of Entreprises pour les Droits de l'Homme (EDH), in 2012, Sanofi participated in the development of a tool to help managers understand human rights due diligence, set out in the United Nations Guiding Principles by John Ruggie, UN Special Representative on Business and Human Rights.



IN THIS SECTION

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WOMEN REPRESENT  
**45.4%**  
 OF OUR TOTAL WORKFORCE

**430,000**  
 HOURS OF HEALTH,  
 SAFETY AND ENVIRONMENT  
 TRAINING

**11,874**  
 NEW HIRES IN 2012

Alex, Research Investigator at Sanofi, United States.

# PEOPLE

Sanofi's highly diverse workforce is the real driver of our performance. We are committed to ensuring our employees' health, safety, and well-being while promoting their professional development.

# HEALTH AND SAFETY IN THE WORKPLACE

## CHALLENGE

Employees are the real drivers of business performance. Sanofi is acutely aware of our responsibilities to our employees and contractors, and we are committed to protecting their health, safety, and well-being.

## STRATEGIC APPROACH

Our HSE management system provides the foundation on which Sanofi has built the Group's approach to health and safety in the workplace.

### Safety in the workplace

To maintain a safe working environment for all employees, Sanofi aims to reduce workplace accidents to the lowest possible level. Our safety approach includes:

- conducting risk assessments as of the initial phases of our activities;
- applying risk minimization methods in all situations, for all processes and projects;
- using the hazard vetting method each time manufacturing or equipment is scaled up;
- focusing on organizational and human factors in safety management; and
- providing continuous employee awareness and training about prevention and protection systems.

Promoting a culture of safety is a priority for us, and the Group organizes various initiatives to reduce the occurrence of workplace injuries by providing support for managers and taking steps to ensure the safety of independent contractors. We also seek to make constant progress on our road safety record and to develop initiatives to improve employees' security, such as training sessions about security during business travel.

### Health in the workplace

Sanofi is committed to endeavoring to safeguard the physical and mental health of each employee by minimizing exposure to chemical, biological, and physical factors and taking measures to ensure their well-being at work. We seek ways to enhance occupational hygiene assessments and use engineering technologies to help protect employees.

Our actions take many forms, such as setting up health programs and sharing best practices among our key medical doctors, who provide leadership for the network of occupational physicians working at Sanofi sites around the globe.

Where appropriate, biomonitoring technologies are used to check for occupational exposure and improve knowledge of chemical agents and their effects. Training sessions organized for employees and managers are designed to enhance their well-being at work. We also rely on the guidance of two important in-house expert groups:

- the COVALIS committee, in charge of providing information about handling of hazardous substances; and
- the TRIBIO committee, responsible for assessing exposure to biological agents.



### Related content online

#### Download center

- Health Safety and Environmental Management System factsheet
- Occupational Health and Safety factsheet
- HSE Policy



## HEALTH AND SAFETY IN THE WORKPLACE

## ACHIEVEMENTS

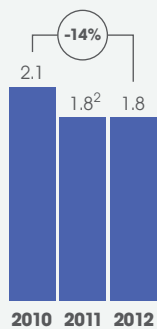
## Safety

Sanofi's lost time injury frequency rate (LTIR) is below average for major pharmaceutical companies and went down by 14% from 2010 to 2012.

## Severity rate trend

Our severity rate remained stable in 2011–2012 and decreased from 2006 to 2011. In 2012, external auditors conducted an in-depth review of this indicator as required by the French Grenelle II Law.

## Sanofi LTIR total



Lost Time Injury Frequency rate by functions (LTIR FR) <sup>1</sup>	2010	2011	2012	2010–2012
Research and Development	1.5	0.9	1.5	0%
Industrial Affairs	2.1	1.6	1.3	-38%
Merial	-	2.6	2.3	-
Genzyme	-	-	2.5	-
Global Operations	2.2	2.1	2.1	-5%
Vaccines	2.3	1.2	1.6	-30%
Support Functions	1.9	1.7	1.5	-21%
Sanofi total	2.1	1.8	1.8	-14%
Temporary employees	2.3	2.0	2.1	-13%

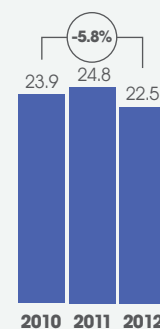
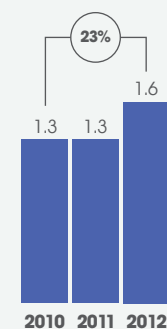
<sup>1</sup> Number of occupational related lost time injuries per one million hours worked. These data are consolidated for all Group companies.

## Motor vehicle accidents (MVA) for medical sales representatives:

While the number of motor vehicle accidents decreased for the period 2010–2012, the number of lost time automobile and motorcycle injuries increased. This occurred primarily in two countries. Following these observations, Sanofi has set up training programs in these two countries to teach safe driving habits.

Since 2009, the medical sales representatives' motor vehicle accident rate has remained at around 22–23%. By 2015, our objective is to reduce this rate by 15% compared to 2010 through a series of actions including the implementation of road safety e-learning, teaching eco-driving techniques, follow-up of practical training on a two- to three-year cycle, the publication of regular newsletters, and the organization of Road Safety Awards.

## Motor vehicle accident rate (%)

Motor vehicle-related lost time injury frequency rate<sup>3</sup>

Motor vehicle accidents (MVA)	2010	2011	2012	2010–2012
Number of motor vehicle accidents <sup>2</sup>	6,721	6,283	5,722	-14.9%
Total number of medical sales representatives vehicles including: – total number of motorcycles	28,063	25,335	25,467	-9.2%
Motor vehicle accident rate in percentage	23.9	24.8	22.5	-5.8%
Motor vehicle-related lost time injury frequency rate <sup>3</sup>	1.3	1.3	1.6	23%
Fatalities	0	0	0	-

<sup>2</sup> 2010–2012 figures have been adjusted to include motorcycle accidents.

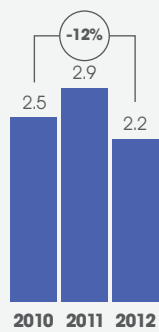
<sup>3</sup> Number of occupational related lost time injuries per one million hours worked.

## HEALTH AND SAFETY IN THE WORKPLACE

### Contractors

The lost time injury frequency rate for independent contractors decreased by 12% between 2010 and 2012. Although this rate has improved, two fatal accidents involving contractors occurred at the end of 2012, a reminder that the risk of a fatal injury can never be ruled out, and that safety must be a constant concern. Sanofi has implemented action plans for 2013 to further improve contractors' safety.

#### LTIR for independent contractors



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

Frequency rates have been adjusted in 2012 based on the following factors: eliminating injuries dismissed by regulatory authorities, including injuries reported late, and changes in the scope of reporting.

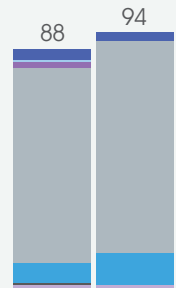
### FOR THE FUTURE

- 2010–2015: 30% reduction in the lost time injury frequency rate (LTIR).
- 2010–2015: 15% reduction in the motor vehicle accidents rate.
- 2011–2016: 15% reduction of musculoskeletal disorders (absolute value).

### Health

In 2012, musculoskeletal disorders (MSD) represented 96% of all reported diseases. A 14% increase in musculoskeletal disorders (upper limb disorders and neck, back, and lower limb disorders) was observed in 2012 compared to 2011. This is due primarily to improved identification of such diseases and improved reporting from our vaccines division (where a majority of MSD occurs). To reach our goal of a 15% reduction in MSD by 2016 compared to 2011, our approach is based on ergonomics training and optimal design of workstations.

#### Occupational diseases reported (including musculoskeletal disorders) (number of cases)



Cause of the disease	Category of disease	2011	2012
Chemical agent	Respiratory disease	4	3
	Skin disease	1	0
	Cancer of malignant blood disease	2	0
Physical agent	Upper limb disorder	72	78
	Neck, back, lower limb disorder	7	12
	Ear disorder	1	0
Biological agent	Disease caused by a biological agent	1	1
<b>Total</b>		<b>88</b>	<b>94</b>



## HEALTH AND SAFETY IN THE WORKPLACE

**HIGHLIGHTS****Safety: a new program to train safety management teams**

A new training program has been launched at Sanofi's industrial activities and R&D sites in France, to focus more strongly on the human aspects of safety management. By taking into account factors such as working conditions, individual differences and how closely employees follow recommendations, the Human Organizational Management for Safety (HOMS) program gives management teams an innovative approach to help transmit a safety culture.



Yaseen, head of a production lab, puts on a safety gown.

In 2012, members of management committees received two days of training. At the Vitry, Le Trait and Toulouse-Merial sites in France, local managers took part in co-development groups taught by HSE site directors, who also received training. These groups provide support for teaching good safety practices on a daily basis. HOMS is a company-wide program that will be expanded throughout France and other countries in 2013.

*The program for site management teams promotes a culture that takes into account the organizational and human factors in safety management systems. This essentially involves taking into consideration working conditions, organization, actual and prescribed operating methods, and individual variability.\**

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

**Safety: training the trainers: road safety in India and Mexico**

India has the highest rate of road traffic fatalities of any country in the world, with one traffic-related death occurring every four minutes. In 2012, Sanofi provided road safety training for drivers of motorcycles (the primary means of individual transportation in India) among our sales force. In Bombay, Hyderabad and New Delhi, over 30% of regional directors took part in these sessions. Moreover, 100% of the trainers received training in order to cascade this module among all our sales forces throughout India. Sessions are planned for medical sales representatives and regional directors in 2013.

A similar program has been developed for automobile drivers in Mexico, where training the trainers sessions were organized for the team that will roll out the program to the Mexican sales force in 2013.

In 2012, the Group provided a total of 42,750 hours of road safety training to employees worldwide.

**Safety: encouraging results for a pilot eco-driving program in Ukraine**

At Sanofi's Ukrainian affiliate, medical sales representatives and regional directors took part in an eco-driving pilot program in 2012. Adopting a smarter and more defensive driving style brings many benefits, including lower fuel costs. Six months after the pilot was launched, preliminary findings revealed:

- drivers reported less fatigue with a more defensive and calmer driving style; and
- the accident rate was reduced four-fold.

The overall decrease in fuel consumption was 12.9% for the duration of the pilot program. In the month immediately following the training session, record fuel savings of 16.6% were reported. These initial results are encouraging and portend well for the future. Sanofi plans to expand the program to a number of other affiliates starting in 2013.

## HEALTH AND SAFETY IN THE WORKPLACE

**Health: a program to promote employee wellness and prevent disease**

According to the World Economic Forum, workplace health and wellness programs based on lifestyle changes can help prevent up to 40% of cardiovascular diseases, cancer, lung disorders and other chronic diseases.

Sanofi's Employee Wellness and Prevention program seeks to promote a healthy lifestyle among employees by focusing on three pillars: healthy nutrition, regular physical activity, and prevention management. Participants receive tips and information about each pillar to promote good habits and help prevent or delay the onset of disease. They can also take advantage of the program's other offerings, such as an individual health risk evaluation, tailored educational and lifestyle management suggestions, and preventive services.

For Sanofi sites in North and South America, India, China, and Europe where initiatives are already in place, the Employee Wellness and Prevention program aims to re-focus existing projects around these three pillars. At the same time, an experimental program will be introduced at two Paris sites in 2013 before being launched at other Sanofi locations.



The fitness center at Sanofi's headquarters in Paris, France.

**Health: stress management**

We continue to organize initiatives at all our French sites to promote psychosocial risk prevention, coordinated by the Workplace Health Committee created in 2010. The Stress Observatory is now up and running at 92% of our sites in France. In June 2012, representatives from Human Resources and HSE, occupational physicians, and members of the Committee for Hygiene, Safety and Working Conditions (CHSW) attended a national meeting where the Stress Observatory's findings were presented at the corporate level. Local results were also presented to the CHSW at each site. Specific action plans were drafted and implemented on the basis of these findings.

We have developed a guide for all Sanofi sites in France about the prevention of psychosocial risks and the promotion of well-being in the workplace.

The guide is designed to present three types of preventive actions according to the prevention levels defined by the WHO: primary, secondary, and tertiary.

Numerous initiatives are organized all year long at our various sites in line with specific characteristics and ongoing initiatives that have been in place for a number of years.

Examples include:

- presenting the psychosocial risk prevention approach to different committees (management committees, employee representative bodies, etc.);
- a stress management training module for new employees;
- manager training that includes well-being in the workplace and the prevention of psychosocial risks;
- practical workshops on managerial and professional practices based on interpersonal relations;
- considering the impact on human and personal factors when supporting change;
- taking into account ergonomics; and
- individual discussions between management and employees about their work.

Quarterly analysis of selected indicators (HR and safety) is performed using a scorecard to orient psychosocial risk prevention initiatives and to monitor their impact over time.

# DIVERSITY

## CHALLENGE

The world we live and work in is characterized by broad diversity, which is reflected in the highly diverse needs of patients and consumers. As a global healthcare company operating in more than 100 countries with more than 110,000 employees, Sanofi benefits from the wide-ranging talents of our multicultural workforce. Thanks to them, we are equipped to develop solutions designed to meet the needs and expectations of all our customers and other stakeholders. The Group embraces diversity as an opportunity.

## STRATEGIC APPROACH

Sanofi believes that facilitating diversity is essential for business, for the communities we serve and, naturally, for all employees. Supporting diversity helps individuals feel confident and empowers them to fulfill their professional potential. We are convinced that the rich diversity of our workforce makes us more innovative, effective and competitive.

We prohibit all forms of unlawful discrimination and comply with international standards and applicable national and local laws and regulations in the area of human rights and labor law. We created a dedicated Diversity Department in 2007, which reports to the Senior Vice President of CSR.

Our recently adopted Diversity Policy is designed to promote diversity in the broadest sense possible. It outlines the framework and principles governing non-discrimination, equal opportunity and respect for individuals. The Diversity Policy is based on:

- non-discrimination, which is integrated into our Human Resources processes;
- equal treatment and equal opportunity for all;
- awareness and training for all employees adapted to local environments;
- follow-up and updates of the policy's orientations and priorities on a yearly basis;
- an established procedure for employees to report complaints; and
- a network of diversity delegates, active in over 78 countries.

### Related content online

[Download center](#)

- Code of Ethics



Supporting diversity helps individuals feel confident and empowers them to fulfill their professional potential.

DIVERSITY

**ACHIEVEMENTS**

**Employee awareness**

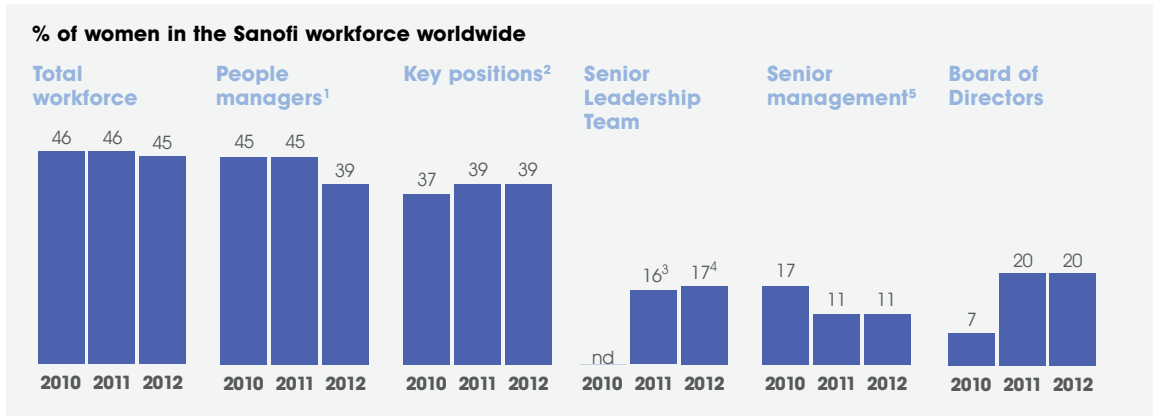
We have sought to improve employee awareness through communication campaigns such as International Women’s Day, the French week to raise awareness about the employment of disabled persons, and other occasions throughout our affiliates. Several training initiatives were organized in 2012, in line with local needs:

- affiliates in 18 countries organized diversity training for 2,189 employees;

- in the United States, all employees took part in Diversity and Inclusion Awareness e-learning; and
- in France, 33 employees in Human Resources took diversity and non-discrimination e-training (216 employees total since 2008), and 74 employees received training about disability,

**Gender balance**

Promoting gender balance continued to be a key component of our business strategy. Our CEO, Christopher A. Viehbacher, has expressed his strong commitment to this issue on several occasions.



1 The definition of “manager” changed in 2012, from a hierarchical definition to one that indicates direct reports, which explains the discrepancy in the 2011 and 2012 figures.

2 Positions of high responsibility considered to be essential to Sanofi’s strategic objectives.

3 Composed of 250 senior managers in 2011.

4 Composed of 272 senior managers in 2012.

5 Executive Committee and Global Leadership Team.

## DIVERSITY

### Gender balance

Our Women’s Leadership Council monitored progress across the globe and promoted best practices and innovative initiatives aimed at enhancing gender balance. The Council, which was created at the impetus of our CEO, Christopher A. Viehbacher, brings together members of our Executive Committee, Group Leadership Team and senior management to sponsor working groups entrusted with proposing initiatives, collecting feedback from women’s networks, assessing proposals, acting as advocates and soliciting support for new programs, and championing the issue of gender balance to the Executive Committee.

#### 2012 milestones in gender balance

##### External events

- Attendance at the Women’s Forum for the Economy and Society in France: 29 Sanofi participants from several countries (30 in 2011).
- Attendance at the First Women’s Forum in Brazil: 20 Sanofi participants.

- Presentation of Sanofi Turkey’s equal opportunity model project at the 56th session of the UN Commission in New York.
- Presentation of our diversity initiatives at a dialogue session of the European Parliament.
- Sponsorship of the Trajectoires HEC au féminin Prize (HEC Business School Women Excelling in their Career) for the sixth consecutive year.
- Acceptance of the E-Quality Award by Sanofi Germany for commitment to equal opportunity and family-friendly policies.

##### Internal programs

- Growth of women’s networks worldwide: WoMen in Sanofi Pasteur, the European Sanofi Women’s network, the Australia/New Zealand network (Swanz), and others.
- Development of the Catalyzer Mentoring program for future women leaders: 24 Sanofi participants.
- Organization of “speed networking” meetings with senior managers: 210 participants.

### Work–life balance

Managing work accountabilities and career aspirations while respecting personal responsibilities and the diversity of lifestyle choices opens the door to initiatives promoting work–life integration. To help employees successfully juggle the demands of their professional and personal lives, Sanofi affiliates in 39 countries organized initiatives designed to increase workplace flexibility and improve work–life balance. Today, our employees in ten countries have a range of teleworking options. In France, we entered into an agreement in June 2012 with employee representative organizations about working from home.

#### Improving work–life balance (number of countries)

##### Work from home



##### Flex time/day



##### Part time



##### Sport facilities

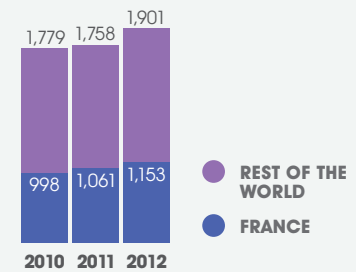


Initiatives to increase workplace flexibility and improve work–life balance at Sanofi affiliates in 39 countries/multi-country organizations.

## DIVERSITY

**Disability**

In 2008, Sanofi extended an agreement to promote integration and job retention of disabled persons in France for the period 2009–2012. Thanks to improved awareness, numerous disabled employees (300 in three years) have declared their disabilities to the Group so that specific measures could be taken as needed to accommodate their needs. In 2012, we renewed the agreement for the third time, for the period 2013–2016.

**Disabled employees in the Sanofi workforce****Interns and apprentices**

Sanofi welcomes less-experienced people through our internship programs worldwide, which allow them to acquire know-how and experience in the business world. In 2012, a total of 1,222 interns took part in work-study programs at our French sites, and we welcomed 468 apprentices in Germany.

**Related content online**

[Sanofi.com Careers page](http://Sanofi.com/Careers/page)

**FOR THE FUTURE**

- Continue to uphold Sanofi's commitment to promoting diversity.
- Roll out our Diversity Policy to all Sanofi affiliates.
- Meet the goals set by the Disability Agreement in France.



## DIVERSITY

**HIGHLIGHTS****Future professionals**

In Germany, a total of 468 apprentices in 16 different job areas were working at our sites by November. We launched two programs in 2012 to support apprenticeships:

- a New Work Abroad program that enabled 64 apprentices to travel to the UK for three weeks, where they lived with families and worked in local stores and industry; and
- a program open to young people regardless of their academic record. Through nine months of training, ten participants became familiar with professions in the pharmaceutical industry so that by the end of the program they were prepared to begin an apprenticeship.

**Integration and job retention of employees with disability**

Recruiting individuals with disability to join our workforce and facilitating their retention has been a Sanofi priority for over 15 years. In 2012, we renewed an agreement in France to promote the integration and job retention of disabled employees. This is the third time we have extended the agreement, which will now cover the period 2013–2016.

The measures it contains apply to all employees, regardless of their disability, and encourage work-study contracts. We are committed to providing suitable working conditions to facilitate job retention among disabled employees. Last but not least, we make an ongoing effort to improve accessibility, especially to information.

Sanofi is committed to programs focusing on the employment of disabled persons, and we organize initiatives to raise awareness about living with disability among our entire workforce.



Takuma and his supervisor, Akitaka. Takuma is an employee of Sanofi Japan at “La Maison Business Support Center”, a service specifically adapted for people with mental health problems.

**Diversity Council**

In 2012, Sanofi affiliates in the United States and Australia/New Zealand created Diversity Councils to champion diversity among the workforce and integrate this important issue into every area of the business. Council members represent various functions and management levels.

The Australia/New Zealand Diversity Council, which has 12 members, seeks to facilitate a diverse population in their workforce. Thanks to the Council’s efforts, the affiliate has:

- strengthened the commitment to flexible work arrangements;
- introduced the Working Parents Toolkit;
- identified and tracked the advancement of women’s talent;
- initiated a mentoring program with a focus on women in Sanofi; and
- started preparing a 2013 survey to identify future initiatives.

In the United States, the Diversity and Inclusion Council has 21 members.

*It has already met several times to ensure that diversity and gender balance are fully integrated into the Group’s business strategy. The Council has identified three main focus areas: the commitment of leaders, the diversity of candidate pools, and widespread employee involvement.\**

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

# WORKFORCE DEVELOPMENT

## CHALLENGE

To accomplish our Company's ambition of improving healthcare worldwide, we rely on a wide range of talents. Developing the skills and cultivating the potential of our workforce is essential to employees' motivation and helps them lead fulfilling careers. In addition, workforce development prepares each individual to adjust to ongoing changes in our industry.

## STRATEGIC APPROACH

We began a far-reaching transformation process across all our entities in 2009. To keep pace with our changing business model and increasingly develop Sanofi's outreach, in particular for research collaborations, we have adapted and improved many of our workforce skill development processes.

### Shifting our focus

The impact of the Group's transformation is reflected in new programs for our employees, for example in line with Sanofi's growing focus on consumer healthcare. In some areas of the globe – emerging markets in particular – we have increased our headcount to satisfy the demands of evolving demographics and improved access to care. At the same time, in certain mature markets, we have made adjustments to the sales force and provided retraining options to employees.

Because the pharmaceutical sector relies on technological progress to assist in providing tomorrow's medicines, we organize training programs for employees to acquire new technical skills as we migrate some of our research and industrial facilities to biotechnology activities.

### Personalized training and development

Our approach is based on an annual review process for all employees and myriad types of training. Each employee is expected to meet with their manager at least once a year to discuss short to medium-term actions, identify needs, and determine professional development goals. Together they should devise an action plan on the basis of this discussion, outlining the core and technical competencies to be enhanced, priorities, and a timetable for the completion of development activities, which may include new assignments, training, etc.

We are committed to the development of our human capital, and our various training programs are one of the ways we meet this goal. Sanofi offers many options as part of a strategy to anticipate future developments in the healthcare sector. Programs aim to match, as closely as possible, specific local and regional needs while supporting the transformation of our organization.

### Related content online

#### [Download center](#)

- Compensation and Employee Benefits factsheet
- Employee Representation and Information factsheet
- Working with Schools and Universities factsheet



Olatunde, Chris and Claire at a Sanofi seminar.

## WORKFORCE DEVELOPMENT

### Management training

To improve management training and interaction between corporate teams and regional teams, we have introduced a global framework known as the Leadership Development Offer.

*The HR function introduced additional initiatives in 2012 to better adapt training efforts to focus on building the skills required for the Group's development.\**

Sanofi's international training programs bring together our managers from diverse geographic horizons and all our functions, allowing them to adopt common managerial practices both as individuals and within teams.

### Skills specific to the pharmaceutical sector

The Group organizes training to maintain and develop employee skills for regulated activities. Within Industrial Affairs, employees receive training on Good Manufacturing Practices and Good Distribution Practices. Designed to ensure compliance with regulations, this type of employee training is mandatory for relevant personnel and is subject to inspections by health authorities. R&D training programs, particularly for Good Clinical Practices and Good Laboratory Practices, are also subject to inspections.

More generally, at each stage of our value chain activities, very specific knowledge and technical skills are required of our employees, and therefore need to be taught and developed. For example, cutting-edge scientific knowledge is required of our researchers, while employees working on development of our products need medical, biological, and statistical skills. Up-to-date operational proficiency is essential for those working at our production plants, and medical as well as regulatory expertise is indispensable for our affiliates worldwide.

### Support function training

For the smooth convergence of all these activities, we rely on the Sanofi support functions, which are increasingly looked to as a source of expertise and advice. In 2011, we created the Support Function Academies to help prepare each function to fulfill its role as an essential strategic partner. Training enables employees in these areas to develop a new approach to their jobs, with a strong emphasis on helping forge business relationships.

To date, six support function academies have been set up. Each academy is sponsored by the global head of the relevant function: Legal, HSE, Communications, Human Resources, Finance, and Procurement. In 2012, the academies designed 21 programs and organized 84 sessions.

#### Related content online

[Download center](#)

• Employee Development factsheet

#### Related content in this report

**p56** [For additional information about the HSE academy training, please refer to the Health & Safety section in this report](#)



Developing the skills and cultivating the potential of our workforce is essential to employees' motivation and helps them lead fulfilling careers.

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## WORKFORCE DEVELOPMENT

### ACHIEVEMENTS

#### 2012 training programs in France, Germany, the U.S., and Brazil

In 2012, we continued to invest extensively in employee training across the entire Company, both in terms of budget and number of people trained. For example, the following figures were reported in the four countries where our workforce is largest:

##### UNITED STATES

OVER \$8 MILLION TRAINING BUDGET

OVER 8,500 EMPLOYEES TRAINED

##### FRANCE

670,862 HOURS OF TRAINING

24,146 EMPLOYEES TRAINED (86% OF FRENCH WORKFORCE, UP FROM 82% IN 2011)



##### BRAZIL

OVER €8.6 MILLION TRAINING BUDGET

4,760 EMPLOYEES TRAINED (94% OF BRAZILIAN WORKFORCE)

##### GERMANY

OVER €5.3 MILLION TRAINING BUDGET

37,000 HOURS OF NON-TECHNICAL TRAINING

136,000 HOURS OF QUALITY AND HSE TRAINING

3,686 EMPLOYEES RECEIVED NON-TECHNICAL TRAINING

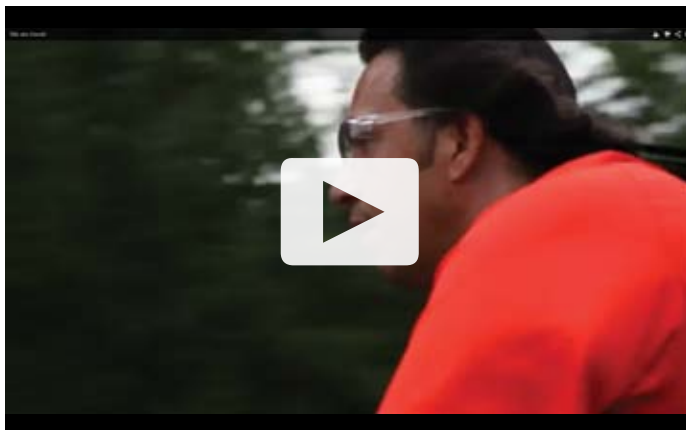
6,549 EMPLOYEES RECEIVED QUALITY AND HSE TRAINING

#### Specialized pharmaceutical training

At each Sanofi industrial and R&D site, employees received training about new developments and regulatory requirements impacting their jobs.

- In Germany, 6,549 employees received 136,267 hours of training on regulatory topics (good practices, HSE, etc.), representing an annual average of 20 hours per person.
- In France, at Vitry-sur-Seine, 218 employees received specialized biotech training.

#### Related content online



Discover testimonies from Sanofi employees from all over the world.

#### FOR THE FUTURE

- **Training indicators:** initiate worldwide consolidation of meaningful indicators on training initiatives to better pilot workforce development across the Company.
- **Corporate development programs:** focus on project management skills, which are critical to monitor the integration of new businesses and to coordinate cross-functional projects.
- **Support function academies:** launch the academies in Latin America as we continue to implement existing learning offers in the U.S. and France.

## WORKFORCE DEVELOPMENT

### HIGHLIGHTS

#### International programs promote global talent development

Sanofi's international job rotation programs are designed to attract, engage, and help retain talented individuals by providing exposure to different business contexts and cultures. These global programs, coordinated at the corporate level, are open to all activities and functions. They contribute to building sustainable leadership for Sanofi.

#### Sanofi Early Executive Development (SEED)

This new program is open to graduates of leading schools and universities with five years' professional experience. Participants are selected internally or recruited externally, and benefit from on-the-job development through four assignments in different countries over a two-year period. They also receive support from senior mentors throughout the program.

Targeted number of participants in 2013: 10

#### Short Term Work Assignment (SWAP)

Intended for less-experienced Sanofi employees, this new program is based on job rotation between emerging and mature markets. Each mission lasts six months and is designed to help prepare participants to reach the next step in their career as managers.

Targeted number of participants in 2013: 40

#### International corporate volunteer program (V.I.E.)<sup>1</sup>

Sanofi and Sanofi Pasteur continue to offer 12- to 24-month assignments abroad with our affiliates all over the world through the V.I.E. program, which is open to candidates from the European Union. Each year, Sanofi hires 15 to 20 young people who have taken part in this program. We are the largest V.I.E. recruiter in the healthcare industry.

Targeted number of participants in 2013: 120

#### Measuring employee engagement

We recently introduced a methodology for employee engagement surveys. Several areas within the organization decided to implement this approach, and in 2012, approximately 25,000 employees took part in the survey. Their insights are being used to help establish priorities and develop local action plans with the aim of more solidly embedding our culture and our ambitions across the workforce.

#### Actor of your Employability

A new workforce planning initiative has been introduced for employees in the U.S., France and Europe. Actor of your Employability aims to strike a balance between the kind of job employees wish to have and what Sanofi is able to offer them. It is designed to match individual competencies to the right job and to facilitate employees' active engagement in their career development. In Europe, this project has been implemented for the commercial operations workforce and we plan to expand it to other functions in the near future.

#### Modernization of Sanofi's employer brand

As a global company employing 110,000 people worldwide, Sanofi wishes to have a powerful employer brand. In 2012, we renewed our brand to build on the strong image and reputation of our growth platforms. As an employer, Sanofi is now able to speak with one voice, allowing us to develop our brand recognition among top-tier talent globally. It helps us attract skilled individuals in high-growth emerging markets while sustaining our presence and visibility as an employer in more mature markets.

To accompany our updated employer brand, new graphic elements and messages are already being used in Russia, Brazil, France, and Germany. In line with our renewed branding and messages, we organized an employee storytelling project. Via video testimonials, ten employees from around the globe share their experience of working at Sanofi, offering diverse insights. A film entitled *We are Sanofi*, which features excerpts from the videos, was distributed internally and externally in 2012, and the videos will be available in 2013.

<sup>1</sup> Sponsored by the French Government collaborating with schools and universities.



IN THIS SECTION

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**14%**

REDUCTION IN SANOFI'S OVERALL WATER CONSUMPTION SINCE 2010

**12%**

DROP IN CO<sub>2</sub> EMISSIONS FOR OUR MEDICAL SALES FLEET SINCE 2010

**80%**

OF OUR PRODUCTS MOVING BETWEEN CONTINENTS WERE TRANSPORTED BY SEA

Daopithak, Patient, Thailand.

# PLANET

To safeguard the health of communities everywhere, we continually seek to limit the environmental impact of our activities for the entire life cycle of our products, from development through marketing and monitoring pharmaceuticals in the environment.



# ENERGY AND CARBON FOOTPRINT

## CHALLENGE

Two issues of growing importance threaten to jeopardize the future of our planet: greenhouse gas emissions leading to climate change, and a limited supply of fossil fuels.

Climate change can trigger natural disasters, lead to the migration of populations, and cause a shift in the geographical distribution of diseases. Energy shortages result in volatile and rising energy prices.

Although the pharmaceutical industry as a whole is regarded as a minor contributor to greenhouse gas emissions when compared to other sectors, Sanofi believes that reducing our carbon footprint and using energy responsibly are part of our mission to help protect life on the planet.

## STRATEGIC APPROACH

Sanofi is committed to optimizing our energy consumption and energy security for all our business activities. We require energy primarily for:

- production of active ingredients;
- formulation, filling and packaging of pharmaceuticals;
- heating and air conditioning for pharmaceutical plants;
- transporting medicines; and
- business travel by sales representatives and other employees.

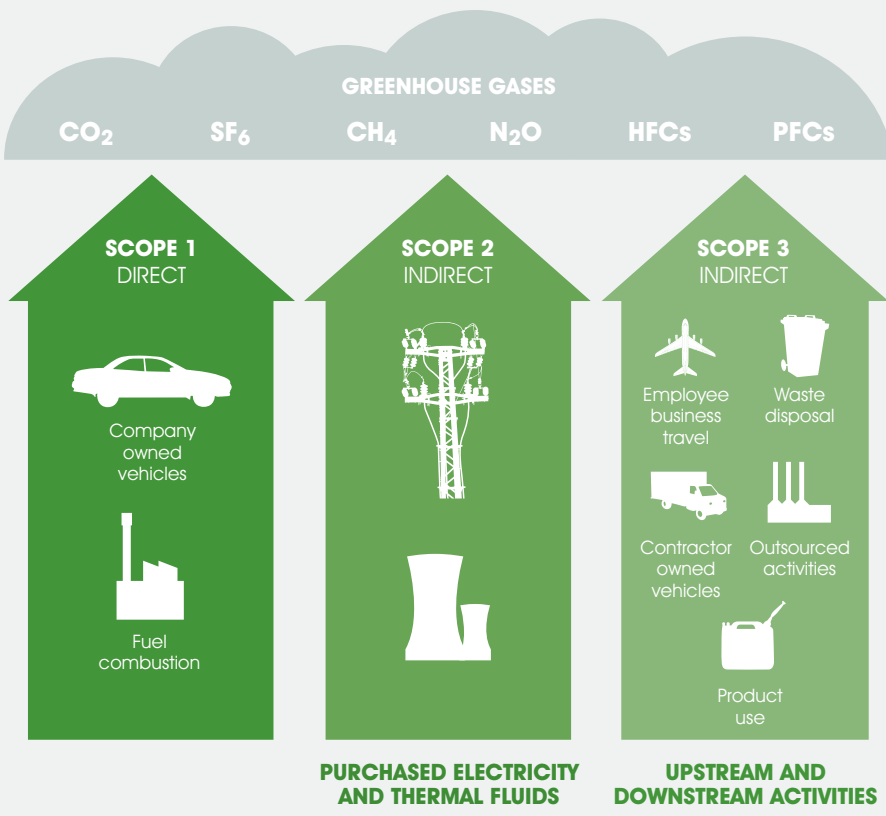
For all these activities, we consume ready-to-use sources of energy (e.g., petrol for cars, natural gas, etc.) as well as transformed purchased energy (e.g., electricity, steam, etc.).

### Related content online

#### [Download center](#)

- HSE policy
- Health Safety and Environmental Management System factsheet
- CO<sub>2</sub> Emissions Scope 3 factsheet
- Energy and Carbon Footprint factsheet
- Protection of the Atmosphere factsheet
- Transport of Medicines factsheet

## Emissions from human and industrial activities



Source: New Zealand Business Council for Sustainable Development:  
<http://www.wri.org/chart/operational-boundaries-ghg-emissions>

## ENERGY AND CARBON FOOTPRINT

We base our approach to responsible energy use on the Sanofi Health, Safety & Environment (HSE) Policy. Our energy strategy is defined through close cooperation among our HSE Department, Purchasing Department, and energy management specialists from various operational units (Industrial Affairs, R&D, etc.). It focuses on the three pillars of the energy/climate challenge, expressed by the E<sup>3</sup> model:

- energy usage,
- energy spending; and
- emissions of greenhouse gases.

**Consuming less energy and reducing CO<sub>2</sub> emissions**

We have developed a three-fold strategy designed to reduce our carbon footprint and limit our energy consumption, which consists of:

- extensive measuring of the relevant indicators for the three pillars described above;
- initiatives to consume less energy (energy efficiency); and
- initiatives to consume differently (changing the energy mix).

Our initiatives focus on:

- improving the energy efficiency and yields of equipment and facilities;
- relying on alternative sources of energy;
- making our buildings and facilities more environmentally friendly;
- limiting CO<sub>2</sub> emissions due to the transport of medicines by increasingly using maritime and railway shipment instead of air freight and road transportation; and
- reducing the environmental impact of business travel and employee commuting by encouraging the use of eco-friendly means of transportation, developing a car policy, and promoting less resource-intensive meetings.

This comprehensive approach is designed to enable us to effectively implement our strategy to increase energy savings and reduce CO<sub>2</sub> emissions through the work of:

- the Sanofi Climate Change Committee, created in 2005, which is composed of representatives of all our functions and business units, including CSR, HSE and procurement. This committee implements our strategy and coordinates energy optimization across the Company; and
- the Sanofi Energy Network, which covers all our industrial and R&D sites and business functions and is in charge of addressing technical issues and monitoring progress. Energy Network task forces include energy managers and other specialists.

*In addition, during site visits, technical experts from the Group's insurers issue recommendations for dealing with extreme weather conditions, in particular those that generate a flood risk requiring the implementation of an emergency plan.\**



Sanofi is committed to optimizing our energy consumption and energy security for all our business activities – utilities network area of Sanofi Pasteur, Toluca, Mexico.

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## ENERGY AND CARBON FOOTPRINT

## ACHIEVEMENTS

**Recognition for Sanofi's energy management programs**

Sanofi was included in the Carbon Disclosure Leadership Index SBF250 with a 93-B score. This distinction was conferred for the way we manage energy demand and greenhouse gas emissions at our sites and globally. In addition, the energy management system we adopted at our entities in Frankfurt, Germany, received ISO 50001 certification.

**The Genzyme energy program**

In 2012, the Genzyme Energy program led to 5% savings on an initial U.S.\$27 million energy budget. This was the result of many different initiatives, including the completion of 35 energy projects, which generated U.S.\$4 million in savings over five years and 11 months' payback. Together these projects reduced CO<sub>2</sub> emissions by an estimated 18,000 tons (the equivalent of planting 420,000 trees).

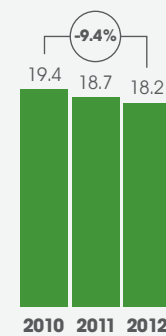
**Energy consumption**

In 2012, Sanofi's overall energy consumption decreased by 9.4% compared to 2010. This was made possible by our energy efficiency program, the reorganization of our R&D activities, and the conversion of chemical plants to biotechnology.

The overall consumption of renewable energies including renewable fuels, electricity, production of which is based on renewable sources of energy, and heating fluids produced using renewable sources (e.g., geothermal energy) reached 687,370 GJ in 2012. This represents 3.8% of our energy consumption.

Including the renewable part of electricity purchased on electricity grid (e-grid), renewable energy consumption represents 7.7% of our total energy consumption.

(GJ)	2010	2011	2012	2010-2012
Natural gas/liquefied petroleum gas	9,374,601	8,877,661	8,721,345	-7.0%
Electricity	7,272,385	7,214,812	6,940,957	-9.5%
Coal	0	0	0	-
Liquid hydrocarbon fuel (excluding car fleets)	888,366	836,960	854,780	-3.8%
Renewable fuels <sup>1</sup>	0	0	7,009	-
Other (steam, thermal fluids, etc.)	1,864,284	1,736,266	1,679,915	-9.9%
<b>TOTAL<sup>2</sup></b>	<b>19,399,636</b>	<b>18,665,699</b>	<b>18,204,006</b>	<b>-9.4%</b>

**Sanofi energy consumption**  
(million gigajoules)

<sup>1</sup> Renewable fuels are only relevant for biomass, biofuel, hydrogen, and other renewable fuels purchased and burnt on-site.

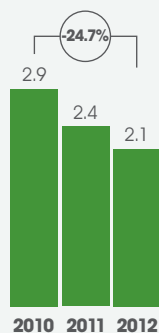
<sup>2</sup> These figures do not include energy used by cars.

## ENERGY AND CARBON FOOTPRINT

### Estimation of total fuel consumed by the medical sales fleet

Three categories of fuel (liquefied petroleum gas, diesel, gasoline) are included in the medical sales fleet's fuel consumption. In 2012, our medical sales vehicles' fuel consumption decreased by almost 25% compared to 2010.

**Medical sales fleet fuel**  
(million gigajoules higher heating value)



### CO<sub>2</sub> emissions

**CO<sub>2</sub> emissions** (tons of CO<sub>2</sub> equivalent tCO<sub>2</sub>e)



	2010	2011	2012	2010–2012
Fossil fuels (direct – scope 1)	536,712	507,973	501,222	-6.6%
Production of electricity and other energies (indirect – scope 2)	689,058	666,966	635,807	-7.7%
Medical sales fleet vehicles	189,429	160,945	144,342	-23.8%

At the end of 2012, we were ahead of schedule to reach our 2020 target for reducing the combined scope 1 and scope 2 CO<sub>2</sub> emissions by 20% for industrial and R&D sites. In 2012, the combined reduction of scope 1 and scope 2 emissions reached 7.2%.

### Promoting “green” building

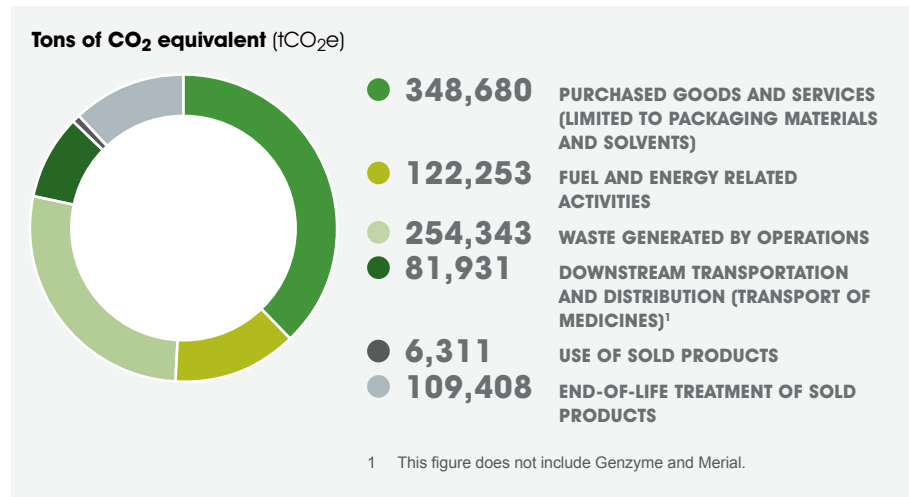
Genzyme, a Sanofi company, obtained LEED® Silver (Leadership in Energy & Environmental Design) certification in the New Construction category for its new bioproduction site in Lyon, awarded by the U.S. Green Building Council (USGBC). This Genzyme site is the first new industrial site in France to receive LEED® Silver in the New Construction category.



## ENERGY AND CARBON FOOTPRINT

### Partial and estimated scope 3 CO<sub>2</sub> emissions

For the first time in 2012, we were able to provide partial scope 3 CO<sub>2</sub> emissions data based on the Greenhouse Gas Protocol recommendations. We selected categories by focusing on the most relevant and simple to address emissions and by using a phased approach. This partial scope 3 CO<sub>2</sub> emission covers six categories:



These figures do not include administrative buildings.

**Related content online**

[Download center](#)

- CO<sub>2</sub> Emissions Scope 3 factsheet

### A 12% drop in CO<sub>2</sub> emissions for our medical sales fleet

From 2010 to 2012, CO<sub>2</sub> emissions generated by medical sales vehicles (per km traveled) were reduced by 12.1%. This represents overall CO<sub>2</sub> emissions of medical sales vehicles divided by their total mileage (in km).

## ENERGY AND CARBON FOOTPRINT

### CO<sub>2</sub> emissions from transporting medicines

CO<sub>2</sub> emissions from the transport of medicines are part of scope 3 emissions and are therefore reported in the scope 3 table in the “downstream transportation and distribution” category. The variation in scope 3 CO<sub>2</sub> emissions from transport of medicines is shown below.

Roughly 50% of the increase in CO<sub>2</sub> emissions between 2010 and 2012 is due to the increase of the activity (shipped weight), and the other 50% to emergency air shipments in the U.S. in 2011, which continued in 2012. These emergencies were largely caused by inventory and production management difficulties at two of our European sites, following building transformation projects. It should also be noted that since the last quarter of 2012, new countries (Vietnam, Indonesia, Cambodia) have been included in reporting, which has increased the volume of shipments to monitor.

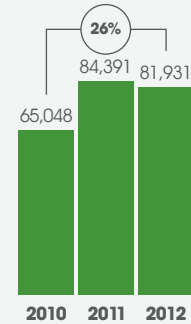
In 2012, over 80% of intercontinental product flows were transported by sea.

In five years in the 2006–2010 period, CO<sub>2</sub> emissions per transported pallet (resulting from the calculation of total CO<sub>2</sub> emitted divided by the total transported pallet, for European and intercontinental transports) have been reduced by 33%. Our Supply Chain teams received a Sanofi HSE Award in 2012 in recognition of this impressive reduction.

In 2011 and 2012, CO<sub>2</sub> emissions per pallet reached respectively 157.7kg and 141kg of CO<sub>2</sub> per transported pallet. This 2011 increase is due to many pressures on stocks needs, which has required emergency air shipments. 2012 saw a beginning of return to values closer to 2010.

For more information on the detailed CO<sub>2</sub> emissions per pallet in 2010, 2011, and 2012 for European and intercontinental transports, please refer to the Transport of Medicines factsheet in the download center.

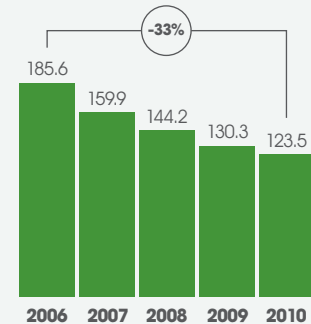
**Variation in CO<sub>2</sub> emissions related to the transport of medicines in tons of CO<sub>2</sub> equivalent**



Represents CO<sub>2</sub> emissions due to the transport of our products from manufacturing sites to distribution centers, wholesalers, third-party customers, etc.

These figures do not include Merial and Genzyme.

**Variation in CO<sub>2</sub> emissions per transported pallet**



### FOR THE FUTURE

#### Objectives

- 2010–2020: 20% reduction on the combined scope 1 and scope 2 CO<sub>2</sub> emissions for industrial and R&D sites.
- 2013: publication of Sanofi partial scope 3 emissions.
- 2012–2015: 10% reduction in car fleet fuel consumption.



## ENERGY AND CARBON FOOTPRINT

## HIGHLIGHTS

**Measuring energy use month by month**

At the corporate level, the reporting and consolidation of energy-related figures (such as consumption, CO<sub>2</sub> emissions, spending) at our industrial sites will now be made on a monthly basis instead of a quarterly basis. More frequent monitoring of these figures will enable us to better analyze how we use energy and the factors that contribute to variations in consumption, and hence greenhouse gas emissions. We will also be able to react more rapidly to significant variations from one month to the next.

**Choosing sources with lower CO<sub>2</sub> emissions**

The key initiatives we launched at various sites in 2012 largely concern the shift to fuels with lower carbon emissions. Our operations in Pirbright (UK) and Ocoyoacac (Mexico) went from using light fuel oil to produce steam to using natural gas, which led to a 675-ton decrease in CO<sub>2</sub> equivalent emissions. This approach will be continued in 2013. Our Swiftwater, Pennsylvania (U.S.) site has launched the construction of a 15-mile long natural gas pipeline. Using natural gas instead of light fuel oil is anticipated to lead to an annual decrease in CO<sub>2</sub>e emissions of 10,000 tons at the site, beginning in 2013.



**PENNSYLVANIA,  
UNITED STATES**

**10,000**

**TONS ANNUAL  
DECREASE IN CO<sub>2</sub>  
EMISSIONS**

**Accelerating our energy program in Europe**

We plan to enhance the Sanofi energy program thanks to a master service agreement we entered into with COFELY GDF SUEZ in 2012. This agreement focuses on the implementation of cogeneration units, biomass boilers, and other high-efficiency energy systems at our major European sites.

**Using renewable energies**

Sanofi strongly supports the use of renewable energies. In India, we undertook a study to better understand the challenges of the local renewable energy market and to attempt to identify opportunities in a country where the reliability of energy supplies is a genuine concern. A similar study was started at the end of 2012 in China, where the government provides incentives to encourage the use of renewable energies. This information helps us to develop action plans and select the best energy options.

Among renewable energy projects at our sites, we have invested in particular in geothermal and “green” energy projects. At our site in Veresegyhasz (Hungary), we shifted 40% of natural gas consumption to hot water produced using geothermal techniques. This project was carried out in close cooperation with the local town government and is expected to decrease CO<sub>2</sub> emissions by an estimated 800 tons for our site and 2,000 tons for the town.

Since 2011, 25% of the electricity purchased by 19 Sanofi sites in France is based on renewable sources of energy. This represents 661,061GJ of our total energy consumption, and enables a saving of 8,339 tons of CO<sub>2</sub> emissions.

# WATER MANAGEMENT

## CHALLENGE

Water scarcity is a key challenge for the global community, given that available fresh water constitutes only about 1% of the water on the planet and that competing demands could lead to an estimated 40% global water supply shortage by 2030 according to the European Commission.

Sanofi uses water in many of our industrial processes – in cooling systems during manufacturing, for fermentation and vaccine manufacturing, and in cleaning processes.

As a global healthcare leader, we are especially aware that safe drinking water is critical to the health of individuals and communities. We are committed to responsibly manage this vital resource in the interest of future generations and their continued access to water for years to come.

## STRATEGIC APPROACH

We take many steps to promote sustainable water management. Our policy focuses primarily on improving discharge treatment systems and implementing systematic quality controls for effluents, which are designed to help preserve the availability of surface water and to prevent sub-soil and groundwater contamination. The management of wastewater effluents is covered by the Group's HSE Policy and falls within the scope of our HSE management system.

Sanofi also undertakes systematic assessments of any areas where water can potentially be saved. We make investment decisions accordingly and implement measures to reduce our consumption.

In addition to overseeing the responsible use of water in manufacturing processes for our medicines and vaccines, we carefully manage wastewater discharge at all Group sites. Industrial wastewater discharge comes from liquid effluents at:

- sites that manufacture active ingredients;
- sites that produce medicines and vaccines; and
- R&D laboratories and pilot plants.

Industrial effluent wastewater is treated either on site at our factories or at treatment plants in nearby cities and communities through agreements with operators. Each site designs its own wastewater effluent management program. These site-specific programs are based on environmental impact assessments and applicable statutory and regulatory requirements. They include:

- characterization of potential principal pollutants and sources of wastewater effluents;
- wastewater effluent treatment using appropriate technologies; and
- effluent water pollution monitoring, control, and reporting.

### Related content online

#### [Download center](#)

- HSE Policy
- Soil and Ground Water Protection factsheet
- Health Safety and Environmental Management System factsheet

### Related content in this report

**p81** [Traces of pharmaceuticals that may be found in water supplies due to patients' use of medicines are addressed in this Report under Pharmaceuticals in the Environment](#)



Sanofi uses water in many of our industrial processes – in cooling systems during manufacturing, for fermentation and vaccine manufacturing, and in cleaning processes.

## WATER MANAGEMENT

### ACHIEVEMENTS

#### The Global Water Tool

Since 2010, we have been using the World Business Council for Sustainable Development (WBCSD) Global Water Tool to determine which of our sites are located in areas of water scarcity and to develop specific action plans.

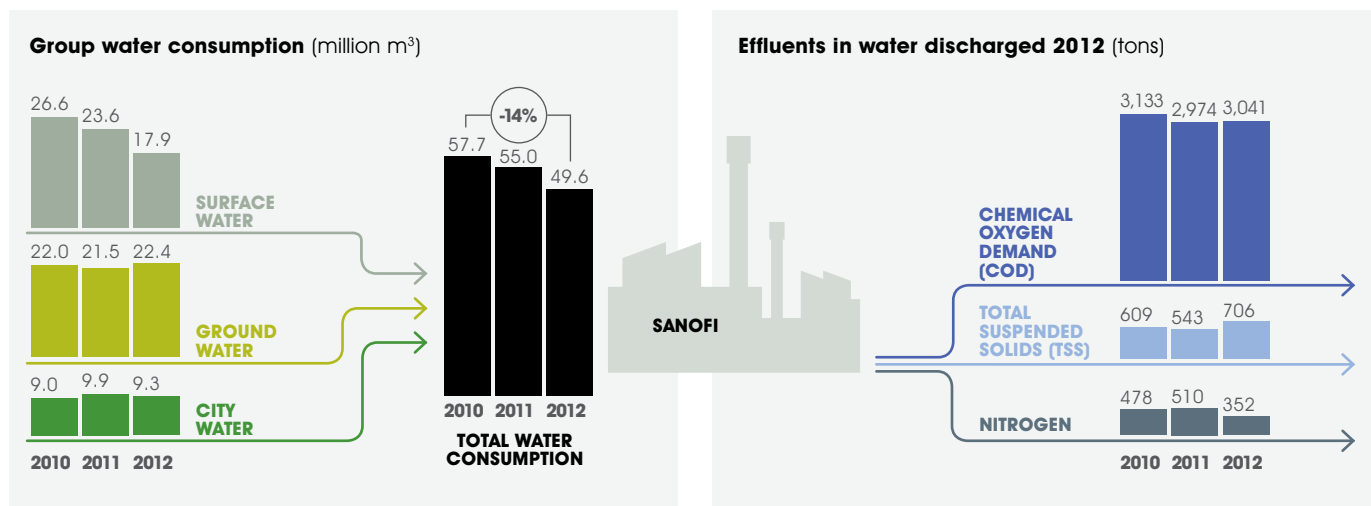
We determined that:

- 42% of our sites are located in areas of water scarcity and water stress; and
- the percentage of water consumed by our sites located in such areas represents 65% of our global water consumption.

Based on this observation, we are working to define specific objectives to reduce water consumption for sites located in these areas. We will be able to communicate these objectives in the next 2013 CSR report.

#### Related content in this report

**p86** [A full review of our performance, all our data can be found in our CSR performance](#)



#### Group water consumption

Water consumption decreased in 2012, primarily due to the conversion of one of our chemical plants to biotechnology production. The overall decrease over the years (a 25% reduction from 2005 to 2011) is the result of our strong commitment to reduce water consumption and related action plans developed at each site.

In addition, water consumption by our factories located in areas of water scarcity or water stress decreased by 26% in 2012 compared to 2010.

#### Effluents in water discharged

Almost all Sanofi sites discharge their water effluent to municipal wastewater treatment plants or treat their effluents on site before discharging to the environment. The chemical oxygen demand (COD), total suspended solids (TSS), and nitrogen figures concern final water pollutant content after various treatment steps. These figures are relatively low when compared to other industries. The sharp increase in TSS observed in 2012 is mainly due to the reorganization of production at Sanofi sites.

#### FOR THE FUTURE

The Group set the objective of reducing water consumption by 25% from 2010 to 2020. To help reach this objective, Group affiliates have committed to performing an assessment of their water consumption and have endorsed an action plan to be implemented during the 2014–2020 period.

## WATER MANAGEMENT

## HIGHLIGHTS

Evolution in the management of water and wastewater treatment solutions is part of an ongoing process designed to improve our sites. In addition to reducing water consumption and helping to preserve the environment, these initiatives generate significant cost savings for the Group.

VAL DE REUIL,  
FRANCE

6.5%  
REDUCTION IN  
TOTAL WATER  
USAGE

## Installing a closed-loop circuit

At the Sanofi Pasteur site in Val de Reuil, France, we installed a closed-loop circuit for incubators used in manufacturing influenza vaccines. Not only has this improvement resulted in water recovery, but daily water consumption has decreased by 50m<sup>3</sup>, leading to annual savings of up to 15,000m<sup>3</sup> (which represents a 6.5% specific reduction in total water usage).

## Using treated wastewater on site

Sanofi's Goa, India, pharmaceuticals production plant has set up a program for wastewater that eliminates the need to send it off site for treatment. Effluents produced at the site are collected before being transferred to an aeration tank. Following a clarifier stage, treated water is filtered through sand and activated charcoal. This water is then stored and used to irrigate the site's grounds and gardens.

At Group facilities in France, such as the Aramon site and the Merial site in Toulouse, we have implemented new waste water treatment solutions aimed at reducing the quantities of effluent water sent to waste incineration plants.

 Related content online

[Download center](#)

• Waste Management factsheet

## Implementing an advanced water production system

Another important development at Sanofi sites concerns expanding the production of high-quality pharmaceutical water for processes using two-step reverse osmosis instead of resin filtration. With this approach, the quantity of chemicals that would have been required to regenerate resins is reduced. A further benefit is that by-product water from this process may be used in certain utility processes.

This technique has been adopted or is under study in a number of our industrial facilities worldwide. The impact is clear: equipment installed at our Csanyikvolgy site in Hungary has led to an annual decrease in water consumption of up to 20,000m<sup>3</sup> (-12.6%) and furthermore avoids using 50 tons of chemicals per year. A similar project in Amilly, France, has cut water consumption by 5,000m<sup>3</sup> per year, i.e. around -7% of the site's water usage.

## AMILLY, FRANCE

7%  
REDUCTION  
IN TOTAL  
WATER USAGE

CSANYIKVOLGY,  
HUNGARY

12%  
REDUCTION  
IN TOTAL  
WATER USAGE



# PHARMACEUTICALS IN THE ENVIRONMENT

## CHALLENGE

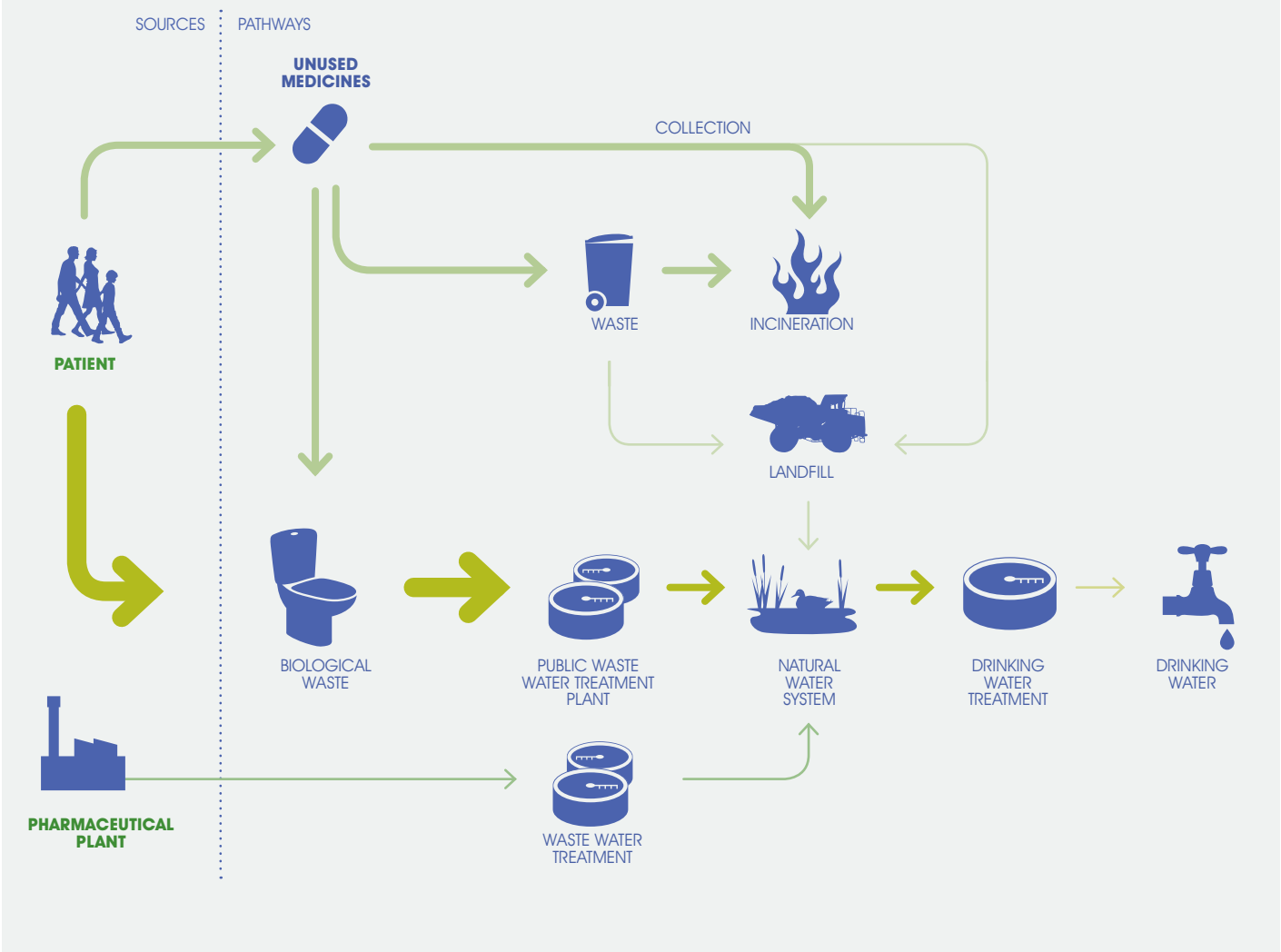
Pharmaceuticals found in the environment due to human activity – such as patients’ use of medicines – are the focus of growing attention. Even in trace amounts, their presence represents a potential environmental concern, and a challenge that Sanofi takes seriously.

## STRATEGIC APPROACH

After pharmaceuticals are absorbed or administered, they are excreted by patients in the same form or they are transformed by the body into metabolites, which may reach the environment through sewers and sewage treatment plants.

There are also other sources of discharge, such as emissions 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).

**Main sources and pathways of pharmaceutical residues in environment (water)**





## PHARMACEUTICALS IN THE ENVIRONMENT

The improvement in analytical methods today has made it possible to detect the presence of an increasing number of pharmaceuticals in the environment. Depending on the substances and where they are found, they may be present in very low concentrations, measured in nanograms or micrograms per liter, even in drinking water.

According to the World Health Organization, current analyses of available data indicate a substantial margin of safety between the very low concentrations of pharmaceuticals that potentially could be consumed in drinking water and the minimum therapeutic doses, suggesting a very low risk to human health.<sup>1</sup>

There is nevertheless a need to improve our understanding of the potential long-term effects of such concentrations on the environment and human health, while considering certain classes of pharmaceutical products such as hormonal substances, cytotoxic drugs and antibiotics.

Since 2006 in Europe and since 1998 in the United States, environmental risk assessments are mandatory for the marketing authorization of new pharmaceuticals.

In anticipation of the potential enhancement of regulations and in response to limited knowledge and growing public concern about the issue of pharmaceuticals in the environment (PIE), Sanofi has developed a specific approach piloted by the Sanofi HSE Direction in line with the Group's HSE Policy and Requirements. Our approach encompasses several initiatives:

- improving the Group's knowledge about the environmental fate and potential impact of our products by conducting both mandatory and voluntary environmental risk assessments on new and marketed products under the guidance of an internal group of experts, the ECOVAL committee;
- developing general knowledge about the issue of pharmaceuticals in the environment (PIE), working in close collaboration with stakeholders (pharmaceutical trade groups, academia, etc.); and
- supporting take-back programs of unused medicines to promote their proper disposal and issuing recommendations for consumers about what to do with unused medicines.

In addition, we provide all our affiliates with recommendations on how to implement local take-back programs to facilitate the proper disposal of unused medicines.

*The Group has set up a system enabling commercial affiliates to share best practices regarding the worldwide implementation of take-back programs for unused medicines or local support for such initiatives.\**

#### Related content online

##### [Download center](#)

- HSE Policy
- Health Safety and Environmental Management System factsheet
- Disposal of unused medicines factsheet
- REACH – Registration Evaluation Authorization and Restriction of Chemicals factsheet

#### Related content in this report

**p78** [Read more about our efforts to reduce water pollutants. see the section on water management](#)

### THE ECOVAL COMMITTEE

Created by the HSE and CSR Direction in 2005, the ECOVAL Committee is in charge of addressing stakeholder concerns surrounding the potential impact of our products on the environment. Members include environmental experts and representatives of product stewardship, science and medical affairs, regulatory affairs, and other Sanofi departments.

The role of the committee is to:

- help Sanofi to protect the environment through the best possible knowledge of our products' environmental impact; and
- address external requests, in particular those linked to regulatory requirements, and to prepare in anticipation of the evolution of such requirements.

<sup>1</sup> World Health Organization, *Pharmaceuticals in drinking-water* information sheet. See [http://www.who.int/water\\_sanitation\\_health/emerging/info\\_sheet\\_pharmaceuticals/en/index.html](http://www.who.int/water_sanitation_health/emerging/info_sheet_pharmaceuticals/en/index.html)

\* This statement was reviewed by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Reference, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## PHARMACEUTICALS IN THE ENVIRONMENT

## ACHIEVEMENTS

**Meeting and exceeding regulatory requirements**

Currently, an environmental risk assessment must be carried out for each new drug marketed in Europe and the United States. In addition to regulatory compliance, we are voluntarily assessing our products introduced to the market prior to these regulations as well. To date, 26 compounds have been subject to voluntary environmental risk assessment by Sanofi. These evaluations, which focus on pharmaceuticals in the environment following use by patients, have not shown any significant environmental risk at the expected environmental concentration.

**A program to assess products with biological activity**

Within the scope of this program, Sanofi developed an initial list (to be expanded in the future) of 30 compounds based on potential environmental hazard properties and annual production tonnage. We also factored in where these compounds are produced. Our Aramon laboratory determined specific analytical methods for these compounds to study effluents from production sites. In 2012, 30% of Sanofi chemical active pharmaceutical ingredient (API) plants worldwide were reviewed.

We are aiming to define target values to protect the environment for each compound and assessing new technologies to remove products that may have biological activity.

Our program also includes the implementation of practices and technologies for risk reduction and mitigation.

**Collaborative projects****With academia**

2008–2011: collaboration within the scope of two French research programs, in Poitiers and Montpellier.

2012–2013: collaboration with the Israel NGO Peres Center for Peace along with Israeli and Palestinian scientific teams.

**With pharmaceutical companies' associations**

- [PhRMA \(United States\)](#)
- [EFPIA \(Europe\)](#)
- [LEEM \(France\)](#)
- [LIF \(Sweden\)](#)

**Encouraging take-back programs for unused medicines**

We supported the development of take-back programs for unused medicines by Sanofi affiliates in many countries, including Ecuador, Austria, Colombia, Mexico, Germany, Italy, France, Belgium, Brazil, and Greece.

**FOR THE FUTURE**

- By 2015: implementation of an assessment plan concerning products with potential biological activity at 100% of our chemistry sites where selected active pharmaceutical ingredients are manufactured.
- By 2015: definition of environmental target values for 30 compounds.

## PHARMACEUTICALS IN THE ENVIRONMENT

## HIGHLIGHTS

**Two French research programs**

Sanofi participates in scientific research to improve our understanding of pharmaceuticals in the environment. From 2008 to 2011, we took part in projects with two French universities:

- Poitiers University analyzed the efficiency of various oxidative treatments (ozonation, H<sub>2</sub>O<sub>2</sub>/UV, chlorination) to remove pharmaceuticals from water. The results revealed differences in the efficiency of different oxidative treatments. For some compounds, an increase in toxicity was observed during and after treatment. These results confirm the need to assess other wastewater treatment technologies.
- Montpellier University studied the environmental fate of some pharmaceuticals in coastal waters, with a particular focus on bioaccumulation in mollusks, which are used in biomonitoring programs. Results showed different bioconcentration profiles depending on the compounds. Further research is needed to better understand these processes in mollusks.

Findings from both projects were published in scientific journals, and additional publications are currently in preparation.

**A Palestinian-Israeli research program**

We are also taking part in a 2012–2013 research project managed by the NGO Peres Center for Peace. This project brings together Israeli and Palestinian researchers and graduate students from the Technion Institute of Technology in Haifa and Al-Quds University near Jerusalem. It aims to assess the efficiency of biological treatments, adsorption and membrane treatments (reverse osmosis/nanofiltration) to remove APIs from wastewater from both domestic and industrial sources.

The teams have reported initial promising findings from this study, which may ultimately help contribute to improving the quality of drinking and irrigation water across the Middle East, an area of high water stress. If the results are confirmed and published, these technologies could potentially be used for effluents from pharmaceutical sites.

**Controlling the environmental impact of our sites**

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. Sanofi worked closely with the authorities, water agencies, ONEMA, INERIS, ecological associations, etc. to understand the cause of the observed effects. We developed a specific analytical method that has been implemented to monitor the potential presence of substances responsible for the effects observed in the fish. In cooperation with a leading water treatment company and following preliminary treatment studies, we further tested a dedicated technology based on active carbon adsorption with pilot equipment on site. Encouraging results suggest that this technology potentially could be considered for use on an industrial scale at the site.

**Promoting the proper disposal of unused medicines in Greece**

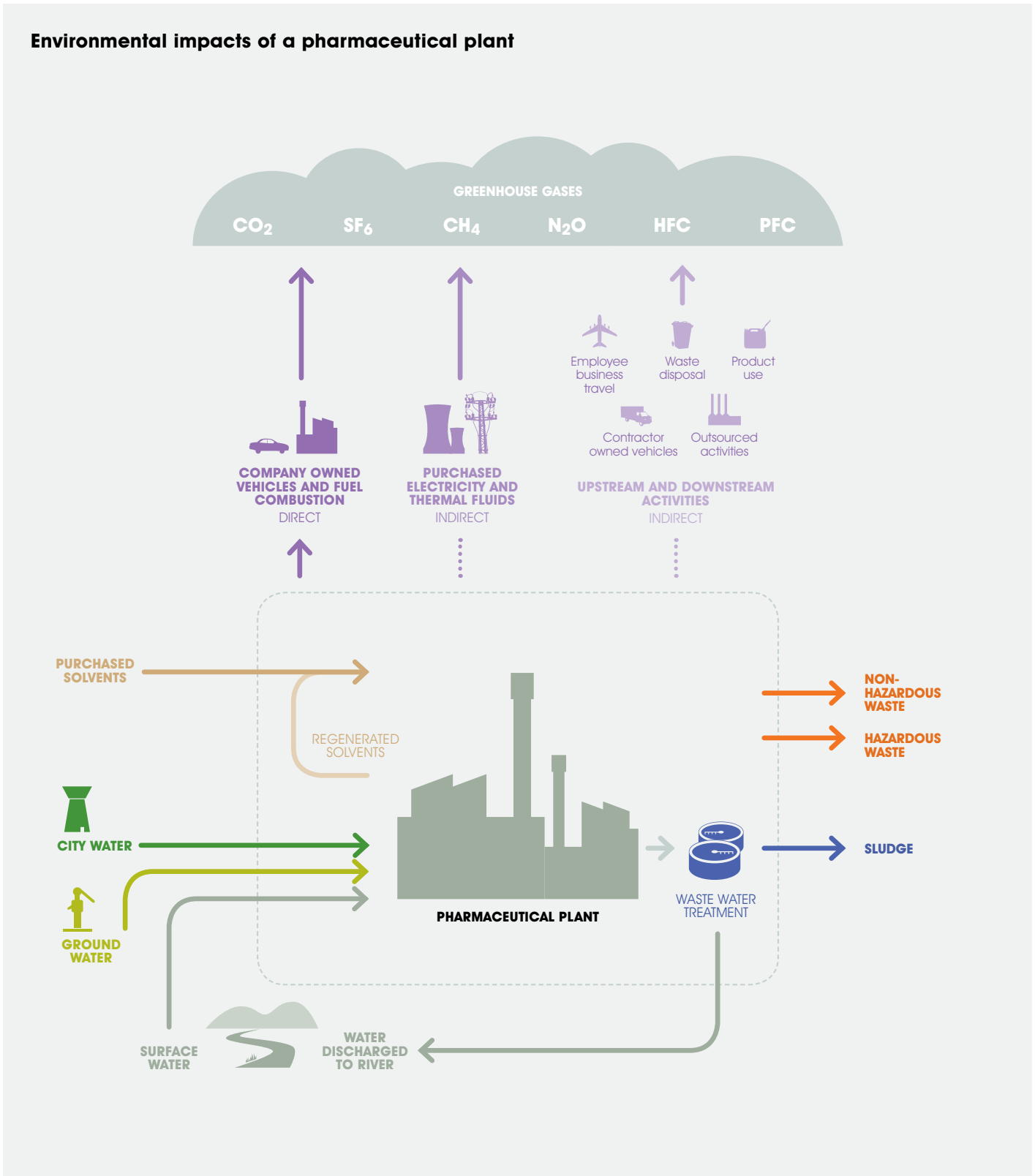
In Greece, Sanofi is the first and only healthcare company to support the collection and safe destruction of unused or expired medicines. Our Xapi-End initiative, launched in 2010, was developed under the auspices of the National Organization of Medicines, Ministry of Environment, the city of Athens, and the Athens Chamber of Commerce. In the Athens area, 22 collection and information points have been set up, making it possible to collect 1.5 tons of medicines. In addition, 100,000 people have received information about this environmental issue via a variety of communication tools.

In 2012, this project served as the basis for the development of an official state program in 12,000 Greek pharmacies.

The Xapi-End initiative received the special award for the best project across the four CSR pillars during the Sanofi CSR Awards ceremony in 2012.

PHARMACEUTICALS IN THE ENVIRONMENT

Environmental impacts of a pharmaceutical plant



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# OUR CSR PERFORMANCE



## OUR INDICATORS

Description	Grenelle II GRI (French law)	Unit	2011	2012
<b>PATIENT</b>				
<b>Access to healthcare</b>	<b>Total number of access to healthcare ongoing programs (worldwide)</b>	<b>number</b>	<b>N/A</b>	<b>232</b>
	Estimated number of beneficiaries of above programs, which included:	number	N/A	277,287,355
	– number of healthcare professionals trained	number	N/A	398,354
	– number of individuals targeted by awareness campaigns	number	N/A	199,118,787
	– number of patients receiving diagnosis, vaccination or treatment	number	N/A	77,770,214
<b>Innovation</b>	<b>Research and development (in our portfolio)</b>			
	Number of New Molecular Entities (NME) and vaccines candidates in clinical development	number	N/A	64
	Number of NME projects or vaccines candidates that are in Phase III studies or have been submitted to the health authorities for potential marketing approval	number	N/A	17
	Number of NMEs that are being developed in collaborations	number	N/A	31
<b>Product quality and safety</b>	Number of internal audits	number	N/A	238
	Number of class 1 recall <sup>1</sup>	number	N/A	1
	Number of class 2 recall <sup>2</sup>	number	N/A	21
	<b>% of customer complaints treated in due time</b> (a maximum of 45 calendar days to close a complaint) <sup>3</sup>	%	N/A	63.6%
<b>Fight against counterfeit drugs</b>	Number of seizures	number	2,400,000	3,750,000
	Number of websites shut down	number	13,500	18,000
	Number of people arrested	number	55	80
	Number of products analyzed by the Sanofi Central Anti-Counterfeit Laboratory teams since 2008	number	3,000	4,000
	<b>Number of people Sanofi has trained about counterfeit drugs</b>	<b>number</b>	<b>5,380</b>	<b>10,000</b>
	– Number of employees	number	1,581	4,000
	– Public health agents, customs officials and police officers from around the world	number	3,799	6,000

Description	Grenelle II GRI (French law)	Unit	2011	2012
<b>ETHICS</b>				
<b>Human rights</b>	<b>Training indicators</b>			
	Employees trained in human rights since 2010 <sup>4</sup>	3.E number	68	76
<b>Supplier-related risks</b>	<b>Total number of suppliers identified in 2012 to undergo CSR evaluation</b>	<b>3.C, 3.E number</b>		<b>354</b>
	Number of supplier evaluations completed	3.C, 3.E number		161
	– number of suppliers evaluated that met our CSR requirements	3.C, 3.E number		96
	– number of suppliers that must initiate corrective action plans in 2013	3.C, 3.E number		65
	Number of suppliers for which the evaluation is on-going	3.C, 3.E number		193
<b>Corruption</b>	Percentage of business units analyzed for risk of corruption	SO2 3.D %	100%	100%
	Total number of people trained through e-learning courses <sup>5</sup>	SO3 3.D number	76,000 <sup>5</sup>	85,000
	Percentage of employees trained in anti-corruption policies <sup>6</sup>	SO3 3.D %	67%	76%
<b>Compliance</b>	<b>Total number of calls received on the Sanofi hotline</b>	<b>SO8 3.D number</b>	<b>388</b>	<b>533</b>
	Number of calls investigated (meeting the definition of a potential violation)	SO8 3.D number	167	230
	– leading to sanctions (from warning letters to contract termination)	SO8 3.D %	15%	25%
<b>Clinical trials</b>	<b>Total number of clinical trials</b>	<b>number</b>	<b>N/A</b>	<b>403</b>
	by Sanofi Pharma and Genzyme	number	N/A	268
	by Pasteur	number	N/A	135
	<b>Number of subjects enrolled</b>	<b>number</b>	<b>N/A</b>	<b>54,822</b>
	for Sanofi Pharma and Genzyme	number	N/A	32,372
	for Sanofi Pasteur (vaccines)	number	N/A	22,450

1 Class 1 recall: defects that are potentially life threatening or could cause risk to health – EMA definition.

2 Class 2 recall: defects that could cause illness or mistreatment, but are not Class 1 – EMA definition.

3 Within scope of Sanofi Pharma and Genzyme.

4 Cumulative 2011–2012.

5 As of mid-February 2012.

6 Training to the Code of Ethics, which includes sections about corruption.

## OUR INDICATORS

		Grenelle II			2011	2012
Description		GRI (French law)	Unit			
<b>PEOPLE</b>						
<b>Workforce</b>	<b>Employees under contract<sup>7</sup></b>	<b>LA1</b>	<b>1.A</b>	<b>number</b>	<b>113,719</b>	<b>111,974</b>
	Employees under contract include all employees who have a contract with Sanofi, including interns and apprentices					
	<b>Workforce by employment type</b>					
	Permanent contract (PC)	LA1	1.B	%	92.8%	91.1%
	Fixed-term contract (FTC)	LA1	1.B	%	7.2%	8.9%
	Permanent/fixed-term ratio	LA1	1.B	%	7.8%	9.8%
	Part time <sup>8</sup>	LA1	1.B	number	4,516	4,655
	Temporary employees (full-time equivalent)	LA1	1.B	number	5,736	5,288
	<b>Workforce by region</b>					
	Europe	LA1	1.A	%	51%	50%
	– France	LA1	1.A	%	25%	25%
	North America	LA1	1.A	%	18%	17%
	Other countries	LA1	1.A	%	31%	33%
	– Pacific Asia	LA1	1.A	%	N/A	17%
	– Latin America	LA1	1.A	%	N/A	9%
	– Japan	LA1	1.A	%	N/A	3%
	– Africa	LA1	1.A	%	N/A	3%
	– Middle East/Central Asia	LA1	1.A	%	N/A	1%
	<b>Workforce by function</b>					
	Sales force	LA1		%	28.9%	28.8%
	R&D	LA1		%	16.6%	15.2%
	Production	LA1		%	39.0%	40.2%
	Marketing and support functions	LA1		%	15.5%	15.7%
	<b>Workforce by activity</b>					
	Pharmaceuticals			%	83.8%	83.1%
	Vaccines worldwide			%	11.3%	11.5%
	Animal health worldwide			%	5.0%	5.4%
	<b>New hires/departures</b>					
	Total number of new hires	LA2	1.A	number	8,659	11,874*
	Total number of departures	LA2	1.A	number	11,354	12,947*
	Resignations	LA2	1.A	%	N/A	27%
	Terminations	LA2	1.A	%	N/A	31%
	End of fixed-term contracts	LA2	1.A	%	N/A	27%
	Retirement	LA2	1.A	%	N/A	8%
<b>Training</b>	<b>Average hours of training per year per employee, France</b>	<b>LA10</b>	<b>1.E</b>	<b>hours</b>	<b>29.5</b>	<b>27.8</b>
	<b>People training</b>					
	France			number	23,288	24,146
	Germany			number	N/A	10,235
	U.S.			number	N/A	8,500
	Brazil			number	N/A	4,760
	<b>Specialized training by type</b>					
	HSE training (number of hours of training)		1.E	hours	N/A	430,000

		Grenelle II			2011	2012
Description		GRI (French law)	Unit			
	Road safe training (number of hours of training)	1.E	hours		N/A	42,750
	<b>Measuring employee commitment</b> (number of employees taking part in survey)	LA10	number		N/A	25,000
<b>Absenteeism</b>	<b>Number of days absent, France<sup>9</sup></b>	LA7	1.B	number	367,423	290,124
	Illness (Fr)	LA7	1.B	number	284,485	215,108
	Occupational and commute-related injuries (Fr)	LA7	1.B	number	9,856	9,400
	Maternity and/or paternity (Fr)	LA7	1.B	number	73,082	65,616
<b>Occupational health – safety</b>	<b>Lost time injury frequency rate<sup>10</sup></b>					
	Lost time injury rate (LTIR) worldwide	LA7	1.D	%	1.8%	1.8%*
	Lost time injury rate (LTIR) France	LA7	1.D	%	3.3%	3.0%
	LTIR for independent contractors	LA7	1.D	%	2.9% <sup>11</sup>	2.2%
	<b>LTIR by function</b>					
	Research and development	LA7	1.D	%	0.9%	1.5%
	Industrial affairs	LA7	1.D	%	1.6%	1.3%
	Global operations	LA7	1.D	%	2.1%	2.1%
	Vaccines	LA7	1.D	%	1.2%	1.6%
	Support functions	LA7	1.D	%	1.7%	1.5%
	Temporary contractors	LA7	1.D	%	2.0%	2.1%
	Genzyme	LA7	1.D	%	N/A	2.5%
	Meril	LA7	1.D	%	2.6%	2.3%
	<b>Severity rate trend</b>	LA7	1.D		Decreased	Remained stable
	<b>Number of motor vehicle accidents (MVA)<sup>12</sup></b>	LA7	1.D	number	6,238	5,722
	Total number of medical sales representatives vehicles	LA7	1.D	number	25,335	25,467
	including: total number of motorcycles	LA7	1.D	number	2,756	3,259
	Motor vehicle accidents (MVA) rate	LA7	1.D	%	24.8%	22.5%
	Motor vehicle-related LTIR	LA7	1.D	number	1.3	1.6
	Fatalities	LA7	1.D	number	0	0

7 The total number of employees contributing to Sanofi's business activity is 119,131 in 2012, including employees under contract, temporary employees, and third-party outside sales forces.

8 Part time: number of employees working part time.

9 These data take into account Sanofi's new entities in France (Genzyme and Meril). They do not include absences authorized by the company: unpaid leave, parental leave, sabbatical leave, business creation leave, leave for family-related responsibility, and unworked notice period.

10 The lost time injury frequency rate (LTIR) is defined as the number of incidents 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.

11 Frequency rates have been adjusted in 2012 by eliminating injuries dismissed by regulatory authorities including injuries reported late, and changes in the scope of reporting.

12 2011–2012 figures have been adjusted to include motorcycle accidents.

\* Indicators identified by an asterisk (\*) were the focus of an in-depth review by our Statutory Auditors, who expressed an assurance specifically concerning these data as part of their review of the Document de Référence, which addresses the French Grenelle II law requirement. Their assurance statement, describing the work they performed as well as their comments and conclusions, is available at the end of this report.

## OUR INDICATORS

Description	Grenelle II		Unit	2011	2012
	GRI (French law)				
<b>Occupational health – diseases</b>	<b>LA7</b>	<b>1.D</b>	<b>number</b>	<b>88<sup>13</sup></b>	<b>94</b>
<b>Total occupational diseases reported</b>					
<b>Occupational diseases reported by type</b>					
<b>Total by chemical agent</b>	<b>LA7</b>	<b>1.D</b>	<b>number</b>	<b>7</b>	<b>3</b>
by respiratory disease	LA7	1.D	number	4	3
by skin disease	LA7	1.D	number	1	0
by cancer or malignant blood disease	LA7	1.D	number	2	0
by other illnesses caused by chemical agents	LA7	1.D	number	0	0
<b>Total by physical agent</b>	<b>LA7</b>	<b>1.D</b>	<b>number</b>	<b>80</b>	<b>90</b>
by upper limb disorder <sup>14</sup>	LA7	1.D	number	72	78
by neck, back, lower limb disorder <sup>14</sup>	LA7	1.D	number	7	12
by ear disorder	LA7	1.D	number	1	0
by other diseases caused by a physical agent	LA7	1.D	number	0	0
<b>Disease caused by a biological agent</b>	<b>LA7</b>	<b>1.D</b>	<b>number</b>	<b>1</b>	<b>1</b>
<b>Other</b>	<b>LA7</b>	<b>1.D</b>	<b>number</b>	<b>0</b>	<b>0</b>
<b>Diversity</b>	<b>LA8</b>	<b>1.A</b>	<b>%</b>	<b>45.7</b>	<b>45.4</b>
<b>Proportion of female employees in the total workforce</b>					
People managers <sup>15</sup>	LA8		%	45%	38.7%
Key positions <sup>16</sup>	LA8		%	39%	39%*
Senior Leadership Team	LA8		%	16% <sup>17</sup>	17.3% <sup>18</sup>
Senior management <sup>19</sup>	LA8		%	11.1% (6/54)	10.6% (5/47)
Board of Directors	LA8		%	20%	20%
<b>Workforce by age</b>					
Less than 21 years	1.A	%		0.3%	0.3%
21 to 30 years	1.A	%		18.0%	18.0%
31 to 40 years	1.A	%		34.4%	33.6%
41 to 50 years	1.A	%		29.9%	30.1%
51 to 60 years	1.A	%		15.9%	16.3%
Over 60 years	1.A	%		1.5%	1.6%
<b>Distribution of employees under contract worldwide based on seniority</b>					
> 35 years of seniority		%		1.6%	1.6%
31 to 35 years		%		2.6%	2.8%
26 to 30 years		%		4.7%	4.7%
21 to 25 years		%		7.2%	7.5%
16 to 20 years		%		8.7%	8.7%
11 to 15 years		%		13.3%	14.5%
6 to 10 years		%		20.9%	21.5%
1 to 5 years		%		31.9%	28.5%
< 1 year		%		9.1%	10.3%
<b>Disabled employees in the workforce</b>			<b>number</b>	<b>1,758</b>	<b>1,901</b>

Description	Grenelle II		Unit	2011	2012
	GRI (French law)				
<b>PLANET</b>					
<b>Materials</b>					
Solvents used	EN1	2.C	number	216,882	180,576
Including % regenerated	EN2	2.B, 2.C	%	64%	60%
<b>Energy</b>	<b>EN3</b>	<b>2.C</b>	<b>GJ</b>	<b>18,665,699</b>	<b>18,204,006*</b>
<b>Total energy consumption</b>					
by natural gas	EN3	2.C	GJ	8,877,661	8,721,345
by electricity	EN3	2.C	GJ	7,214,812	6,940,957
by liquid hydrocarbon (fuel) excluding car fleet	EN3	2.C	GJ	836,960	854,780
by coal	EN3	2.C	GJ	0	0
by other (steam, thermal fluids, etc.)	EN3	2.C	GJ	1,736,266	1,679,915
by renewable fuels <sup>20</sup>		2.C	GJ		7,009
Total fuel consumption by medical sales fleet vehicles (In Gigajoules Higher Heating Value – GJHHV)	EN3	2.C	GJHHV	2,441,768	2,156,778
<b>Water</b>	<b>EN8</b>	<b>2.C</b>	<b>m<sup>3</sup></b>	<b>55,010,611</b>	<b>49,654,399*</b>
<b>Total water consumption</b>					
by surface water	EN8	2.C	m <sup>3</sup>	23,597,685	17,863,051
by well water	EN8	2.C	m <sup>3</sup>	21,486,370	22,451,483
by city water	EN8	2.C	m <sup>3</sup>	9,926,556	9,339,865
<b>Percentage reduction (baseline year: 2010)</b>	<b>EN8</b>	<b>2.C</b>	<b>%</b>	<b>-4.7%</b>	<b>-13.96%</b>
<b>Percentage of sites located in water scarcity and water stress areas</b>	EN9	2.C	%	N/A	42%

13 Occupational diseases reported in 2011 and 2012 have been adjusted by eliminating diseases dismissed by regulatory authorities, including diseases reported late, and changes in the scope of reporting.

14 Musculoskeletal disorders.

15 The definition of "manager" changed in 2012, from a hierarchical definition to one that indicates direct reports, which explains the discrepancy in the 2011 and 2012 figures.

16 Positions of high responsibility considered to be essential to Sanofi's strategic objectives.

17 Composed of 250 senior managers in 2011.

18 Composed of 272 senior managers in 2012.

19 Executive Committee and Global Leadership Team.

20 Renewable fuels are only relevant for biomass, hydrogen, and other renewable fuels purchased and burnt on-site and do not include energy used by car.

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## OUR INDICATORS

	Description	Grenelle II		Unit	2011	2012
		GRI (French law)				
<b>Biodiversity<sup>21</sup></b>	Number of plant substances on which the Group conducted research	EN11	2.E	number	152 between 2003 and 2010	
	Number of natural plant substances studied by the Group	EN11	2.E	number	647 between 2003 and 2010	
	Percentage of plants held by the Group appearing on the IUCN (International Union for Conservation of Nature) Red List of Threatened Species	EN15	2.E	%	1.3%	N/A
<b>Emissions to air</b>	<b>Total CO<sub>2</sub> emissions</b>					
	by fossil fuel (direct CO <sub>2</sub> )	EN16	2.D	tCO <sub>2</sub> eq	507,973	501,222*
	by production of electricity and steam (indirect CO <sub>2</sub> )	EN16	2.D	tCO <sub>2</sub> eq	666,966	635,807*
	by medical sales fleet vehicles (estimated)	EN16	2.D	tCO <sub>2</sub> eq	160,945	144,342
	<b>Percentage of the Group vehicles compliant with the 120g CO<sub>2</sub>/km maximum defined by Sanofi</b>			%	N/A	24.6%
	<b>Transporting medicines</b>					
	CO <sub>2</sub> emissions related to the transport and distribution of medicines	EN29, EN16	2.D	tCO <sub>2</sub> eq	84,391	81,931
	CO <sub>2</sub> emitted by pallet transported	EN29, EN16	2.D	kg of CO <sub>2</sub> /pallet transported	157.7	141
	<b>Total waste generated by operations</b>			<b>tCO<sub>2</sub> eq</b>	<b>N/A</b>	<b>254,343</b>
	<b>Purchased goods and services (limited to packaging materials and solvents)</b>	<b>EN26</b>		<b>tCO<sub>2</sub> eq</b>	<b>N/A</b>	<b>348,680</b>
	<b>Use of sold products</b>	<b>EN26</b>		<b>tCO<sub>2</sub> eq</b>	<b>N/A</b>	<b>6,311</b>
	<b>End-of-life treatment of sold products</b>	<b>EN26</b>		<b>tCO<sub>2</sub> eq</b>	<b>N/A</b>	<b>109,408</b>
	<b>Fuel and energy-related activities</b>			<b>tCO<sub>2</sub> eq</b>	<b>N/A</b>	<b>122,253</b>
<b>Other emissions to air</b>						
VOC emissions	EN20	2.B	tons	2,267	2,563*	
NOx emissions	EN20	2.B	tons	404	402*	
SOx emissions	EN20	2.B	tons	200	213*	
ODS emissions	EN19	2.B	tCFC-11 eq	<1	<1	
<b>Emissions to water</b>	<b>Wastewater discharge</b>	EN21	2.B			
	by chemical oxygen demand (COD)	EN21	2.B	tons	2,974	3,041
	by total suspended solids (TSS)	EN21	2.B	tons	543	706
	by nitrogen	EN21	2.B	tons	510	352

	Description	Grenelle II		Unit	2011	2012
		GRI (French law)				
<b>Product impact assessment</b>	Percentage of chemical sites with micro-pollutant action plan in place	EN26		%	N/A	30%
	No. of molecules assessed voluntarily	EN26		number	N/A	26
<b>Waste</b>	<b>Total hazardous waste</b>	<b>EN22</b>	<b>2.B</b>	<b>tons</b>	<b>127,066</b>	<b>139,365*</b>
	Recycled	EN22	2.B	tons	20,734	22,545
	Incinerated (with thermal recovery)	EN22	2.B	tons	40,067	49,329
	Incinerated (without thermal recovery)		2.B	tons	65,247	65,140
	Sent to authorized landfill	EN22	2.B	tons	1,018	2,351
	<b>Total non-hazardous waste</b>	<b>EN22</b>	<b>2.B</b>	<b>tons</b>	<b>115,834</b>	<b>106,589*</b>
	Recycled	EN22	2.B	tons	72,525	64,359
	Incinerated (with thermal recovery)	EN22	2.B	tons	15,009	16,673
Incinerated (without thermal recovery)	EN22	2.B	tons	8,438	7,245	
Sent to authorized landfill	EN22	2.B	tons	19,862	18,312	
<b>Expenditures/investment</b>	<b>Total remediation cost</b>	<b>EN30</b>	<b>2.A</b>	<b>euros</b>	<b>41,000,000</b>	<b>45,000,000</b>
	Provisions for environmental risks and remediation	EN30	2.A	euros	764,000,000	728,000,000

<sup>21</sup> In its position paper on biodiversity Sanofi acknowledges that each country has sovereignty over its natural resources and traditional knowledge for their use, and commits to supporting internal and/or external initiatives against biopiracy.\*\*

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# GLOBAL REPORTING INITIATIVE

This report is aligned with the Global Reporting Initiative (GRI) G3.1 Sustainability Reporting Guidelines, at a GRI-checked application level of B+. To locate the elements and information contained within the guidelines, use the index below.

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Report Application Level	C	C+	B	B+	A	A+
<b>G3 Profile Disclosures</b> OUTPUT	Report on: 1.1 2.1 - 2.10 3.1 - 3.8, 3.10 - 3.12 4.1 - 4.4, 4.14 - 4.15	Report Externally Assured	Report on all criteria listed for Level C plus: 1.2 3.9, 3.13 4.5 - 4.13, 4.16 - 4.17	Report Externally Assured	Same as requirement for Level B	Report Externally Assured
<b>G3 Management Approach Disclosures</b> OUTPUT	Not Required		Management Approach Disclosures for each Indicator Category		Management Approach Disclosures for each Indicator Category	
<b>G3 Performance Indicators &amp; Sector Supplement Performance Indicators</b> OUTPUT	Report on a minimum of 10 Performance Indicators, including at least one from each of: Economic, Social and Environmental.		Report on a minimum of 20 Performance Indicators, at least one from each of Economic, Environmental, Human rights, Labor, Society, Product Responsibility.		Report on each core G3 and Sector Supplement* Indicator with due regard to the Materiality Principle by either: a) reporting on the Indicator or b) explaining the reason for its omission.	

\*Sector supplement in final version

**GRI index**

LEVEL OF REPORTING: ● FULL ○ PARTIAL

Strategy and analysis		
1.1	Statement from the most senior decision-maker	●
1.2	Description of key impacts, risks, and opportunities	●
2.1	Name of the organization	●
2.2	Primary brands, products, and/or services	●
2.3	Operational structure of the organization	●
2.4	Location of organization's headquarters	●
2.5	Number of countries where the organization operates	●
2.6	Nature of ownership and legal form	●
2.7	Markets served	●
2.8	Scale of the reporting organization	●
2.9	Significant changes during the reporting period	●
2.10	Awards received in the reporting period	●
3.1	Reporting period	●
3.2	Date of most recent previous report (if any)	●

3.3	Reporting cycle (annual, biennial, etc.)	●
3.4	Contact point	●
3.5	Process for defining report content	●
3.6	Boundary of the report	●
3.7	Limitations on the scope or boundary of the report	●
3.8	Basis for reporting on joint ventures, subsidiaries etc.	●
3.9	Data measurement	●
3.10	Re-statements of information	●
3.11	Significant changes from previous reporting periods	●
3.12	GRI table	●
3.13	Policy and practice with regard to external assurance	●
4.1	Governance structure of the organization	●
4.2	Indicate whether the Chair of the highest governance body is also an executive officer	●
4.3	Number and gender of members of the highest governance body that are independent and/or non-executives	●



GLOBAL REPORTING INITIATIVE

LEVEL OF REPORTING: ● FULL ☉ PARTIAL

4.4	Mechanisms for shareholders and employees to provide recommendations or direction to the highest governance body	●
4.5	Linkage between compensation and the organization's performance	●
4.6	Processes in place for the highest governance body to ensure conflicts of interest are avoided	●
4.7	Composition, qualifications, and expertise of the members of the highest governance body and committees	●
4.8	Internally developed statements of mission or values, codes of conduct, and principles	●
4.9	Procedures of the highest governance body for overseeing the organization's identification and management of economic, environmental, and social performance	●
4.10	Processes for evaluating the highest governance body's own performance	●
4.11	Whether and how the precautionary approach or principle is addressed	●
4.12	Externally developed economic, environmental, and social charters, principles, or other initiatives	●
4.13	Memberships	●
4.14	List of stakeholder groups	●
4.15	Basis for identification and selection of stakeholders	●
4.16	Approaches to stakeholder engagement	●
<b>Disclosures on management approach</b>		
	Economic performance	●
	Market presence	●
	Indirect economic impacts	●
	Materials	●
	Energy	●
	Water	●
	Biodiversity	●
	Emissions, effluents, and waste	●
	Products and services	●
	Compliance	●
	Transport	●
	Overall	●
	Employment	●
	Labor/management relations	●

Occupational health and safety	●
Training and education	●
Diversity and equal opportunity	●
Equal remuneration for women and men	●
Investment and procurement practices	●
Non-discrimination	●
Freedom of association and collective bargaining	●
Child labor	●
Prevention of forced and compulsory labor	●
Security practices	●
Indigenous rights	●
Assessment	●
Remediation	●
Local communities	☉
Corruption	●
Public policy	●
Anti-competitive behavior	●
Customer health and safety	●
Product and service labeling	●
Marketing communications	●
Customer privacy	●
Compliance	●

<b>Economic</b>		
EC1	Direct economic value generated and distributed	☉
EC2	Financial implications and other risks and opportunities due to climate change	●
EC3	Coverage of the organization's defined benefit plan obligations	●
EC6	Policy, practices, and proportion of spending on locally based suppliers	☉
EC8	Infrastructure investments and services provided primarily for public benefit	●
EC9	Understanding and describing significant indirect economic impacts	●

<b>Environmental</b>		
EN1	Materials used by weight or volume	☉
EN2	Materials used that are recycled input materials	☉
EN3	Direct energy consumption by primary energy source	●
EN7	Initiatives to reduce indirect energy consumption	☉

GLOBAL REPORTING INITIATIVE

LEVEL OF REPORTING: ● FULL ☉ PARTIAL

<b>EN8</b>	Total water withdrawal by source	●
<b>EN9</b>	Water sources affected by withdrawal of water	●
<b>EN11</b>	Location and size of land in, or adjacent to, protected areas and areas of high biodiversity	☉
<b>EN12</b>	Impacts of activities, products, and services on biodiversity in protected areas	●
<b>EN13</b>	Habitats protected or restored	☉
<b>EN14</b>	Plans for managing impacts on biodiversity	☉
<b>EN15</b>	IUCN Red List species and national conservation list species	☉
<b>EN16</b>	Total direct and indirect greenhouse gas emissions	●
<b>EN17</b>	Other relevant indirect greenhouse gas emissions	●
<b>EN18</b>	Initiatives to reduce greenhouse gas emissions	●
<b>EN19</b>	Emissions of ozone-depleting substances by weight	☉
<b>EN20</b>	NOx, SOx, and other significant air emissions	●
<b>EN21</b>	Total water discharge by quality and destination	●
<b>EN22</b>	Total weight of waste by type and disposal method	●
<b>EN23</b>	Total number and volume of significant spills	☉
<b>EN26</b>	Initiatives to mitigate environmental impacts of products and services	●
<b>EN28</b>	Fines and non-monetary sanctions	●
<b>EN29</b>	Environmental impacts of transporting products and other goods and materials	●
<b>EN30</b>	Environmental protection expenditures and investments	●
<b>Social: labor practices and decent work</b>		
<b>LA1</b>	Total workforce	☉
<b>LA2</b>	New employee hires and employee turnover	☉
<b>LA4</b>	Collective bargaining agreements	●
<b>LA7</b>	Rates of injury, occupational diseases, lost days, and absenteeism, and number of fatalities	☉
<b>LA8</b>	Education, training, counseling, prevention, and risk-control programs in place regarding serious diseases	☉
<b>LA10</b>	Average hours of training	☉
<b>LA11</b>	Programs for skills management and lifelong learning	☉

<b>LA12</b>	Employees receiving regular performance and career development reviews	●
<b>LA13</b>	Composition of governance bodies and breakdown of employees	☉
<b>Social: human rights</b>		
<b>HR1</b>	Investment agreements and contracts that include human rights concerns or screening	☉
<b>HR2</b>	Significant suppliers, contractors, and other business partners that have undergone human rights screening	●
<b>HR3</b>	Employee training on policies and procedures concerning human rights	☉
<b>HR4</b>	Total number of incidents of discrimination and actions taken	☉
<b>HR5</b>	Right to exercise freedom of association and collective bargaining	☉
<b>HR6</b>	Risk for incidents of child labor	☉
<b>HR7</b>	Risk for incidents of forced or compulsory labor	☉
<b>HR10</b>	Human rights reviews and/or impact assessments	☉
<b>Social: society</b>		
<b>SO1</b>	Local community engagement, impact assessments, and development programs	☉
<b>SO3</b>	Employees trained in organization's anti-corruption policies and procedures	●
<b>SO5</b>	Public policy positions and participation	●
<b>SO7</b>	Anti-competitive behavior, anti-trust, and monopoly practices and their outcomes	☉
<b>SO8</b>	Fines and non-monetary sanctions	☉
<b>Social: product responsibility</b>		
<b>PR1</b>	Life cycle stages in which health and safety impacts of products and services are assessed	●
<b>PR2</b>	Incidents of non-compliance with regulations and voluntary codes concerning health and safety impacts of products and services	●
<b>PR3</b>	Type of product and service information required by procedures	☉
<b>PR5</b>	Practices related to customer satisfaction	●
<b>PR6</b>	Programs for adherence to laws, standards, and voluntary codes related to marketing communications	●

# REPORTING METHODOLOGY

## HOW CORPORATE SOCIAL RESPONSIBILITY INFORMATION IS REPORTED: METHODOLOGICAL NOTE

### Scope of consolidation

Unless otherwise specified:

- HR data are consolidated for all Group companies worldwide that are fully consolidated, regardless of their activity (industrial or research sites, commercial affiliates, administrative headquarters);
- at the end of 2012, health and safety data (occupational accidents and injuries) covered the same scope; and
- environmental data (including spending and investments) are consolidated for all industrial and research sites. Environmental impact measured as CO<sub>2</sub> emissions from all company vehicles includes all Pharmaceutical Operations affiliates with the exception of Genzyme. The environmental impact of administrative headquarters locations is not included within this scope.

Data for Merial were included in consolidated Sanofi data as of December 31, 2012. Merial has 17 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.).

### Changes in scope

Within the Group, changes in scope (new sites, site closings, transfers of activity) between 2011 and 2012 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 has 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 across the entire Group: definitions, methodological principles, calculation formulae and emission factors. In addition, Sanofi has adopted standard data collection tools:

- **Social data:** as of 2012, Convergence – Sanofi's global HR data platform – covers almost all of Sanofi's workforce. The platform was launched in 2011 to facilitate managing personnel, implementing processes, and providing managers and employees with access to a wide array of HR information and tools. In 2012, the quality of Convergence data was enhanced through the implementation of a data control process.
- **Safety data:** the MSRS system makes it possible to collect safety data for Sanofi for the entire scope in 2012.
- **Environmental data:** the GREEN tool enabled the consolidation of all 2012 Sanofi data contained in the report.

These tools and guidelines are updated and improved on a regular basis. In particular, the Group carried out a hard close in 2012, leading to minimum estimations of data for the last month, either by prorating data for the year or by applying 2011 data values, depending on the indicators.

### Additional information and methodological limits

The methodological principles for certain HSE and labor 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; and
- 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

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 home–workplace commutes 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

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

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

- Emissions in connection with electricity production:
  - for countries other than the United States, emission factors are obtained from the report entitled *CO<sub>2</sub> Emissions from Fuel Combustion 2012 – Highlights*, published by the International Energy Agency (IEA). Emissions in 2012 were estimated on the basis of the most recent emission factors (end of 2010). For the preceding years, emissions for the year “Y” were calculated on the basis of the emission factor for the year “Y-2.”
  - for the United States, the Group refers to GHG Protocol data, which are based on U.S. EPA 2009 data. In the absence of more recent data, the 2009 emission factor is applied to all years (2010, 2011, and 2012) to estimate CO<sub>2</sub> emissions in connection with electricity production in the United States.

## REPORTING METHODOLOGY

- Emissions in connection with the production of steam are calculated on the basis of site-specific factors.
- 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), or on the basis of mileage (in the absence of fuel consumption data) under the conservative assumption of use vehicles in the Euro 1 category.

**Percentage of renewable electricity**

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)**

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%. The classification of volatile organic compounds is based on EU regulations.

**Wastewater discharge**

Data correspond 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**

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.

**Social indicators****Worldwide workforce**

Employees under contract include all employees that have an employment contract (permanent or fixed-term) with a Sanofi Group company as of the last calendar day of the month. Employees under contract are measured in terms of headcount, irrespective of hours worked or their date of hiring during the month.

**Worldwide new hires**

New hires refer to employees hired from outside the Group and do not include movements within the Group, such as international, inter-company or inter-site transfers.

**Worldwide departures**

Departures refer to employees who leave the Group and do not include movements within the Group, such as international, inter-company or inter-site transfers.

For 2012, all intra-Group movements were specifically excluded. For 2011, because data on new hires and departures could not be processed in the same manner as for 2012, the data published includes intra-Group movements. Fixed-term contracts that were converted into permanent contracts were not taken into account for either new hires or departures.

**Percentage of women in key positions**

Data relating to key positions – or positions of high responsibility considered to be essential to Sanofi's strategic objectives – were obtained using eTalent, Sanofi's global talent management system.

**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, which are listed in the Statutory Auditors' assurance report included on page 96 of this document. The report describes the work they performed and includes their comments and conclusions.

Selected HSE and social data published in this report were specifically reviewed by the Statutory Auditors in accordance with the relevant legislation and French professional practices.

# STATUTORY AUDITORS' REPORT

This Statutory Auditors' Disclosure Statement and Limited Assurance Report on corporate social responsibility information, is an extract from the Document de Référence 2012, on which the Statutory Auditors performed their verifications. The CSR qualitative information and consolidated quantitative data verified as part of this verification exercise are also reported on the present report and identified by an asterisk and a footnote.

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

## Statutory Auditors' Disclosure Statement and Limited Assurance Report on corporate social responsibility information

### Financial year ended December 31, 2012

To the Senior Management of Sanofi:

Further to the request received and in our capacity as Sanofi's Statutory Auditors, we hereby present our report on the consolidated corporate social responsibility information presented in the Rapport de Gestion (Management Report) prepared for the financial year ended December 31, 2012 in accordance with the provisions of Article L. 225-102-1 of the French Commercial Code.

### Responsibility of management

The Board of Directors is responsible for preparing a *Rapport de Gestion* containing the consolidated corporate social responsibility information required under Article R. 225-105-1 of the French Commercial Code (hereinafter the "Information"), determined according to the guidelines used by the company (the "Guidelines"), which are available from Sanofi upon request and are summarized in the "How corporate social responsibility information is reported: Methodological note" section of the *Rapport de Gestion*.

### Independence and quality control

Our independence is defined by regulatory requirements, the code of ethics of the profession (*Code de déontologie*) and the provisions of Article L. 822-11 of the French Commercial Code. We maintain a comprehensive system of quality control including documented procedures and policies to ensure compliance with ethical requirements, professional standards, and applicable legal and regulatory requirements.

### Responsibility of the statutory auditors

Based on our work, it is our responsibility to:

- attest that the required Information is included in the *Rapport de Gestion* or, if it is not included, attest that an appropriate explanation for the omission is provided in accordance with Article R. 225-105 of the French Commercial Code and French Decree No. 2012-557 of April 24, 2012 (Disclosure Statement);
- provide limited assurance on whether the Information is fairly presented, in all material respects, in accordance with the Guidelines. (Limited Assurance Report).

In performing our work, we requested the assistance of our corporate social responsibility experts.

### 1. Disclosure Statement

We conducted the work described below in accordance with the professional standards applicable in France:

- We compared the Information presented in the *Rapport de Gestion* against the list provided for by Article R. 225-105-1 of the French Commercial Code;
- We verified that the Information covered the scope of consolidation, that is, Sanofi and its affiliates within the meaning of Article L. 233-1, and the companies it controls within the meaning of Article L. 233-3 of the French Commercial Code;
- In the event of an omission of certain consolidated information, we verified that explanations were provided in accordance with the provisions of French Decree No. 2012-557 of April 24, 2012.

Based on this review, we attest that the required Information is presented in the *Rapport de Gestion*.

### 2. Limited Assurance Report

#### Nature and scope of our review

We conducted our work in accordance with the International Standard on Assurance Engagements (ISAE) 3000 and the professional standards applicable in France. We planned and performed the procedures described below to provide limited assurance that the Information is free of any material misstatements that might cause us to believe that the Information has not been fairly presented, in all material respects, in accordance with the Guidelines. A higher level of assurance would have required more extensive procedures.

Our procedures included the following:

- We assessed the Guidelines' appropriateness with respect to their relevance, completeness, neutrality, understandability and reliability, taking best practices in the industry into consideration where applicable.
- We verified that the Group has set up collection, compilation, processing and control processes aimed at ensuring that the Information is exhaustive and consistent. We assessed internal control and risk management procedures relating to the preparation of Information. We conducted interviews with the individuals in charge of social and environmental reporting.
- We selected the qualitative information and consolidated quantitative data to be tested and determined the nature and scope of the tests while taking into consideration their importance with regard to the social and environmental consequences associated with the Group's business activity and specific characteristics as well as its corporate social responsibility commitments. This qualitative information and consolidated quantitative data is presented in the table below, and in the body of the *Rapport de Gestion*, the qualitative information is identified by the symbol (\*) and is presented in italics.



## STATUTORY AUDITORS' REPORT

**Qualitative information:**

Selection of qualitative information relating to the 12 topics below:

- Human rights
- Equal treatment
- Measures to fight corruption
- Occupational health and safety policy
- Training
- Pharmaceuticals in the environment
- Climate change
- Biodiversity
- Subcontracting and suppliers
- Patient and consumer safety
- Good corporate governance
- Stakeholder relations

**Consolidated quantitative data:****Social**

- Employees under contract worldwide
- Total number of new hires worldwide
- Total number of departures worldwide
- Percentage of women in key positions

**Environment**

- Air emissions – VOCs
- Air emissions – SO<sub>x</sub>, NO<sub>x</sub>
- Greenhouse gas emissions – fuels (direct), and production of electricity and other energy sources (indirect)
- Total energy consumption
- Total volumes of hazardous and non-hazardous waste
- Total water consumption

**Safety**

- Lost time injury frequency rate worldwide

For social data, we selected a sample of administrative management entities in three countries (Brazil, France and the United States).

For environmental data, we selected a sample of seven industrial and research sites (Aramon, Elbeuf, Framingham, Neuville, Swiftwater, Toronto and Ujpest). For safety data, in addition to these seven sites, we also selected a sample of pharmaceutical operations sites in five countries (China, the United States, France, India and Italy).

- The selected sample accordingly represents:
  - 40% of the workforce (quantitative social data);
  - Depending on the indicators selected, between 12% and 39% of the quantitative environmental data tested (27% on average for the various topics);
  - 20% of hours worked and 28% of lost time injuries (quantitative safety data).
- We assessed the fairness and consistency of the other consolidated information published relative to our knowledge of Sanofi and, where applicable, by conducting interviews or consulting documentary sources. With regard to fair business practices, interviews were conducted only at the level of the consolidating entity.
- Finally, where applicable, we assessed the relevance of any explanations relating to the absence of certain information.

**Conclusion**

Based on our review, no material misstatement has come to our attention that causes us to believe that the Information has not been fairly presented, in all material respects, in accordance with the Guidelines.

Concerning the qualitative information that we considered the most important:

- We conducted interviews with:
  - the CSR Excellence Direction, 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, HSE, Legal;
  - individuals involved in implementing the approach in cross-functional departments such as human resources, procurement and global compliance.
- 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 and assess its fairness.

Concerning the consolidated quantitative data that we considered the most important:

- with regard to the consolidating entity and the controlled entities, we performed analytical procedures and verified, on a sample basis, the calculations and data consolidation;
- with regard to the sites that we selected based on their business activity, their contribution to consolidated indicators, their location, as well as a risk analysis, we carried out the following:
  - we conducted interviews to verify the proper application of procedures;
  - we carried out detailed tests to verify the calculations made and reconcile the data with the substantiating documents.

Neuilly-sur-Seine (France), March 6, 2013

The Statutory Auditor  
Ernst & Young Audit

The Statutory Auditor  
PricewaterhouseCoopers Audit

Christian Chiarasini

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The CSR report was designed and produced by Sanofi CSR Excellence, Sanofi Corporate Communications and Flag. It was written by Mary Shaffer.

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#### Photo credits:

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#### Forward-looking statements

This CSR report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2012. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.



Each day, across the globe, Sanofi's 110,000 employees are working to protect your health and improve access to healthcare for as many patients as possible. As a healthcare company, Sanofi places quality, safety, ethics, and respect for the planet at the heart of our business.



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