



2015 CORPORATE SOCIAL RESPONSIBILITY REPORT

PARTNERING TO PROMOTE ACCESS TO HEALTHCARE



SANOFI

ABOUT THIS REPORT

Our 2015 CSR report offers a close look at Sanofi's Corporate Social Responsibility (CSR) priorities and practices. It also describes the challenges we face, the strategic approaches we use to address them, and our progress toward meeting our goals. For each challenge, we 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. Sanofi announced a new global business structure in July 2015, which has been implemented progressively since January 1, 2016. We are pleased to present the new organization on [page 12](#) of this report as one of the milestone events of 2015. The new strategic business organization will be reflected in the reporting framework of our 2016 CSR Report.

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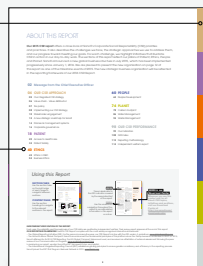
Using this Report

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These labels refer to the GRI indicator covered by the associated text of the report.

Links:

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MORE in our Download Center

Whenever you see this symbol and for all Sanofi CSR topics, initiatives and positions, visit our Download Center at <http://csr.sanofi.com/downloadcenter>

INDEPENDENT VERIFICATION OF THE REPORT

Each year, the reliability and thoroughness of our CSR data are audited by independent verifiers. Their review report appears at the end of this report.

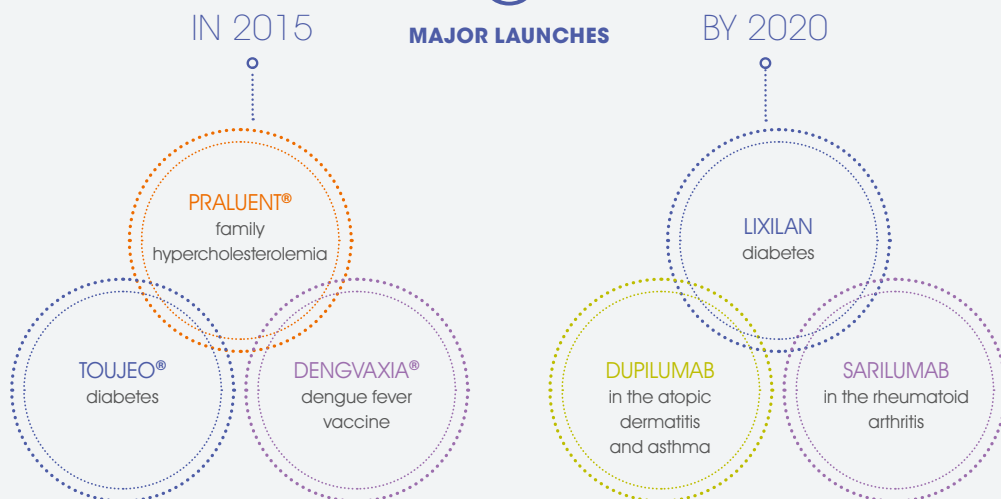
OUR REPORTING FRAMEWORK Sanofi's CSR Report complies with the most widely recognized international standards:

- The Global Reporting Initiative (GRI): For the second consecutive year, our CSR Report is in line with the GRI version 4 guidelines. www.globalreporting.org
- The United Nations Global Compact: Sanofi has embraced the fundamental principles of this platform since the Group became a member in 2000. In 2015, Sanofi attained for its 2014 CSR Reporting, the UN Global Compact Advanced Level, and received an attestation of external assessment following the peer review of our Communication on Progress. www.unglobalcompact.org
- In producing our report, we also found the IIRC framework to be very helpful: the International Integrated Reporting Council (IIRC) establishes guiding principles to ensure greater consistency and efficiency in the reporting process. Sanofi joined the IIRC Pilot Program Business Network in 2013. www.theiirc.org

INNOVATIVE HEALTHCARE SOLUTIONS

6

MAJOR LAUNCHES



2015 KEY RESEARCH & DEVELOPMENT FIGURES

More than

45

MOLECULES AND VACCINES IN THE DEVELOPMENT PORTFOLIO (16 in Phase III or currently registering)

14%

OF SALES INVESTED IN R&D
Increasing annual R&D investments up to **€6bn** by 2020

More than

16,000

R&D EMPLOYEES

2015 KEY CORPORATE SOCIAL RESPONSIBILITY FIGURES

-14.8%

WATER CONSUMPTION REDUCTION
compared to 2010

-15.8%

CO₂ EMISSIONS REDUCTION (SCOPE 1 AND SCOPE 2)
compared to 2010

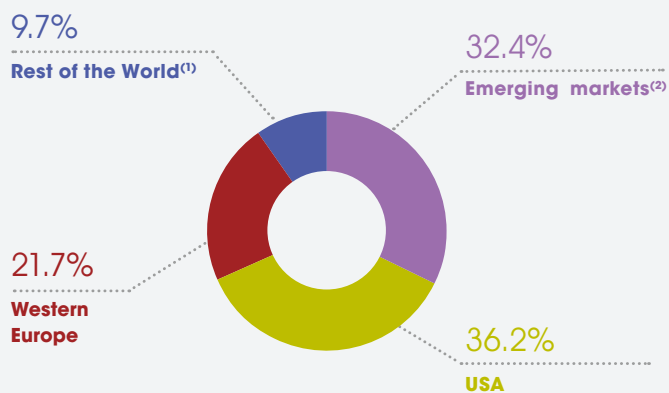
More than

280

ACCESS TO HEALTHCARE PROGRAMS conducted in more than **80 countries**, benefiting to more than **325 million people**

OUR WORLDWIDE PRESENCE

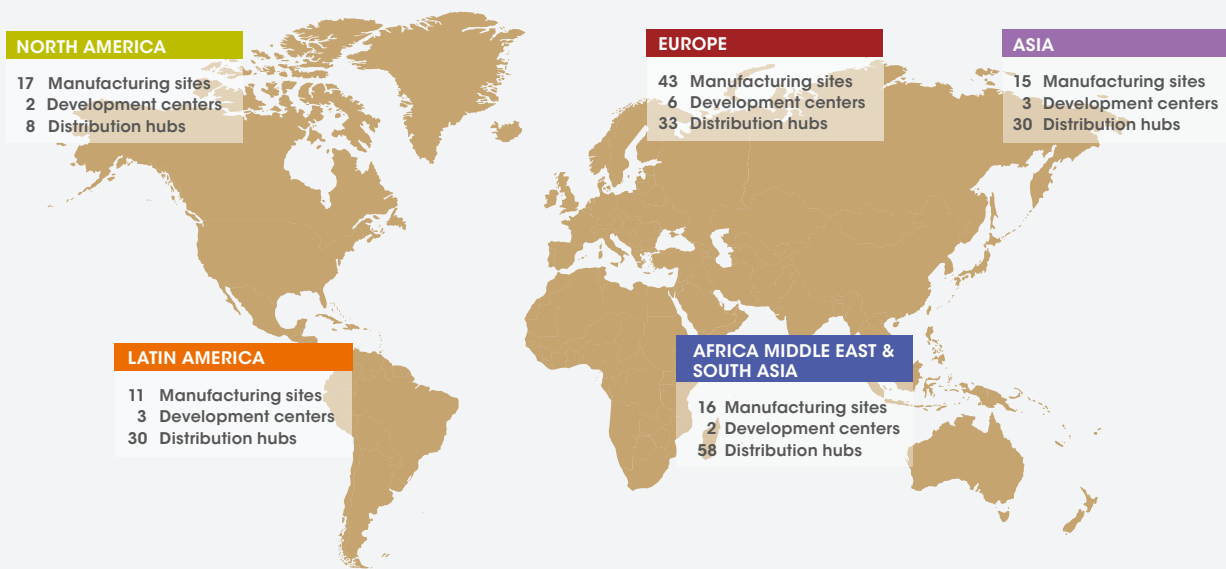
2015 GEOGRAPHIC BREAKDOWN OF SALES



⁽¹⁾ RoW: Japan, South Korea, Canada, Australia, and New Zealand

⁽²⁾ World excluding U.S., Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, the Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark), Japan, South Korea, Australia, and New Zealand

MORE THAN 100 INDUSTRIAL SITES ACROSS THE GLOBE



More than
€ 1bn
 INVESTED every year
 in production capacities

More than
40,000
 INDUSTRIAL AFFAIRS EMPLOYEES
 in 2015

A WORLDWIDE LIFE SCIENCES COMPANY

While scientific progress in the medical field has contributed to doubling average life expectancy in the 20th century, new healthcare challenges have emerged. Chronic and age-related diseases are expanding all over the world, and climate change has significant impact on people's health. In a time of constant change and scientific advances, our role as a leader in the life sciences is to contribute to better living conditions for 7 billion women and men. We will continue our efforts to develop innovative solutions that respond to the needs of patients—regardless of where they live—, and to improve access to healthcare for all. We are dedicated to patients in what we call the "continuum of care": from prevention to treatment, including patients' support—to help them better manage their disease and make a difference in their day-to-day lives.

#5

healthcare company
in the world

#1

in the emerging countries

€37 bn

turnover in 2015

located in

100 countries

more than

110,000 employees

including

147 nationalities





CONTRIBUTING TO THE ADVANCEMENT OF HEALTH”

*Olivier Brandicourt,
Chief Executive Officer, Sanofi*



At Sanofi, as one of the leading healthcare groups, we work tirelessly to improve the health and quality of life for people around the world. With 110,000 dedicated and talented employees, we have always striven to advance the cause of health by developing treatments that prevent and treat disease and by enhancing access to healthcare. We also ensure the way we contribute to improving health is one which is both sustainable and responsible. We are convinced that each of us has an obligation to leave the world a better place for the next generation.

The expertise we have developed along the way has had a profound effect, particularly in the developing world. Thanks to systematic vaccination campaigns, we are close to eradicating polio; while over the last decade, sleeping sickness treatments have saved more than 180,000 lives, and we are on the way to eliminating the disease by 2020.

Yet, there is much to be accomplished; a third of the world still lacks access to healthcare. That's over 2 billion people. The need to develop innovative treatments for the diseases that affect those people – and to develop innovative ways to ensure they get to those in need – has never been more urgent.

To ensure we help meet these needs and close the gap, we concentrate our focus on where we have the most experience for the biggest impact, and this year has been no different for Sanofi, in continuing to demonstrate our fruitful efforts in innovation and access to medicine. We developed and launched the first ever dengue vaccine, a historic milestone for Sanofi and indeed for half the population of the world exposed to it. I was proud to see the first children vaccinated in the Philippines this year.

Equally, we also realize we cannot do it alone, and treatments are not enough. This is why we continue to strengthen and deepen our partnerships with Bill & Melinda Gates Foundation, the GAVI Alliance and the Drugs for Neglected Disease initiative. We contribute to the UN Global Compact, and to the achievement of the United Nations Sustainable Development Goals to increase access to healthcare and quality medicines.

Every moment of the day somewhere in the world, there is a Sanofi employee working diligently to ensure patients receive safe and effective solutions produced to the highest standards. They carry on this commitment through community and volunteer activities. In 2015, more than 25,000 employees volunteered for initiatives in support of children who are sick, underprivileged or disabled. Internally, any decision is driven by strong ethical and social principles to ensure we protect and serve the populations we aim to support, as well as the environment.

Our commitment to global health also requires us to look to the future. Healthcare challenges continue to emerge as result of climate change, demographic and societal evolutions. Beyond treatments, we also engage both public and private stakeholders, starting with other life sciences companies, to take actions to mitigate climate change and anticipate its health consequences. This is why we have been actively participating in COP21 Paris Climate Conference.

Our work in health, environment, human rights, working conditions and business integrity has been recognized for the ninth consecutive year by the Dow Jones Sustainability Index. We are proud of this recognition of Sanofi and its people, and will continue to ensure we do even better next year.

Our dedication to make a real difference in the lives of people every day is fundamental in how we operate our business.

OUR CSR APPROACH

Corporate Social Responsibility is embedded into Sanofi's core business strategy, focused on patients at the center of our activity. Our ambition is to play a wider role in enabling individuals to take control of their health by innovating and developing solutions that meet their needs, and by seeking to improve business performance and remain global leaders in our sector.

OUR INTEGRATED CSR STRATEGY

Every challenge is an opportunity to improve our business. Each time we respond to a CSR challenge, we mitigate risks to find solutions that improve our overall performance while upholding our responsibilities. As we develop pragmatic and innovative responses to the CSR challenges facing us—through teamwork and drawing on valuable expertise—we are convinced that we also improve our business.



MATERIALITY ANALYSIS: SHARPENING THE FOCUS ON OUR CSR PILLARS AND PRIORITIES

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Our Corporate Social Responsibility strategy is the natural outcome of our materiality analysis and ongoing stakeholder engagement. To keep pace with new business priorities and growing stakeholder expectations, Sanofi performed a materiality analysis in 2013 to define our CSR roadmap. Our four pillars form the cornerstones of our CSR approach. We naturally devote particular attention to the priorities of the Patient pillar, Access to Healthcare and Patient Safety. The second pillar covers Ethics in R&D and Business Ethics. Our third pillar focuses on our employees, or more specifically, People Development. For the fourth pillar, Planet, we updated our materiality analysis in 2015 within the scope of a new environmental strategy. Based on the results of this analysis, our planet priorities going forward will be Carbon Footprint, Water Management and Waste Management.

HUMAN RIGHTS: THE FOUNDATION OF SANOFI'S CSR STRATEGY

Our commitment to respect human rights is the foundation of our CSR approach, as we are convinced that our role is to support each person's fundamental right to health through our daily efforts to improve access to healthcare for people everywhere.

INTERCONNECTIONS AND INTEGRATED THINKING

All CSR topics are interconnected in one way or another. For instance, we believe that acting to combat climate change is largely about protecting human health and well-being. The 21st United Nations Climate Change Conference (COP21) held in Paris in November 2015 provided an opportunity to draw attention to the health consequences of climate risks and give this issue the prominence it deserves. Sanofi believes it is essential to address the question of climate change and health. Sanofi is devoting creative energy to develop both mitigation and adaptation solutions.

Another example is the way in which interconnections between financial and non-financial data are becoming increasingly apparent for decision makers within corporations, as well as for regulators, investors and other stakeholders. In terms of both volume and speed, data and information flows are growing ever more complex, and thus, an integrated thinking approach will help enable better decision making. This is one of the reasons Sanofi decided to use the International Integrated Reporting Council (IIRC) framework to move gradually towards an integrated report. We are already developing charts, diagrams and other tools to show the

connection between financial and non-financial information sets (value chain & value distribution graphs p.6, integrated reporting matrix & cross reference index p.13, key figures & group profile p.11 - 111).

RELATED CONTENT in this report

- Page 76, Planet mobilization
- Page 24, Climate Change and Health

MORE in our Download Center

- **Materiality Analysis factsheet**
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- **Updating our Materiality Analysis factsheet**
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"Sanofi has decided to be an official partner of COP21 in order to raise awareness on the consequences of climate change on health, but also to take action to prevent such impacts."



Gilles Lhernould,
Senior Vice-President,
Corporate Social Responsibility

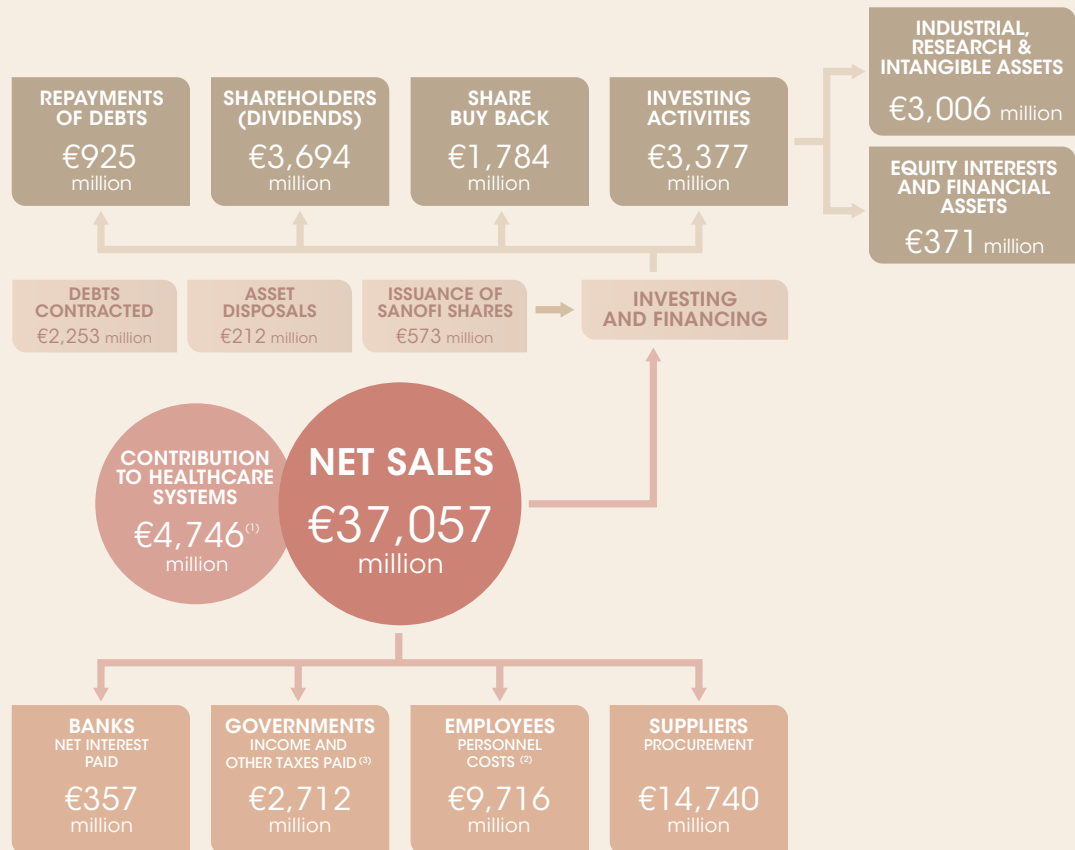
VALUE CHAIN

What we produce is the result of working across a number of operational stages. At each stage, we create value by addressing various challenges. **G4-12**



VALUE DISTRIBUTION

Sanofi contributes to local and global economic development through the distribution of the value generated by its activities. Our financial performance impacts our stakeholders around the world—employees, partners, suppliers, NGOs, and public authorities.



(1) In addition to income tax, Sanofi pays numerous levies and contributions, the most significant being pharmaceutical contributions to healthcare systems globally (mainly deducted from gross sales), which amounted to more than €4,746 million in 2015 (see Tax Policy Page Z).

(2) Including social security contributions of €2,083 million.

(3) Based on business operating income, income tax expense amounted to €2,187 million. The effective tax rate based on our business net income was 23.0% in 2015. Other levies and taxes amounted to more than €500 million.

TAX POLICY

Our objective is to ensure that tax is paid and tax returns are filed on time in each jurisdiction in compliance with the governing laws and rules. The Sanofi Tax Department is involved in all relevant aspects of our business, partnering closely with management to provide guidance and ensure efficient and compliant operations. As a multinational corporation, Sanofi has a responsibility to pay an appropriate amount of tax and comply with the laws and rules in force in all countries where we do business.

HOW WE IMPLEMENT OUR TAX POLICY

The Tax Department is responsible for implementing the Group's tax policy, which is defined by management and regularly reviewed by the Board Audit Committee. We practice transparency to build trust in our relationships with the tax authorities. In most countries of operation, we are subject to audits by the tax authorities on a nearly constant basis. As part of our tax approach, we engage in advance pricing agreements for structural flows with major countries to ensure long-term visibility for Sanofi and the tax authorities. We participate in policy debate whenever possible and in many countries are part of groups that interact regularly with the tax authorities. Our tax experts are often invited to speak at local universities, business schools and public meetings.

AN EFFECTIVE ORGANIZATION

To manage the tax liability of the Group and its affiliates, we rely on a team of highly trained, qualified professionals. We have established clear income tax policies and procedures, which are available to all employees on our intranet and communicated every three months to our tax professionals. Our robust tax reporting processes include quarterly reporting by the affiliates, reviewed by the corporate tax team. A project to improve the quality and level of detail in tax reporting is in the advanced stages. During the last quarter of 2015, more than 200 tax specialists and accountants were trained on the new tax reporting system in preparation to go live in 2016.

VALUE DISTRIBUTION

As a global corporation with over 110,000 employees worldwide, Sanofi has subsidiaries in 83 countries where taxable income is naturally located. Income tax is paid on profits and not on revenues. If an affiliate makes little profit, for example following capital investment, significant R&D expenditure or because margins are regulated, it will accordingly pay less income tax.

In addition to income tax, Sanofi pays numerous levies and contributions, the most significant being pharmaceutical contributions to healthcare systems globally (mainly deducted from gross sales), which amounted to more than €4,746 million in 2015. Payments of other types of levies and taxes amounted to more than €500 million in 2015. Most of these levies and contributions have the effect of reducing profit and therefore taxable income. Sanofi also contributes significantly to local communities, directly and indirectly, through local taxes and social security.

TRANSFER PRICING

The volume of product and service flows among entities within the Group is significant, and the price of transactions among Sanofi entities is an important factor in Sanofi's overall tax organization. Our transfer pricing team determines Group policy for the pricing of such transactions based on a full analysis of the value drivers of our business, ensuring that international and local rules are respected. Our objective is for all entities to be remunerated at "arm's length" in accordance with Organization for Economic Co-operation and Development (OECD) and country-specific rules.

PROMOTING INTERNATIONAL TRANSPARENCY

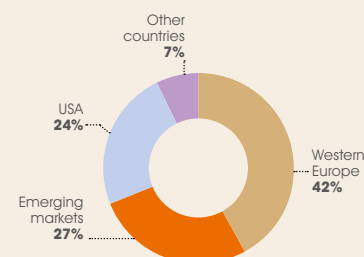
Today's international multi-jurisdictional dynamic tax environment increases the complexity of our task. Therefore, we fully understand the initiative of country-by-country reporting to tax authorities announced by OECD.

Facts and figures

OUR TAX CONTRIBUTION

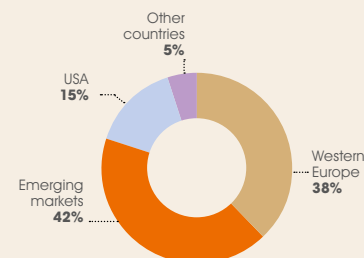
In 2015 the Group's Income Tax charge on Business Operating Income was €2.2 billion worldwide. A breakdown by region is as follows:

INCOME TAX ON BUSINESS NET INCOME



The long history of Sanofi results in a significant proportion of income tax being paid in Western Europe where the intellectual property of many of our leading products is located. Our headquarters are located in France. More than 30 manufacturing sites (including most of the principal ones) and more than half our Research and Development sites are located in Western Europe.

EMPLOYEES DISTRIBUTION BY GEOGRAPHIC AREA



Around 38% of employees are located in Western Europe.

IMPLEMENTING OUR CSR STRATEGY

Our Corporate Social Responsibility strategy is rolled-out at every level—from global to local. Along with coordinating our major initiatives and ensuring that we fulfill our responsibilities, the CSR department raises awareness about key CSR issues, promotes good practice across our operating units and keeps our many stakeholders informed about Sanofi's activities. We also engage with stakeholders to develop action plans designed to address Sanofi's specific CSR challenges and improve our business performance.

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Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
Include stakeholder expectations in our CSR strategy by conducting materiality analysis; communicate with our stakeholders	Materiality findings implemented	Completed
	Local implementation of materiality: <ul style="list-style-type: none"> Local materiality toolkit finalized Roll-out of the materiality test in 4 pilot countries: Japan, Canada, Germany and Brazil 	Completed
	CSR quarterly newsletter distributed to 1,200 external stakeholders and published on sanofi.com	Completed
Integrate human rights into our operations	Human rights training sessions held for senior managers and internal auditors (147 trained since 2010)	On track
	Gap analysis of our human rights approach against the requirements of the UN Guiding Principles	Completed
	Priorities determined for continuous improvement in identifying, preventing and mitigating human rights risks	On track
Build CSR awareness among employees worldwide	Internal CSR collaborative platform with CSR blog developed: 150 CSR country initiatives posted in 2015	Completed
	CSR monthly newsletter sent to more than 600 internal stakeholders	Completed
	Face-to-face CSR training program developed for CSR correspondents; 5 modules shared with all CSR correspondents in countries and functions	Completed
	Development of a CSR e-learning module for all Sanofi employees in France	Completed
	Translation of CSR e-learning module into several languages	On track
	2016 CSR Awards Challenge launched across functions and countries	Completed

CSR NETWORKS

One of the ways we accomplish our CSR goals is through complementary networks. These regional and functional networks cascade our CSR approach and gather valuable feedback from our sites. We work together to devise action plans and monitor progress.

• **The CSR Regional Network** is made up of more than 60 correspondents from seven regions covering 80 countries where we operate. It implements, adapts and develops our global strategy locally and regionally.

• **The CSR Functional Network** includes over 100 people from all our corporate functions and divisions, including Compliance, Human Resources, Finance, Health, Safety & Environment (HSE), Industrial Affairs, Quality, R&D, Commercial Operations, Sanofi Pasteur, Genzyme and Meril. It coordinates the implementation of our CSR strategy across all business activities.

CSR TRAINING

We provided training for all our CSR correspondents in different countries and in corporate functions on the CSR fundamentals and strategy. Addressing topics from how to launch a CSR project to how to produce a CSR report, the program was well received and the feedback from correspondents very positive.

We have now developed an e-learning module for all Sanofi employees who want to learn more about CSR. It provides an overview, outlining our CSR strategy and giving real-life examples and key figures concerning each of our priorities. The e-learning module was launched in France in December 2015 and will be translated into English and other languages in 2016.

THE 2016 CSR AWARDS



In September 2015, we launched the new round of the CSR Awards. This highly popular initiative serves to recognize and reward Sanofi teams' best projects to foster creativity in each of our four CSR focus areas:

- **PATIENT**;
- **ETHICS**, with a special prize for the 3Rs (replacement, reduction and refinement of the use of animals in research, development, testing and production);
- **PEOPLE**, with a special Diversity prize; and
- **PLANET**, with a special Climate Change and Health prize.

We have received over 180 submissions from more than 40 countries for the 2016 competition. The winning initiatives will be announced during our CSR Awards ceremony in June 2016.

PUTTING "THINK GLOBALLY, ACT LOCALLY" TO THE TEST

While materiality at the global level is strategically important for the Group, affiliates in different countries will naturally focus on additional priorities.

For this reason, we have developed a dedicated toolkit to support our affiliates as they put Sanofi's global CSR priorities into action locally.

MORE in our Download Center

- [Updating our Materiality Analysis factsheet](#)

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Facts and figures

SOME OF OUR AFFILIATES PRODUCED THEIR OWN CSR PUBLICATION IN 2015

- Brochures: Canada, Japan, Egypt
- Reports: China, Brazil, Germany, Spain, Russia



MORE in our Download Center

- [CSR Brochure 2015 Egypt](#)
- [CSR Brochure 2014 Canada](#)
- [Planet Report 2014 Canada](#)
- [CSR Brochure 2014 Japan](#)
- [CSR Report 2015 China](#)
- [CSR Report 2015 Spain](#)
- [CSR Report 2014 Germany](#)
- [CSR Report 2013-2014 Russia](#)
- [CSR Report 2013-2014 Brazil](#)



"We pay constant attention to the expectations of the stakeholders engaged in our continuous improvement approach, which prompted us to conduct a new materiality analysis of Sanofi's environmental challenges in 2015."



Didier Terrolle,
Associate Vice President, CSR Excellence

STAKEHOLDER ENGAGEMENT

At Sanofi we seek to maintain close relationships with our stakeholders. Representatives from all areas of our business interact on an ongoing basis with a wide variety of stakeholders. Our R&D division, industrial activities and commercial operations all engage with stakeholders, particularly in the healthcare field. We listen to their concerns and expectations, and use their input to devise our CSR strategy and action plans.

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WHY ARE STAKEHOLDER RELATIONS IMPORTANT?

G4-16

Stakeholder engagement is based on an ongoing dialogue that embraces different points of view and allows those views to inform decision making. It is a powerful source of mutual learning and shared solutions. In our relations with stakeholders, Sanofi seeks to involve them to varying degrees—from simply monitoring initiatives and targeting messages to soliciting their feedback. The highest degree of involvement consists of partnering with stakeholders to pursue common objectives, which can create the greatest value for businesses. Our stakeholder engagement helps us develop a deeper understanding of the challenges and expectations of patients, healthcare professionals, policy makers, NGOs, communities and many others.

TRANSPARENCY: BUILDING TRUST THROUGH DIALOGUE

Vital to building trust with our stakeholders, transparency is one of the key components in our CSR approach. The Sanofi Transparency Initiative was introduced to help ensure that interactions with healthcare professionals and patient associations remain transparent, and that our clinical trial data and publications are made available.

OUR STAKEHOLDERS AT THE HEART OF OUR STRATEGY



MORE in our Download Center

• [Stakeholder Engagement factsheet](#) G4-16 G4-19 G4-24 G4-25 G4-26 G4-27

STAKEHOLDER ENGAGEMENT AT THE LOCAL LEVEL

G4-27

In addition to building relations with our stakeholders through activities at the Group level, Sanofi affiliates around the world organize their own initiatives to engage with local stakeholders.

The French Stakeholder Panel

Since 2012, Sanofi has established a forum for ongoing dialogue with our stakeholders in France. The French Stakeholder Panel is composed of nearly 20 individuals from outside Sanofi who may be academics, politicians, representatives of NGOs, patient associations, healthcare professionals, socially responsible investment funds and professional organizations. The diversity of our panel provides insight and expertise covering the four CSR pillars (Patient, Ethics, People and Planet).

The panel also includes around 15 individuals with decision-making responsibilities from Sanofi's main activities and functions in France, including R&D, Industrial Affairs, Public Affairs, Purchasing, Communications, and our business units, Sanofi Pasteur, Merial and Genzyme.

The panel discusses a wide range of topics—such as Sanofi's approach to ethics in R&D, potential conflicts of interest with healthcare professionals or political representatives, Sanofi's role in improving access to healthcare, labor questions for Sanofi France, the continuity of our supply chain, pharmaceuticals in the environment, pricing policies for medicines, compensation policies and responsible purchasing. Gilles Lhernould, Senior Vice President of CSR, chairs the French Stakeholder Panel, which meets twice a year for one full day to address questions from our stakeholders.

Depending on the complexity of the topics under discussion, we may organize half day workshops on specific CSR challenges and invite experts from related fields. In 2015, we hosted a workshop to address public distrust of vaccination and another one to explore innovation. In line with our commitment to transparency, summaries of the proceedings of our plenary sessions are published on www.sanofi.fr (in French only).

The Access to Healthcare Stakeholders Committee in Egypt

Created in 2013, the Access to Healthcare Stakeholders Committee in Egypt remains the only such committee created by a pharmaceutical company in this country. In 2015, 20 external participants met for the third consecutive year to work on two topics: how to address the burden of mental health and how to support the health of children in communities. They agreed on recommendations to increase public awareness, monitoring and education.

BRINGING A HUMAN RIGHTS LENS TO OUR CSR CHALLENGES

Bringing a human rights lens to the challenges linked to our eight CSR priorities for action from 2016 to 2020 is one of the cornerstones of our CSR approach. The Group acknowledges the spectrum of human rights that may potentially be impacted by our activities and business relationships. Human rights are embedded into the design, implementation, monitoring and evaluation of the policies, procedures and actions deployed for each of our CSR priorities. Our work to integrate human rights guidance into Sanofi's internal control system provides a good example.

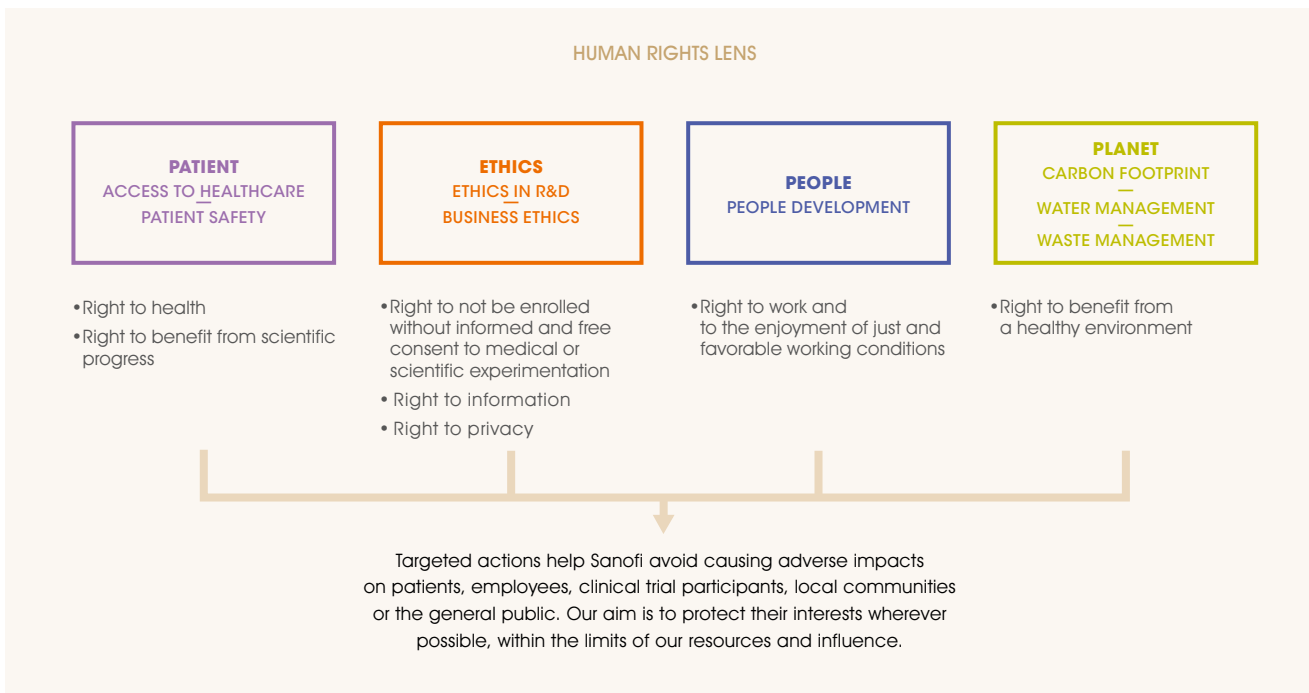
A COMPREHENSIVE FRAMEWORK TO APPLY THE GUIDING PRINCIPLES DAY TO DAY

To facilitate a shared understanding of the controls dedicated to human rights across the Group, we issued three new global policies in 2015, covering freedom

of association and collective bargaining, child labor and forced labor. They complement our existing diversity policy to support a comprehensive framework on human rights at work for both the Group and our suppliers. Finally, to ensure the effective application of our framework, we organized Human Rights training for our team of internal auditors covering Europe, Africa, the Middle East and South Asia.

MORE in our Download Center

- [Human Rights factsheet](#)
G4-15 G4-DMA G4-HR11
- [Human Rights in our Activities \(guide\)](#)
G4-15 G4-DMA G4-HR11
- [Children's Rights factsheet](#)
G4-15 G4-DMA G4-HR11
- [Code of Ethics](#)
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A NEW STRATEGIC ROADMAP FOR SANOFI

As a direct response to an evolving context, Sanofi has developed a new strategic roadmap for 2020 (announced on November 6, 2015). The Group will continue to be a global healthcare company focused on disease prevention and treatment. The strategic roadmap has four pillars, namely reshape the portfolio to be more focused on businesses where we have or can build a strong position, deliver outstanding launches, sustain innovation in R&D, and simplify the organization.

RESHAPE THE PORTFOLIO

To reshape the portfolio, we have segmented our businesses into three groups: businesses where we will sustain leadership (Diabetes and Cardiovascular, Vaccines, Rare Diseases and Emerging Markets), build competitive positions (Multiple Sclerosis, Oncology, Immunology and Consumer HealthCare), and explore strategic options (Animal Health and Generics in Europe).

Sustain leadership

Sanofi is already a leader in diabetes, rare diseases, vaccines, and emerging markets. All are attractive businesses where we will defend and strengthen our positions. In Diabetes, Sanofi remains committed – for the long term – to fighting the global epidemic of diabetes and to treating cardiovascular disease, the leading cause of death globally. First, we are developing our insulin franchise with Lantus®, Toujeo®, and soon LixiLan (the lixisenatide/insulin glargine association project). Second, we are also strengthening our pipeline through external and internal R&D opportunities. Our third priority is to lead the market shift to managing diabetes outcomes. Our collaboration with Verily (formerly Google Life Sciences) provides an excellent illustration of how we want to manage this shift. In cardiovascular, we have the opportunity to transform the management of hypercholesterolemia with Praluent®. Sanofi is one of four leading companies in vaccines. Over the next five years, we expect

to grow faster than the market. Our growth will be driven by Sanofi Pasteur's Dengvaxia®, and our leading products in flu, pediatric combinations, and boosters. Vaccination rates for these products remain below public health targets.

Genzyme created the rare genetic disease market and we are confident in our ability to sustain leadership.

Sanofi is the leader in emerging markets and is a major multinational player in the BRIC-M⁽¹⁾. Here we will sustain leadership through greater focus.

Build competitive positions

Sanofi already has a competitive position in multiple sclerosis, built in three short years with Aubagio® and Lemtrada®. We need to complete their global launches and strengthen our portfolio. In oncology, in addition to some existing clinical assets and several collaborations in particular in immuno-oncology, Sanofi continue to look for business development and M&A opportunities in an effort to rebuild critical mass. With sarilumab and dupilumab, developed in partnership with Regeneron, we have the cornerstones of an important new franchise in immunology. Sarilumab will allow to enter the rheumatoid arthritis market.

In consumer healthcare, we aim to achieve leadership. Today, we are the number 5 player globally, with 3% market share. The business of assets in exclusive negotiations with Boehringer Ingelheim could potentially make Sanofi a global leader in this market.

Explore strategic options

In December 2015, we made progress on our strategic objective of reshaping the portfolio and announced that we are in exclusive negotiations with Boehringer Ingelheim on a business swap which would bolster our CHC business in exchange for our animal health business. The proposed deal would allow us to become the leader in the growing but highly fragmented global CHC market.

DELIVER OUTSTANDING LAUNCHES

We now focus the organization on six major product launches. In 2015 we successfully launched three of them (Toujeo®, Praluent® and Dengvaxia®) and submitted three dossiers for regulatory review: LixiLan (U.S.), sarilumab (U.S.) and dupilumab (U.S.). We are also excited about the next wave of potential launches of other products currently in late-stage clinical development in various therapeutic areas.

SUSTAIN INNOVATION IN R&D

To focus on patient needs from early-stage R&D and deliver targeted healthcare solutions, we continue to strengthen our R&D pipeline and evolve our R&D model based on project teams and alignment with Sanofi's Global Business Units. In addition, we are continuing to foster our ongoing R&D collaborations while increasing our capacity for external innovation.

SIMPLIFY THE ORGANIZATION

To drive focus and simplification within our organization, the gradual shift to five global business units⁽²⁾ (GBUs) began in January 2016. Full implementation of the new organizational structure remains subject to ongoing negotiations with labor unions/employee representatives. At the same time, we continue to reshape our plant network in line with the evolution of the business and a greater emphasis on our growing biologics portfolio. In addition centralized global functions will be aligned with the GBUs.

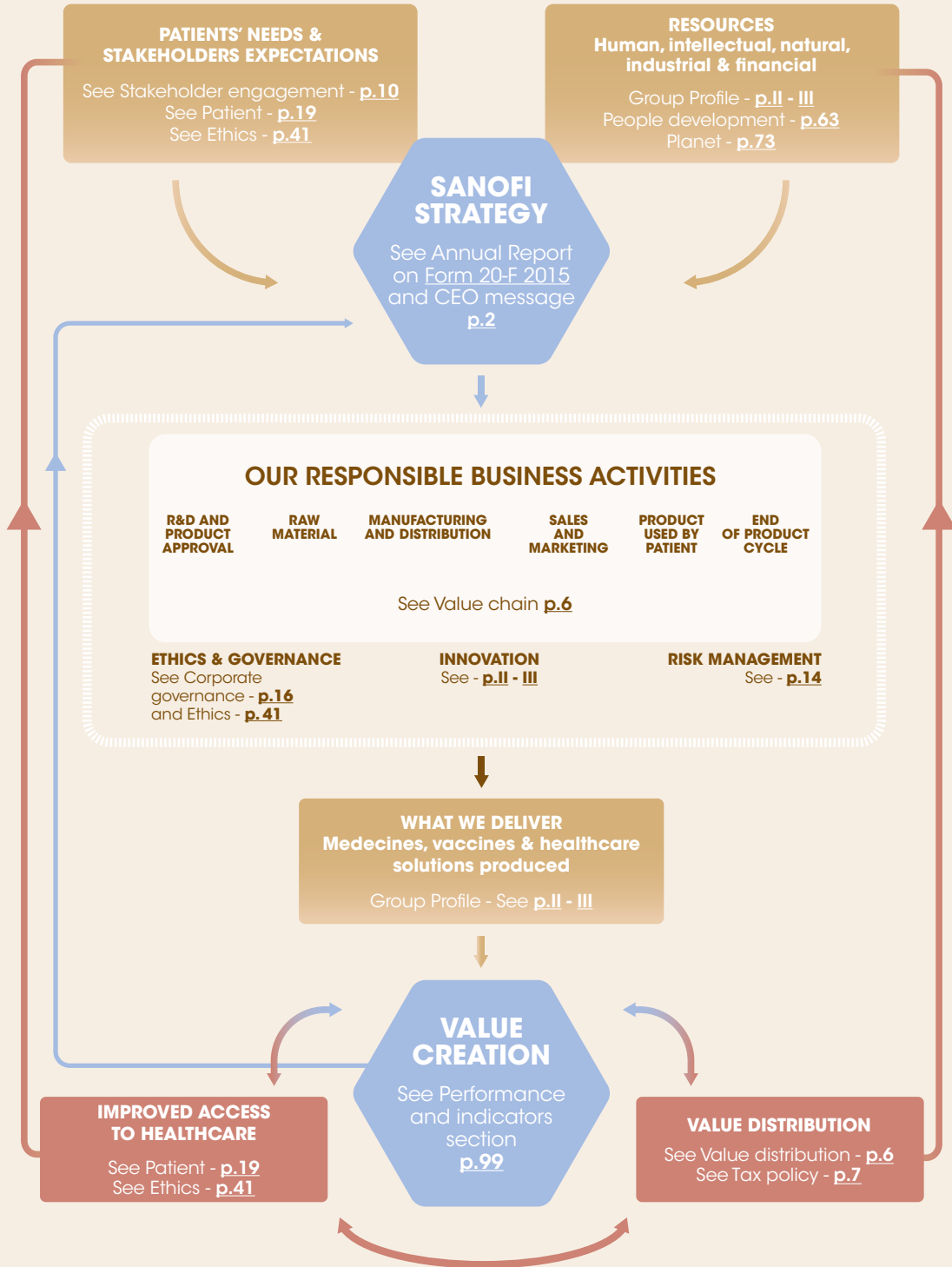
This new structure aligned with a more focused portfolio is projected to also allow cost savings, which we plan to reinvest primarily in the business.

(1) Brazil, Russia, India, China, Mexico.

(2) Our 5 Global Business Units as of January 2016 are: Diabetes & Cardiovascular, General Medicines & Emerging Markets (including established products, generics and consumer healthcare products), Sanofi Genzyme (specialty care including rare diseases, multiple sclerosis, oncology and immunology), Sanofi Pasteur (human vaccines), and Meril (animal health).

OUR INTEGRATED APPROACH

We take into account the full range of inputs to deliver high quality medicines, vaccines and healthcare solutions, which ultimately create shared value for everyone.



MORE online
• [Integrated Reporting](#)

Source: The IIRC framework was used in developing this diagram.

POLICIES & MANAGEMENT SYSTEMS

OUR FRAMEWORK

G4-14 G4-15

Sanofi has a comprehensive set of policies and guidelines that support our activities around the world. This framework not only incorporates the various regulatory requirements that apply to our business, but is also designed to exceed those requirements in certain cases. Our willingness to go beyond basic compliance reflects our desire to achieve the highest standards in our activities.

MANAGEMENT SYSTEMS

G4-56

Our CSR approach relies on an internal framework and tailored management systems, which together guide us to act responsibly and ethically. These systems include training and awareness programs, quality controls and regular internal audits to monitor compliance and drive continuous improvement. The table provides more details on the management systems that are important for CSR. It covers six key areas, all of which are critical to our business.

FOCUS ON RISK MANAGEMENT

The management of risks and opportunities, which is an integral part of governance across the Sanofi Group, aims to anticipate and mitigate potential risks that could impact our strategy or operational objectives. They include emerging risks due to a fast-changing business environment, a more volatile economy, a changing stakeholder landscape and new stakeholder expectations, and the business model's shift towards biotechnology.

RISK MANAGEMENT GOVERNANCE

The Group Risk Committee assists the Executive Committee by identifying, assessing and monitoring transversal and strategic risk areas. The Risk Committee ensures that risks with a potential critical impact are monitored to an acceptable level and continuously evaluates internal and external changes and risk exposure to support decision-making processes

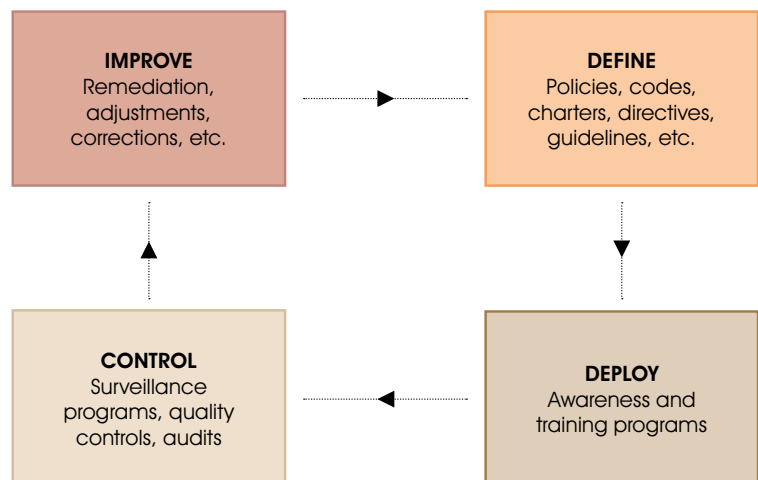
MANAGEMENT SYSTEM	PURPOSE
QUALITY	Deliver quality in the research, development, manufacturing, distribution and promotion of our products, including activities outsourced to third parties; ensure compliance with relevant applicable regulatory requirements and internal standards covering the full product life cycle.
HSE	Protect the health and safety of all employees; develop safe industrial processes; limit the environmental impact of the Group's activities.
ETHICS & BUSINESS INTEGRITY	Develop processes to instill ethical values and clear standards of compliant behavior.
PHARMACOVIGILANCE (product safety monitoring)	Seek to ensure patient safety by constantly evaluating and monitoring the risks potentially associated with the use of our products; seek to monitor the benefit/risk profile of our medicines and vaccines over their entire life cycle.
INTERNAL CONTROL & INTERNAL AUDIT	Provide reasonable assurance to senior management about the level of control over operations, including efficiency and compliance with all internal and external requirements.
RISK MANAGEMENT	Foster a culture of risk management and assess cross-company risks that could impact the Group's business strategy and values.

MORE in our Download Center

- [Quality Management Systems factsheet](#)
G4-15 G4-56 G4-DMA G4-PR1
- [HSE Management System factsheet](#)
G4-56 G4-DMA G4-SO1
- [Sanofi Manufacturing System factsheet](#)

- [The Group Internal Audit and Internal Control & Processes factsheet](#)
- [Corporate Governance factsheet](#)
G4-34 G4-56
- [Code of Ethics](#)
G4-15 G4-56
- [Risk Management factsheet](#)
G4-14

OPERATING CYCLE OF OUR MANAGEMENT SYSTEMS



as well as resource and budget allocation. Major risks are reported annually to the Executive Committee and reviewed by the Audit Committee of the Board of Directors. The Group Risk Management team supports the Risk Committee by consolidating and maintaining the Group Risk Profile for interconnected, transversal and emerging risks that require strong cross-organizational leadership to define and execute mitigation plans. In close connection with other strategic initiatives, the team proposes relevant improvements to the Risk Committee to provide reasonable assurance that the risk assessment and reporting processes are effective.

MORE In our Download Center

• [Risk Management factsheet](#)

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RISK MANAGEMENT APPROACH

Consistent with ISO 31000 and COSO standards, Sanofi's Risk Management Policy and Guidance define our risk management roles, responsibilities and processes for identifying, assessing, treating, monitoring and reporting internal and external risks and opportunities.

This approach relies on a comprehensive risk assessment methodology that allows us to capture all categories of opportunities and threats closely tied to our strategy and inherent to our business. Accountability for risk mitigation remains with operational and corporate functions.

Using a consistent approach across the Group allows us to obtain comparable assessments and improves our ability to consolidate risk areas identified by the operational and corporate functions, which are part of the risk management network led by the Risk Management Team.

Principal risks and opportunities

The principal risks monitored by the Risk Committee are included in the risk factors listed on the annual report on Form 20-F, filed with the United States Securities and Exchange Commission (SEC), and the French annual report (*Document de Référence*), filed with

the *Autorité des Marchés Financiers* (AMF).

For each of the risks mapped on the Group Risk Profile, leaders are appointed to coordinate multidisciplinary teams across the Group in charge of:

- assessing, prioritizing, executing and monitoring mitigation plans;
- identifying key individuals to be involved in the risk management process; and
- reporting to risk owners who are accountable for managing and controlling risks and to members of the Risk Committee to allow decision making.

The foregoing list of risk factors is not exclusive and does not reflect any order of priority. Risk factors, disclosed under "Item 3. Key Information—D. Risk Factors" of our annual report on Form 20-F, could affect the future results and cause actual results to differ materially from those contained in any publication of Sanofi. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect.

SOME OF THE RISK FACTORS FACED BY THE COMPANY	
RISKS RELATING TO LEGAL AND REGULATORY MATTERS	We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.
	Product liability claims could adversely affect our business, results of operations and financial condition.
RISKS RELATING TO OUR BUSINESS	Our research and development efforts may not succeed in adequately renewing our product portfolio.
	The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.
	We may lose market share to competing remedies, biosimilar or generic brands.
	A substantial share of the revenue and income of the Group continues to depend on the performance of certain flagship products.
	The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image.
RISKS RELATING TO THE GROUP STRUCTURE AND STRATEGY	Our strategic objectives for long-term growth may not be fully realized.
	We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.
ENVIRONMENTAL RISKS OF OUR INDUSTRIAL ACTIVITIES	The globalization of the Group's business exposes us to increased risks in specific areas.
	Risks from the handling of hazardous materials could adversely affect our results of operations.

CORPORATE GOVERNANCE

Sanofi respects high standards of good corporate governance. As a company governed by French law, Sanofi's practices comply in relevant part with the recommendations contained in the *Nouvelles Régulations Économiques* (NRE) law and in the *Corporate Governance Code of the Association Française des Entreprises Privées* and the *Mouvement des Entreprises de France* (AFEP-MEDEF). **G4-34**

Sanofi prides itself on having strong governance fundamentals including:

- the separation of the offices of Chairman and Chief Executive Officer (CEO);
- a high level of independence and diversity in the composition of the Board and its committees;
- an independent Chairman of the Board who also chairs the Appointments and Governance Committee;
- a longstanding policy of engagement with stakeholders to discuss governance as well as CSR topics through extensive roadshow campaigns; and
- a compensation policy that aligns pay and performance, share-based compensation subject to long-term performance conditions, stringent lock-up obligations applied to shares the CEO obtains on the exercise of stock options or disposition of performance shares, and a high degree of transparency.

BOARD COMPOSITION

Serge Weinberg is Chairman of the Board of Directors, currently comprised of 14 members, including the CEO. Five directors are women and 11, including the Chairman of the Board, are deemed to be independent directors pursuant to the independence criteria set out in the AFEP-MEDEF Corporate Governance Code.

In line with the recommendations of the AFEP-MEDEF Corporate Governance Code, since 2008 the terms of the directorships have been established such that only a fraction of the directorships terminate in a given year to ensure stability and continuity. The Board

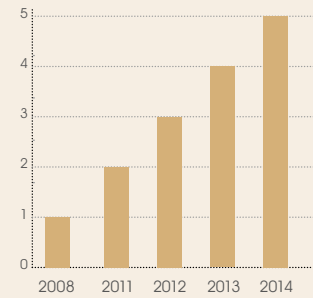
reserves the right to occasionally propose shorter terms for one or more directors to avoid excessive turnover in any one year. This also facilitates succession planning for directors. Over the last several years, upon the recommendation of the Appointments and Governance Committee, the Board has established a roadmap for changes in the composition of the Board. In particular, the Board seeks to secure a balanced representation of men and women and a diversity of background and country of origin, since the Group is both diversified and global.

Recent appointments have aimed to reinforce the Board's scientific and pharmaceutical expertise, to enhance gender balance as well as international and cross-generational representation, and, when possible, reduce the size of the Board.

In 2014 Patrick Kron's appointment continued our policy of renewing the Board and brought in additional industrial know-how and international awareness.

The same year, the arrival of Bonnie Bassler reinforced the scientific and pharmaceutical expertise within our Board and is in line with our policy of enhancing gender balance and international and cross-generational representation.

WOMEN ON THE SANOFI BOARD OF DIRECTORS



In 2008 Claudie Haigeneré was the first woman to join the Sanofi Board of Directors.

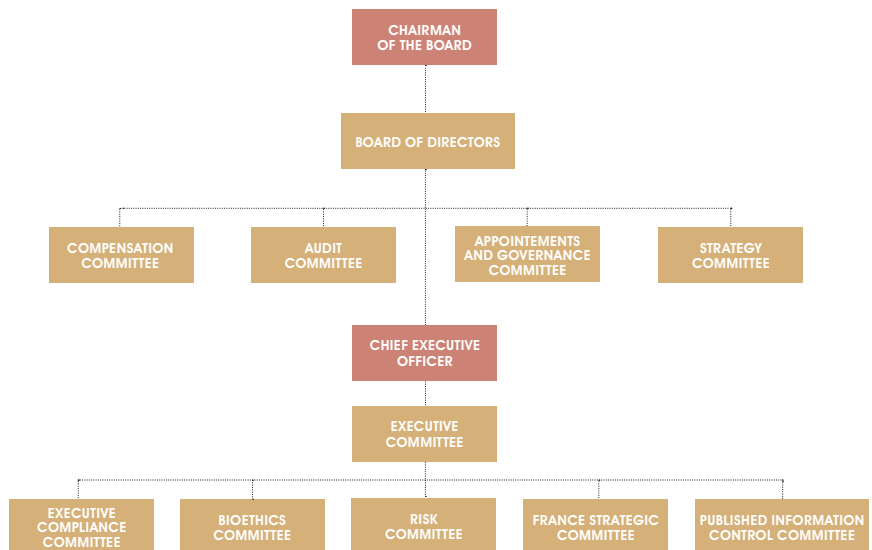
Suet-Fern Lee joined in 2011.

Carole Ptwnica joined in 2012.

Fabienne Lecorvaisier joined in 2013.

Bonnie Bassler joined in 2014.

The appointment of Diane Souza and Thomas Südhof as members of the Board is submitted to the 2016 Annual General Meeting. Diane Souza is the former CEO of UnitedHealthcare Specialty Benefits, with over 25 years of managed care and health benefits experience. Thomas Südhof, MD, is the Avram Goldstein



Professor in the School of Medicine of Stanford University, as well as a Professor of Molecular & Cellular Physiology, Psychiatry, and Neurology. He won the Nobel Prize in Physiology or Medicine in 2013.

MISSION AND ACTIVITY OF THE BOARD OF DIRECTORS

The Board's core mission is to determine Sanofi's strategic direction. A part of the Board's time is dedicated to Corporate Social Responsibility issues related to the Group's strategy. The Board is attentive to the interests of shareholders and other stakeholders. Five non-voting employee

representatives attend and participate at Board meetings. Employee input on key corporate issues is also solicited through the corporate intranet and the establishment of non-mandatory consultative bodies such as the European Works Council. In 2015 the Board placed greater emphasis on management succession planning in light of lessons learned from the recent change of Chief Executive Officer.

The arrival of a new CEO provided an opportunity to revisit governance topics such as the limitations of the CEO's powers to ensure they remain adapted to the Group. In 2015 the Board decided that from now on, there would not be one but two executive sessions

of the Board each year to review the CEO's performance as well as other topics, such as the evaluation of the Board and its committees. The Board decided to have the 2015 evaluation of the functioning of the Board and its committees performed by an outside consultant.

MORE online

- [Document de référence 2015 - section 1.2 Gouvernement d'entreprise](#)
- [2015 Annual Report on Form 20-F - Item 6 Directors, Senior Management and Employees](#)

MORE in our Download Center

- [Corporate Governance factsheet](#)

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CSR RECOGNITIONS

In recognition of our performance, we were included on several major global CSR indexes in 2015. Our CSR report also complies with the most widely recognized international standards.

DOW JONES SUSTAINABILITY INDEX (DJSI)

For the ninth consecutive year, we were included on the Dow Jones Sustainability Index (DJSI World), one of the most renowned sustainability indexes among investors worldwide. Sanofi is one of the five pharmaceutical companies selected for the DJSI Europe, a first in the company's history. As one of the top-scoring companies in the healthcare sector, Sanofi qualified for inclusion in the 2016 Sustainability Yearbook and received the Silver Class distinction for our excellent sustainability performance.

CLIMATE DISCLOSURE PROJECT (CDP) INDEX

Sanofi remains among the leaders in climate change reporting, with a score of 99/100 in disclosure and B in performance.

OTHER LEADING GLOBAL CSR INDICES

- FTSE 4 Good
- Stoxx® Global ESG Leaders indices
- Oekom Prime

In 2015, Sanofi was ranked among the top 3 CSR performers in the pharma sector by the rating agencies Vigéo and MSCI.



GLOBAL REPORTING INITIATIVE (GRI)

Since 2014, our CSR reports have applied the G4 guidelines of the Global Reporting Initiative and met the criteria for the "Core" application level.

RELATED CONTENT in this report

- [Page 108](#) : GRI index

UNITED NATIONS GLOBAL COMPACT (UNGC)

The UN Global Compact is a strategic public-private initiative for organizations committed to social and environmental sustainability. As a signatory to the UNGC

since 2000, Sanofi is fully committed to upholding the 21 advanced criteria in connection with the Global Compact's ten principles in the areas of human rights, labor standards, environmental sustainability and anti-corruption. In 2015 Sanofi reached the UN Global Compact Advanced Level and received an attestation of external assessment following the peer review of our Communication on Progress.

MORE online

- [2015 Sanofi Communication on Progress & Attestation of External Assessment](#)

In addition to international recognition for our CSR performance, Sanofi received CSR awards from national and local organizations in many of the countries where we operate.

MORE in our Download Center

- [External CSR Awards Received factsheet](#)

G4-DMA G4-SOI

How does medical innovation benefit those who truly need it?

According to WHO, dengue cases have increased thirtyfold over the past 50 years. Today, half of the global population is at risk, making dengue the world's fastest growing mosquito-borne infectious disease. In response to this worldwide issue, Sanofi dedicated 20 years to developing the first-ever dengue vaccine. In order to provide the most widespread prevention, we started the vaccine registration process in the most vulnerable endemic areas of Latin America and Asia. In December 2015, the vaccine was approved in Mexico, the Philippines and Brazil.



PATIENT

Because advancements in healthcare must benefit the greatest number of people, Sanofi constantly works towards expanding access to healthcare, ensuring patient safety and developing solutions that improve people's health and patients' lives.





ACCESS TO HEALTHCARE

Access to quality healthcare remains beyond the reach of roughly one-third of the world's population. Addressing this situation, which not only threatens global health but also human development, is our greatest challenge. We believe it is our responsibility to try to ensure that as many patients as possible have access to the medicines and vaccines they need as well as a full continuum of care. At Sanofi, we remain committed to drawing upon our expertise and resources to find innovative solutions to bring healthcare to all people across the globe.

G4-EC7 G4-EC8 G4-DMA G4-SO1

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
OUR PRESENCE AND IMPACT IN TERMS OF ACCESS TO HEALTHCARE		
Continue to include eligible beneficiaries in our many Access to Healthcare programs	<ul style="list-style-type: none"> We conducted more than 280 access to healthcare programs in more than 80 countries. Around 56 million patients received diagnosis, vaccination, treatment or disease self-management training. Efforts to raise awareness about diseases and help train healthcare professionals continued. 	On track
Strengthen our presence in emerging markets by responding to local health needs through innovative programs	<ul style="list-style-type: none"> In Brazil, the StarBem program for patients with diabetes continued. In Brazil and India, Sanofi is a partner of Kids and Diabetes in Schools (KiDS) to foster a safe and supportive school environment. In South Africa, Sanofi is partnering with University Research Co. (URC) and the Department of Health to increase early detection of concomitant diabetes and tuberculosis and support patient management. In Latin America, Asia and Africa, we pursued our "Healthy Children Happy Children" program for pediatric care. In Ghana and the Philippines, since 2014, we have been part of a public private partnership to support access to non-communicable disease treatments through tiered-pricing policies. 	On track
FIGHTING SPECIFIC DISEASES IN OUR AREAS OF EXPERTISE		
Eliminate lymphatic filariasis by 2020 through collaboration with the Bill & Melinda Gates Foundation and Eisai within the scope of the London Declaration on Neglected Tropical Diseases	<ul style="list-style-type: none"> As per the terms of the collaboration: <ul style="list-style-type: none"> Sanofi donated 120 million tablets of diethyl carbamazine (DEC) to the WHO in 2012 and 2013. Eisai took over the production and provision of DEC tablets for the years to come. 	Completed
Eliminate sleeping sickness by 2020	<ul style="list-style-type: none"> Through our partnership with the WHO, since the start of the program more than 34 million people have been screened and more than 200,000 treated. As per our collaboration with Drugs for Neglected Diseases <i>Initiative</i> (DNDi) to develop new treatments, recruitment has been finalized for the Phase II/III trials of fexinidazole compound. 	On track
Support the WHO's target to reduce dengue mortality by 50% and morbidity by 25% by 2020 by marketing dengue vaccines in endemic countries and continuing our awareness efforts	<ul style="list-style-type: none"> After 20 years of R&D, Sanofi Pasteur launched the first vaccine against dengue. Dengvaxia® was approved in Mexico, the Philippines and Brazil in 2015. See p.25. 	On track
Support the WHO's Global Polio Eradication Initiative to eradicate polio by end 2018 by providing vaccine at affordable prices	<ul style="list-style-type: none"> Through the price mechanism developed together with the Bill & Melinda Gates Foundation, we provide significant quantities of inactivated polio vaccine (IPV) to Gavi countries for delivery in routine immunization. See p.27. 	On track
Support the Global Technical Strategy for Malaria 2016-2030 aiming to reduce malaria incidence and mortality rates by at least 90% by 2030 through our integrated approach	<ul style="list-style-type: none"> We extended our collaboration with Medicine for Malaria Venture (MMV) to jointly develop a new single administration, fixed-dose combination therapy. We continue offer treatments at pricing designed to be affordable and raise awareness about prevention, diagnosis and appropriate treatment methods. See p.25. 	On track
By 2030, contribute to reducing premature mortality from non-communicable diseases by 1/3 through prevention and treatment; promote mental health and well-being	<ul style="list-style-type: none"> We continue our efforts to promote diabetes awareness and education. In the fields of epilepsy and mental health, we continue to develop an integrated approach to healthcare in low-income countries. See p.29. 	On track

STRATEGIC APPROACH

We are committed to working in collaboration with relevant stakeholders to increase access to healthcare and quality medicines designed to improve people's health within an economically sustainable framework that supports future innovation. As a global healthcare leader operating in more than 100 countries, our aim is to meet the needs of the greatest number of patients worldwide. We have the expertise and the resources to make a real difference and offer a wide range of products and services in both human and animal health.

DRUGS ALONE ARE NOT ENOUGH: OUR INTEGRATED APPROACH TO OPTIMIZE PATIENT OUTCOMES

Over several decades, Sanofi has made a sustained contribution to meeting global health challenges by developing a large portfolio of medicines and vaccines for a wide range of diseases that threaten millions of lives. At the same time, we know that providing health products and services is just one

part of the solution. For this reason, our strategy spans the continuum of care, from prevention to diagnosis and treatment, including disease monitoring and long-term care. Our integrated approach begins with wellness and evolves throughout the patient journey as we seek to continually contribute to the best possible healthcare experience and outcomes. Our expertise enables us to address different aspects of access to healthcare—from innovation to availability, affordability, quality care and patient support.

MORE in our Download Center

• [Access to Healthcare Programs developed by our Affiliates - 2015 factsheet](#)

G4-24 G4-DMA G4-SO1

• [Access to Medicines Direction Programs - 2015 factsheet](#)

G4-DMA G4-SO1

• [Access to Healthcare Position Paper](#)

MORE online

• [Sanofi Espoir Foundation website, map of our projects](#)



Facts and figures

18

Number of disease areas⁽¹⁾ in the WHO top 20 list for which we have products or R&D (excluding our generic portfolio)

6 out of 17

Number of Neglected Tropical Diseases⁽²⁾ (NTDs) for which we have products or R&D

(1) Disease areas based on the WHO Global Health Estimates (GHE) 2014: deaths by age, sex and cause.

(2) As defined by the WHO.

More than

55%

PERCENTAGE OF SALES

corresponding to the WHO top 20 list of diseases, Neglected Tropical Diseases and rare diseases

More than

280 ACCESS

TO HEALTHCARE PROGRAMS IN MORE THAN 80 COUNTRIES

More than

325 MILLION PEOPLE

BENEFITED, INCLUDING

Around

56 MILLION PATIENTS

received diagnosis, vaccination, treatment, or disease self-management training

Around

269 MILLION PEOPLE

targeted by awareness campaigns

Around

570,000

HEALTHCARE PROFESSIONALS trained

SUPPORTING LONG-TERM EFFORTS TO IMPROVE GLOBAL HEALTH

Contributing to the Sustainable Development Goals

Health plays a decisive role in fostering economic growth and sustainable development. Because of its indirect impact on human development, better health boosts rates of economic growth and contributes to wealth creation. During the period 2000-2015, Sanofi was involved in addressing the health challenges set out in the United Nations Millennium Development Goals (MDGs) in an effort to help reduce poverty and advance human development—for instance, by decreasing infant mortality rates, improving maternal health, fighting infectious diseases like malaria, investing in R&D and creating global partnerships for development.

Sanofi supports the more ambitious health objectives of the new Sustainable Development Goals (SDGs) covering 2016-2030, which replace the MDGs. As a healthcare company, we are committed to scaling up our engagement to help achieve health-related goals, such as those concerning infectious and non-communicable diseases and universal health coverage. We are ready to provide our support through the development of new medicines and vaccines, but also through innovative collaborations in a wide range of areas: research and development, training for healthcare professionals, integrated access schemes for patients and disease management programs.

During the United Nations Private Sector Forum 2015, of the 35 business commitments selected to achieve the new SDGs, two were proposed by Sanofi. The first is "My Child Matters," the Sanofi Espoir Foundation's program to fight childhood cancer in low- and middle-income countries in cooperation with our partners (see page 30). The second commitment is the joint price support mechanism announced by Sanofi Pasteur and the Bill & Melinda Gates Foundation, making it possible for us to provide inactivated poliovirus vaccine (IPV) to 73 of the world's poorest countries in order to help reach the goal of polio eradication by 2018.

OUR INTEGRATED APPROACH CREATES VALUE FOR BOTH OUR STAKEHOLDERS AND SANOFI

	VALUE FOR STAKEHOLDERS	VALUE FOR SANOFI
INNOVATION	<ul style="list-style-type: none"> • Fulfill unmet medical needs • Tailored products offering to meet local conditions • Develop local R&D capabilities 	<ul style="list-style-type: none"> • Develop innovative culture and portfolio • Control R&D cost, risks and complexity • Partner to foster innovation • Differentiate from competitors
AVAILABILITY	<ul style="list-style-type: none"> • Increase number of patients treated • Production and distribution centers in developing/emerging countries • Local manufacturing and supply chain to the highest quality standards • Fight against counterfeit drugs 	<ul style="list-style-type: none"> • Increase number of patients treated • Ensure full production capacity • Facilitate access to new markets
AFFORDABILITY	<ul style="list-style-type: none"> • Increase number of patients treated • Differentiated pricing where appropriate • Offer includes generics • Decrease financial burden on healthcare systems • Contribution toward universal health coverage 	<ul style="list-style-type: none"> • Increase number of patients treated • Develop relations with authorities and other payers • Improve licence to operate
QUALITY CARE AND PATIENT SUPPORT	<ul style="list-style-type: none"> • Raise awareness about disease • Training of healthcare professionals • Improve health literacy and patient empowerment • Improve disease management 	<ul style="list-style-type: none"> • Collaborate with health authorities physicians and patient associations • Improve usage of medicines for optimal benefit/risk ratio • Foster innovation roll-out in patient-centered solution

Addressing the impact of climate change on health

The impact of climate change on health is a topic of growing concern. There is a general consensus that effects of climate change on health are already being felt, and the most vulnerable populations are those living in countries with inadequate or fragile healthcare systems. To help address this important challenge, Sanofi created an advisory board including external experts to identify the issues that must be addressed. We are taking an approach with a triple focus: first, on mitigation and how to best manage our carbon emissions and water use; and second, on adaptation and how to contribute to improving the health of people with diseases that are potentially impacted by climate change (e.g., malaria, dengue and cholera) while addressing the effect of climate change on animal health. The third and final focus of our approach explores ways to create impetus for change by raising awareness internally and externally and developing initiatives with key stakeholders.

MORE in our Download Center

- [Sanofi's Commitment and Contribution to the UN Sustainable Development Goals factsheet](#)
- [Sanofi and the Impact of Climate Change on Health factsheet](#)

RELATED CONTENT in this report

- [Page 79](#), Climate change

RELATED VIDEOS online



▶ [Understanding the link between climate change and health](#)



▶ [Adaptation: Our solutions to tackle health issues related to climate change](#)



▶ [Mitigation: Sanofi's carbon path](#)

▶ [R&D: Sanofi's research on infectious diseases and their evolutions due to climate change](#)

▶ [Dengue: Our commitment against dengue fever, a disease impacted by climate change](#)

Facts and figures

PARTNER OF COP21

Sanofi was the only healthcare company among the sponsors of COP21. During this global conference on climate change held in late 2015, we organized a series of conferences, roundtables, media events and other initiatives, both internally and externally, to mark our engagement and call attention to how climate change impacts people's health.

MORE online



▶ [Sanofi's engagement in COP21](#)

HIGHLIGHTS

THE FIRST EVER DENGUE VACCINE IS LAUNCHED

After 20 years of research and development, Sanofi Pasteur launched the first vaccine to prevent dengue fever. On December 9, 2015, Mexico was the first country to grant marketing authorization to Dengvaxia®, our tetravalent vaccine for the prevention of diseases caused by all four dengue virus serotypes in preadolescents, adolescents and adults (aged 9 to 45) living in endemic areas.

The marketing authorization of Dengvaxia® in Mexico was followed by approvals in the Philippines and Brazil, also in 2015. We are introducing Dengvaxia® first in these countries, where the vaccine has the greatest potential to reduce the dengue burden globally and help achieve the WHO's goal to reduce dengue mortality by 50% and morbidity by 25% by 2020 in endemic countries. Regulatory review processes for Dengvaxia® continue in other endemic countries, and Sanofi Pasteur remains committed to introducing the vaccine first in countries where the disease is a major public health priority. Sanofi Pasteur enrolled over 40,000 participants in extensive safety and clinical efficacy studies and built a dedicated vaccine production facility in France in an effort to ensure that the quality and quantities of the vaccine will be sufficient to meet demand upon introduction. Moreover, we continue to help raise awareness and promote prevention. In 2015, Sanofi Pasteur organized the "Dengue Mission Buzz" across the ASEAN region in collaboration with health ministries, healthcare educators and NGOs. This program makes use of an educational tour bus to empower communities, encourage preventive measures and increase dengue awareness to help achieve better health outcomes. The bus travelled 4,000 kilometers in Indonesia, Malaysia, the Philippines, Thailand and Vietnam, reaching about 50 million people in 30 communities.

MORE in our Download Center

• [Access to Vaccines – 2015 factsheet](#)

FIGHTING MALARIA, TUBERCULOSIS AND NEGLECTED TROPICAL DISEASES

Our Access to Medicines Department has long been focusing on malaria, tuberculosis and neglected tropical diseases, as well as epilepsy and mental disorders, to provide innovative and adapted healthcare solutions to people in low- and middle-income countries.

Important strides in the fight against malaria

Sanofi is a major player in the fight against malaria through our dedicated Infectious Diseases R&D Unit and Access to Medicines Department. We have been active since the 1930s in the research, production and distribution of anti-malarial drugs and today our comprehensive approach focuses on initiatives designed to prevent, diagnose, treat and inform. In particular, we are committed to finding sustainable solutions to provide medicines at preferential prices to patients in need, in compliance with applicable law.

Sanofi receives "Patent for Humanity" award for our innovative process to produce anti-malarial agent

In April 2015, during a ceremony at the White House, Sanofi received the "Patent for Humanity" award from the United States Patent and Trademark Office. This award was conferred in recognition of Sanofi's patent for an innovative chemical and industrial process to produce semi-synthetic artemisinin, used in making artemisinin-based combination therapies. Artemisinin, which is derived from the sweet wormwood plant, is a key component in the production of anti-malarial drugs recommended by the WHO. Natural artemisinin—grown in China, Vietnam and some African countries—is often in short supply and subject to price fluctuations.

The process to create semi-synthetic artemisinin promotes a stable supply to complement natural sources, limiting the risk of shortages and reducing production lead times. The semi-synthetic artemisinin

Facts and figures



"Our company set out more than 20 years ago to develop a dengue vaccine to address the significant unmet public health need in Latin America and Asia, where dengue is endemic. We remain focused on bringing this innovative vaccine first to these countries where it can have the greatest impact on the disease burden."

Olivier Charmeil,
President and CEO, Sanofi Pasteur

OUR DENGUE VACCINE IN FIGURES:

20 YEARS
of research and development

25 CLINICAL STUDIES
in 15 countries

40,000 PARTICIPANTS
in the clinical study program
(Phases I, II, III)

€350 MILLION
invested in a dedicated manufacturing
facility in Neuville-sur-Saône, France

100 MILLION DOSES
of vaccine planned annually at
full-scale production capacity

partnership began in 2004 under the leadership of PATH, an NGO specialized in health solutions, with funding from the Bill & Melinda Gates Foundation. Other partners include the University of California-Berkeley and the industrial bioscience company Amyris.

Developing new malaria treatments to address resistance to artemisinin-based therapies

Sanofi continues to invest in innovation to address unmet needs in malaria control. Increasing resistance to currently-used artemisinin-based combination therapies (ACTs) in Southeast Asia has led to growing concern that such resistance could spread to Africa, where about 90% of malaria deaths occur. In order to establish a new generation of antimalarial combinations, especially in regions that have developed resistance to ACTs, in 2015 Sanofi extended its collaboration with the Medicines for Malaria Venture (MMV) to jointly develop a one-shot, fixed-dose combination therapy.

The Sanofi-MMV R&D cooperation began a three-year research project agreement in May 2011 to develop drug candidates from Sanofi's compounds selected for their potential activity against malaria parasites. To date, this joint effort has yielded two candidate combination treatments expected to be active against malaria parasites resistant to artemisinin derivatives.

Providing affordable treatments in low-income countries

ArteSunate AmodiaQuine Winthrop® (ASAQ Winthrop®) was developed through an innovative partnership with Drugs for Neglected Diseases *initiative* (DNDi), an independent non-profit foundation.

This combined, fixed-dose formulation improves patient adherence to treatment and reduces the risk of drug resistance. Sanofi did not seek any patent protection for this drug. ASAQ Winthrop® is available at a price of less than U.S.\$1 for adults and U.S.\$0.50 for children for a full three-day treatment regimen. Of the 34 countries where the treatment is registered, 31 are in Africa.

Raising awareness among communities

Alongside our partners, we seek to develop educational programs and materials adapted to local contexts and make them available to health authorities and NGOs. As the primary victims of malaria, children must be informed about how to stop transmission of the disease, because awareness contributes to sustainably changing behaviors. Designed specifically for youngsters in primary school, "Schoolchildren Against Malaria" is an awareness program implemented in schools in collaboration with the National Malaria Control Programs, Ministries of Health and Ministries of Education.

 [Schoolchildren against Malaria – Niger, 2015](#)

Our long-term commitment to fighting neglected tropical diseases (NTDs)

NTDs thrive among the world's poorest populations, where they are an obstacle to poverty reduction and socioeconomic development. Sanofi has been committed to the fight against neglected tropical diseases since 2001, working alongside the WHO. We will have contributed U.S.\$75 million over the period 2001-2016, including financial support and donations of medicines. In January 2012 we became a signatory of the London Declaration on NTDs, along with public and private entities including other pharmaceutical firms and the Bill & Melinda Gates Foundation.

Our Access to Medicines Department has developed and implemented policies for several NTDs: sleeping sickness, lymphatic filariasis, leishmaniasis, Chagas disease and Buruli ulcer. In October 2015, Sanofi and the Institut Pasteur de Tunis signed a collaboration agreement to combat leishmaniasis. Within the scope of an awareness program to be launched in schools in March 2016, around 70,000 educational comic books in French and Arabic will be distributed to schoolchildren in seven endemic governorates. The program has received support from the Tunisian Ministry of Health and the Ministry of Education.

Facts and figures

€29.9 MILLION
INVESTED IN RESEARCH AND
DEVELOPMENT TO FIGHT MALARIA,
TUBERCULOSIS (INCLUDING
VACCINES), LEISHMANIASIS
AND SLEEPING SICKNESS

MALARIA: DID YOU KNOW?

Malaria is the world's most common and deadliest parasitic disease. According to WHO estimates, there were 214 million cases and 438,000 deaths from malaria in 2015⁽¹⁾, mostly among African children.

In 2015 alone, we provided more than 50 million treatments of ASAQ Winthrop®. To date, around 400 million treatments have been delivered.

Within the scope of "Schoolchildren against Malaria", in Niger in 2015, 50 primary schools, 140 teachers, 50 health workers and more than 5,000 children cascaded messages to more than 100,000 people in the community. To date, the program has reached more than 7.7 million people in more than 15 African countries.

(1) WHO, 10 Facts on Malaria.

MORE in our Download Center

- [Fighting Malaria factsheet](#)
- [Fighting Tuberculosis factsheet](#)
- [Fighting Neglected Tropical Diseases factsheet](#)
- [Participating in Collaborative Efforts to Promote Access to Healthcare factsheet](#)
- [Access to Medicines 2014-2015 \(brochure\)](#)
- [Sanofi and Africa – A sustained commitment to serving patients \(brochure\)](#)

COMBATting INFECTIOUS DISEASES

In 2015, Sanofi Pasteur, our vaccines division, embraced new commitments to address major infectious diseases worldwide.

Strengthening our support for Gavi's global health commitments

Along with other public health stakeholders, Sanofi Pasteur has made new pledges to support Gavi, the Vaccine Alliance, in fulfilling its vision to save children's lives and improve health. Gavi's goal is to immunize 300 million children in the world's poorest countries between 2016 and 2020, which is projected to save five to six million lives. Sanofi Pasteur's contribution takes many forms:

- We are making significant investments in our manufacturing capacity, ultimately aimed at doubling our yellow fever vaccine production capacity to supply endemic countries faced with chronic shortages;
- We will honor Gavi-level pricing through 2018 for countries transitioning from Gavi support that have since 'graduated' from Gavi;
- We plan to complement the EPIVAC vaccinator training program by co-funding a similar program in Nigeria; and
- Sanofi Pasteur has worked with global partners to facilitate the affordability and optimal use of inactivated polio vaccines (IPV). Through the price mechanism developed together with the Bill & Melinda Gates Foundation, we provide significant quantities of IPV to Gavi countries for delivery in routine immunization. In November 2015, we announced the shipment of ShanIPV™, a new injectable, inactivated polio vaccine manufactured by our affiliate Shantha Biotechnics in Hyderabad, India. The first vaccine doses will be available to implement one dose of IPV in India's immunization schedule for all infants. Over 20 million infants will eventually receive this new vaccine every year.

Working together to devise new ways to fight infectious diseases

In October 2015, Sanofi Pasteur announced the creation of a Global Health Vaccine Center of Innovation (GHVCI) with the Infectious Disease Research Institute (IDRI), a United States-based global health, non-profit institute with a focus on developing new products to combat the world's most devastating infectious diseases. This project is also funded by a grant from the Bill & Melinda Gates Foundation. The GHVCI was established to accelerate the development of vaccines and supporting technologies to address infectious diseases and help ensure that new critical vaccines are available for people in developing countries. Sanofi Pasteur will leverage the resources and expertise of this external R&D innovation center and obtain access to IDRI's adjuvants and vaccine antigens.

MORE in our Download Center

- [Access to Vaccines – 2015 factsheet](#)

TACKLING NON-COMMUNICABLE DISEASES

Addressing the burden of diabetes globally

Today, 415 million people are estimated to have diabetes and the International Diabetes Federation expects there will be 642 million people with diabetes by 2040⁽¹⁾. Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. By working in collaboration, Sanofi pioneers sustainable solutions designed to provide comprehensive care to people living with diabetes, delivering impactful programs to improve patient outcomes by:

- Advancing science and knowledge; and
- Strengthening healthcare systems through awareness, education and better disease management.

Advancing science and knowledge

Around 86,000 children under the age of 15 develop Type 1 diabetes annually⁽¹⁾. Sanofi funds the TEENS registry study, the largest worldwide observational study assessing Type 1 diabetes management and the psychosocial characteristics of nearly 6,000 young people (aged 8 to 25) with Type 1 diabetes. This study aims to better understand the difficulties faced by these young people. Sanofi has collaborated with more than 200 centers, in particular the T1D Exchange in the U.S., for interviews of healthcare providers, young people with Type 1 diabetes and their families in 20 countries across five continents. TEENS provides a unique opportunity to lay the groundwork for implementing recommendations to enhance care and patient outcomes by focusing on modifiable factors associated with glycemic control and quality of life.

In order to understand the management of diabetes in low- and middle-income countries and support policymaking, the International Diabetes Management Practice Study (IDMPS) assesses changes in diabetes management and education. IDMPS, the largest worldwide study of adults living with diabetes (Type 1 and

(1) International Diabetes Federation, Diabetes Atlas 7th edition, 2015.

Type 2), has been ongoing since 2005 in more than 50 countries, including 24 developing countries. It involves approximately 5,000 investigators and 75,000 patients. Since 2005, six waves of studies have shed light on many aspects of diabetes practices, from management of care to education, resource consumption, barriers to insulin, and diabetes and depression. A seventh wave is currently in progress.

To facilitate evidence-based decision making by Russian authorities, in 2013 Sanofi Russia and the Federal Endocrinology Scientific Center in Russia launched the largest-ever epidemiological study of Type 2 diabetes prevalence among Russian adults. On the basis of study findings, Sanofi will endeavor to develop primary and secondary prevention programs, increase public awareness about the importance of timely diagnosis, and improve active control of diabetes. The results from a cohort of 26,000 people from 65 Russian regions were presented in December 2015 during the World Diabetes Congress.

Working to strengthen healthcare systems through awareness, education and better disease management

In 2015, Sanofi continued to take part in initiatives to strengthen healthcare systems through better disease management, education and awareness. These initiatives are the result of research and identifying knowledge gaps in the field while engaging with and listening to people living with diabetes, as well as our partners.

"Be He@lthy, Be Mobile"

Sanofi is a partner of "Be He@lthy, Be Mobile," a ground-breaking initiative led by the International Telecommunication Union in collaboration with the WHO, public and private sector organizations, governments, the United Nations, industry and academia. This program uses technology to improve the prevention, treatment and care of non-communicable diseases in several priority countries. One of its ambitions is to enhance national capacities to strengthen health systems in order to assess the growing burden of non-communicable

diseases. Mobile solutions for diabetes represent a unique opportunity to create a much-needed continuum of care, including prevention and support targeting different segments of the population. Sanofi is involved in "mDiabetes," part of the "Be He@lthy Be mobile" global initiative. The project, which was recently introduced in Senegal, makes use of targeted text messages for people living with diabetes and healthcare professionals—for instance, to help people manage diabetes during the month of Ramadan, when sugar consumption rises steeply and health authorities witness a peak in the urgent hospitalization of people with uncontrolled diabetes. The second "mRamadan" campaign reached more than 10,000 people (an increase of around 65% compared to the pilot year), with an observed impact on eating habits. The "mRamadan" campaign illustrates the strengths of a multi-sector initiative that brings together expertise, knowledge and determination to address a broad-based public health concern. The initial results of this second campaign were presented during the World Diabetes Congress in December 2015.

Supporting patients with concomitant diabetes and tuberculosis

The co-existence of two epidemics, tuberculosis and diabetes, represents a serious public health challenge for health care systems, particularly in low- and middle-income countries. While the biological basis for the association between diabetes and tuberculosis is not fully understood, together they make an infectious and deadly combination that is more complex than either disease alone. A person with diabetes has a two to three times greater risk of developing active tuberculosis. Diabetes is also a risk factor for tuberculosis treatment failure and death. An estimated 2.3 million adults in South Africa have diabetes, and prevalence is on the rise. In November 2015, Sanofi announced a joint program with the University Research Co. and South African Aquity Innovations and the National Department of Health. The goal of this project is to improve early detection of concomitant diabetes and

tuberculosis, and support patient management. Targeting the provinces of KwaZulu Natal, Eastern Cape, Gauteng and Free State, it aims to help bolster healthcare workers' skills and practices, integrate diabetes and tuberculosis care into routine health services, and teach patients about disease prevention and control.

"KiDS" helps create a supportive school environment for children with diabetes

The number of children with Type 1 and Type 2 diabetes is increasing worldwide and today it is estimated that 542,000 children have Type 1 diabetes⁽³⁾. Sanofi launched the "Kids and Diabetes in Schools" (KiDS) program in India in 2013 and Brazil in 2014 in collaboration with the International Diabetes Federation, the International Society for Pediatric and Adolescent Diabetes and local entities. KiDS aims to foster a safe and supportive school environment that creates a better understanding of diabetes and supports children with this condition. It also provides information about how suitable lifestyle choices can help prevent Type 2 diabetes. To date, nearly 1,400 staff and 38,000 students have been trained in 30 pilot schools in New Delhi and São Paulo. The KiDS pilot program reports an overall improvement in meal quality and access to healthy food choices, with some schools taking steps to ban junk food. A greater focus on physical activity includes, for example, yoga classes in some schools in India. Following the success of the KiDS pilot programs in India and Brazil, which received strong support from health and education ministries, we plan to scale up the project in the pilot countries while introducing it in additional countries in 2016. Sanofi is involved in similar awareness and education programs in schools in Turkey, Canada and Algeria.

(3) International Diabetes Federation, Diabetes Atlas 7th edition, 2015.

Addressing epilepsy and mental health in low- and middle-income countries An integrated epilepsy management approach

Epilepsy is one of the most common chronic neurological disorders. Worldwide, about 50 million people live with epilepsy, nearly 80% of them in low- and middle-income countries. About three fourths of people with epilepsy living in these countries do not get the treatment they need.⁽⁴⁾ Sanofi is one of the first healthcare companies to become actively involved in improving access to care for people with epilepsy in developing countries. In collaboration with the Institute of Neuroepidemiology and Tropical Neurology in Limoges (France), local NGOs, ministries of health and academic institutions, we support programs in Latin America, Africa and Asia to improve access to care, raise awareness and fight stigmatization, as well as to train healthcare professionals. In addition, medicines are made more accessible to the most disadvantaged patients through preferential pricing policies, in compliance with applicable laws and procurement processes. In Laos, where such a program has been launched, around 200 general healthcare professionals were trained in 2015.

[▶ Developing access to care for epilepsy in Laos and Cambodia](#)

There is no health without mental health

According to the WHO, 450 million people experience mental or neurological disorders across the world. In developing countries, a majority of patients do not receive suitable treatment and are often marginalized and rejected by society. Since 2008, we have been instigating programs and collaborations to improve access to mental healthcare in developing countries. Initially launched in Morocco and Mauritania in collaboration with local authorities, health professionals, patient organizations and NGOs, our programs were subsequently implemented in Armenia, Benin, Comoros, Madagascar and Guatemala. In most countries, they were

introduced through the Fight Against Stigma (FAST) project, an innovative public-private partnership with the World Association of Social Psychiatry (WASP). The FAST project seeks to bring together the various stakeholders involved in mental health, educate communities, fight stigmatization and train front-line healthcare professionals. Our initiatives are aligned with the objectives set out in the WHO Mental Health Action Plan 2013-2020, which aims to provide integrated community-based services, boost prevention strategies and reinforce information systems relating to mental health. In addition, a specific Sanofi department works on setting up solutions to make medicines sustainably accessible to the most disadvantaged patients through preferential pricing, consistent with applicable laws.

In Madagascar, Sanofi has joined with the Ministry of Public Health and WASP to improve access to information and care for patients and their families. Since the program was launched in 2013, specialists have provided training about schizophrenia and epilepsy for more than 100 general practitioners. Additional training sessions about depression, anxiety disorders, addictions, pediatric psychiatric disorders and providing care for patients with violent behavior are planned as part of the program. These general practitioners play a key role when it comes to raising awareness within communities. Communication tools in the Malagasy language were provided to help general practitioners educate patients and their families about the disease.

[▶ For Better Healthcare Management in Madagascar](#)

MORE in our Download Center

• [Epilepsy and Mental Illness factsheet](#)

(4) WHO, Epilepsy Fact sheet No 999, May 2015.

Facts and figures

DIABETES: "KIDS" PROGRAM

To date, nearly 1,400 staff and 38,000 students have been trained in 30 pilot schools in New Delhi and São Paulo.

EPILEPSY: DID YOU KNOW?

Worldwide, about 50 million people live with epilepsy, nearly 80% of them in low- and middle-income countries.

COMMITTED TO IMPROVING MATERNAL AND INFANT HEALTH

Reducing child mortality and improving maternal health figure among the United Nations Millennium Development Goals. These health challenges remain important in the new Sustainable Development Goals, and Sanofi is committed to continuing our efforts to address them. The Sanofi Espoir Foundation focuses on reducing maternal and neonatal mortality and fighting childhood cancer as two of its longstanding priorities.

Training midwives to combat maternal and neonatal mortality

To help reduce maternal and neonatal mortality, the Foundation put in place a unique initiative, "Midwives for Life," aimed at combating largely preventable complications and deaths in developing countries through more and better trained health personnel. Midwives are key players in this fight. At the end of 2015, 11 long-term programs were underway, including six pilot projects in Asia (Myanmar, Cambodia), Latin America (Mexico) and Africa (Senegal/Ivory Coast, Tanzania and Ethiopia). In 2014 the Sanofi Espoir Foundation launched the "Midwives for Life Awards" to reward initiatives by midwives to reduce maternal and newborn mortality and improve the health of women and newborns in developing countries. For the second year of the awards, 10 winning projects from Cambodia, India, Morocco, Democratic Republic of Congo, South Africa, Vanuatu, Zambia, Zimbabwe and two twin projects in Japan/Mongolia and the Netherlands/Sierra Leone/Morocco were selected by a jury of experts.

Fighting childhood cancer: "My Child Matters"

In wealthier countries, 80% of childhood cancers can be cured, but in low-resource countries this figure drops to 20% or even 10%, and yet 80% of affected children live in these regions. The "My Child Matters" program has been developed by the Foundation since 2006 to help enable children with cancer in low- and middle-income countries in Africa, Asia and Latin America to benefit from earlier and better-supported diagnoses. This program aims to strengthen the capacity of local teams deployed in collaboration with the St Jude Children's Research Hospital, the International Society of Pediatric Oncology, the Union for International Cancer Control, the French-African Pediatric Oncology Group (GFAOP), Childhood Cancer International and other organizations to fight against childhood cancer. Since 2006, this program has supported 45 projects in 33 countries. Results from the "My Child Matters" program were highlighted during the World Cancer Leaders' Summit in November 2015. For example, in the Philippines, an archipelago of thousands of islands, access to care remains a major challenge for poor families, in particular those living in remote areas. Thanks to ten years of collaboration and mobilization by stakeholders from civil society and the Filipino Ministry of Health, the Philippines Children's Medical Center in Manila has become a national reference center for childhood cancers. The rate of late diagnosis has dropped from 70% to 30%, and the survival rate has been multiplied by four.

Facts and figures

"MY CHILD MATTERS" IN 2015

50,000 CHILDREN
taken into care

16,000 HEALTHCARE
PROFESSIONALS trained

25,000 FAMILIES
helped

GENZYME: TREATING PATIENTS WITH RARE DISEASES

More than 650 patients are currently receiving free therapy through Genzyme Humanitarian Programs and more than 1,700 patients in 70 countries have received free therapy since these programs were introduced. Today Genzyme Humanitarian Programs are meeting the needs of eligible patients on six continents and include the International Charitable Access Program plus country specific programs in the United States, China, India and Egypt. Since 2000, Project HOPE has joined with Sanofi Genzyme in Egypt to implement the Gaucher Initiative. The mission of the program is to provide access to therapy to eligible Gaucher disease patients in Egypt who have no means of obtaining treatment on their own. In November 2015, representatives from Project HOPE, Sanofi Genzyme, the Egyptian medical community and physicians from the Medical Expert Committee of the Gaucher Initiative gathered in Dubai to celebrate 15 years of successful, shared commitment to helping Gaucher disease patients in Egypt. Since the inception of the program, hundreds of patients in Egypt have received treatment free of cost. Additionally, the program has helped build the capacity of the Egyptian health system to properly diagnose, refer and manage Gaucher disease patients, and has contributed to worldwide understanding of the disease.

ANIMAL HEALTH AND THE “ONE HEALTH” CONCEPT

Animal health and human health are closely intertwined. The “One Health” concept recognizes that the health of humans is connected to the health of animals and the environment⁽¹⁾.

Meril, Sanofi’s animal health division, is leading the “Zoonoses⁽²⁾ Anticipation and Preparedness Initiative” (ZAPI) program, which started in March 2015. ZAPI is the first “One Health” project supported by the European Union as part of the Innovative Medicine Initiative public-private partnership. ZAPI is a five-year project involving 20 entities from six countries, including three industrial enterprises. The project took shape to design new R&D and manufacturing processes with the aim of producing vaccines and neutralizing agents against zoonotic diseases in less than six months, in the event of an emergency. Included in ZAPI’s development programs are vaccines to prevent Rift Valley Fever Virus (RVFV) and Schmallenberg Virus (SBV) and neutralizing reagents targeting RVFV and the Middle-East Respiratory Syndrome Coronavirus (MERS-CoV). The new R&D and manufacturing processes are designed to should be applicable to preparedness for both animal and human health needs to address infectious diseases.

MORE in our Download Center

- [Developing Access to Animal Health factsheet](#)

Facts and figures

RARE DISEASES: DID YOU KNOW?

Gaucher disease is an inherited genetic disorder that often causes an enlarged liver and spleen as well as bone pain and other skeletal problems. It affects 1 in 40,000-60,000 people worldwide.

MORE in our Download Center

- [Discovering and Treating Rare Diseases factsheet](#)

(1) Center for Disease Control and Prevention: www.cdc.gov/onehealth

(2) Diseases and infections that are naturally transmitted between vertebrate animals and humans.



PATIENT SAFETY

Sanofi provides medicines, vaccines and innovative therapeutic solutions to patients and consumers across the globe. Ensuring their safety is one of the most important requirements in our daily work.

G4-15 G4-DMA G4-PR1 G4-PR3

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
Ensure that employees at all levels and in all positions understand and embrace the fundamentals of quality.	The quality fundamentals e-learning program was launched company-wide, and more than 82,000 people had been trained by the end of 2015.	On track
Achieve "Best in Class" management of preventive and corrective action plans (CAPA) by using a single inspection management approach and CAPA tool at all entities and sites.	A new inspection database has been implemented progressively by all entities; the CAPA module has been deployed in 89 manufacturing sites (77%).	On track
Continuously improve the oversight of pharmacovigilance data sources.	Research projects were initiated to develop methodologies for assessing digital media content (big data) as a complementary source of safety signal detection and epidemiology analysis.	On track
Ensure that all employees are aware of counterfeit risks so they can report any suspicious products.	More than 50 sites participated in the 2015 Anti-Counterfeit Day. E-learning modules (general and specific) were designed and launched.	On track
Improve sampling, analysis and data collection for counterfeit Sanofi products.	More than 30,000 entries have been recorded since 2008 by the Central Anti-Counterfeit Laboratory to analyze potential counterfeit products.	On track

STRATEGIC APPROACH

Patient safety is the primary focus of our pharmacovigilance, quality and anti-counterfeiting teams. The Pharmacovigilance Department monitors the safety of our products, and ultimately contributes to the continuous assessment of their benefit-risk profile. The mission of Pharmacovigilance is to safeguard patient safety, and the Department is strongly committed to appropriate transparency and compliance with all applicable regulations and policies. Our approach involves guaranteeing quality at each phase of a product's life cycle, from the earliest steps of development to the distribution of products to sales channels: this is the responsibility of Sanofi's Quality organizations. Lastly, because we are concerned about the threat to patient safety posed by counterfeit medicines, Sanofi is involved in assisting enforcement authorities to combat counterfeit drugs.

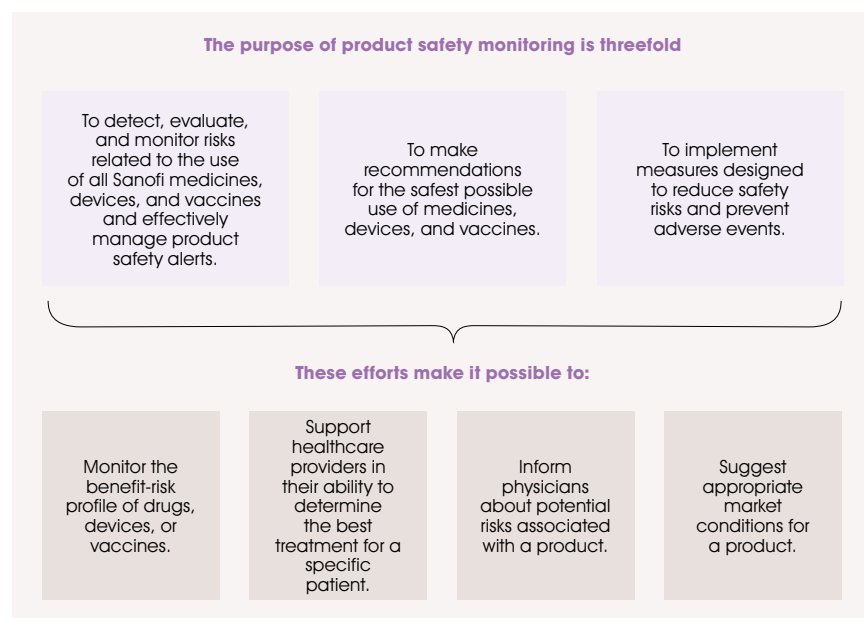
PHARMACOVIGILANCE: MONITORING PRODUCT SAFETY TO PROTECT PATIENTS

Our pharmacovigilance teams monitor safety and are able to adjust the benefit-risk profile of our products: prescription medicines, vaccines, consumer health products, generics, medical devices and animal health products. Pharmacovigilance helps determine the best conditions of use for treatments, and provides physicians, healthcare professionals and patients with comprehensive, up-to-date safety information, including potential risks associated with a product.

Centralizing our pharmacovigilance expertise

Sanofi's Global Pharmacovigilance & Epidemiology (GPE) Department is responsible for pharmacovigilance. As one of our centers for medical and clinical expertise, GPE works closely with healthcare professionals, health authorities and the patient community to help reduce safety risks and prevent adverse events for patients. The GPE Department issues recommendations designed to ensure the safest possible use of medicines.

PURPOSE OF PHARMACOVIGILANCE



Facts and figures

PHARMACOVIGILANCE

is the process of monitoring the safety and contributing to the continuous assessment of the benefit-risk profile of our products at every stage of their life cycle.

QUALITY MANAGEMENT SYSTEMS

cover every aspect of our business—development, manufacturing, distribution and marketing—to ensure compliance with corporate and regulatory requirements.

A COUNTERFEIT MEDICINE

is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. (WHO definition)

6 PHARMACOVIGILANCE

INSPECTIONS were carried out by public health authorities in 2015: 3 in Europe, and 1 each in Argentina, Canada and Saudi Arabia.

On a continuous basis, it detects, evaluates and monitors potential risks related to the use of all our products from all sources of pharmacovigilance information, collected in a passive or active manner, based on interactions with patients and healthcare professionals.

In 2015, Sanofi stepped up scrutiny of the surveillance of patient support and market research programs, implementing a more robust governance model designed to ensure stronger oversight and complete safety data collection and maximize our knowledge about the use of our products in real-life conditions.

GPE's global safety governance organization is made up of cross-functional teams in charge of monitoring and assessing safety information for all our products in development and products on the market. To support the comprehensive characterization of safety profiles and appropriate risk mitigation measures, the governance organization follows a streamlined process illustrated (see illustration).

This process extends from the early detection of a potential safety signal to its adjudication by the board of experts. When necessary, patient leaflets and product information are updated in close collaboration with regulatory bodies worldwide to support transparency and effective communications with physicians and patients.

In addition, to enhance our benefit-risk analysis capabilities, Sanofi is increasingly integrating signal detection, epidemiological information and input from risk management centers of excellence.

As an active member of several public-private consortia focused on patient safety, Sanofi continues to explore the value of digital media screening as a potential source of safety signals, using epidemiological methodologies. We contribute to the Innovative Medicine Initiative (IMI) WEB-RADR project, which evaluates the use of mobile devices and social media to improve the reporting of suspected adverse drug reactions by patients. The project also explores how these tools may be used to detect potential safety issues related

to medicines, or to improve interactions with healthcare professionals and patients.

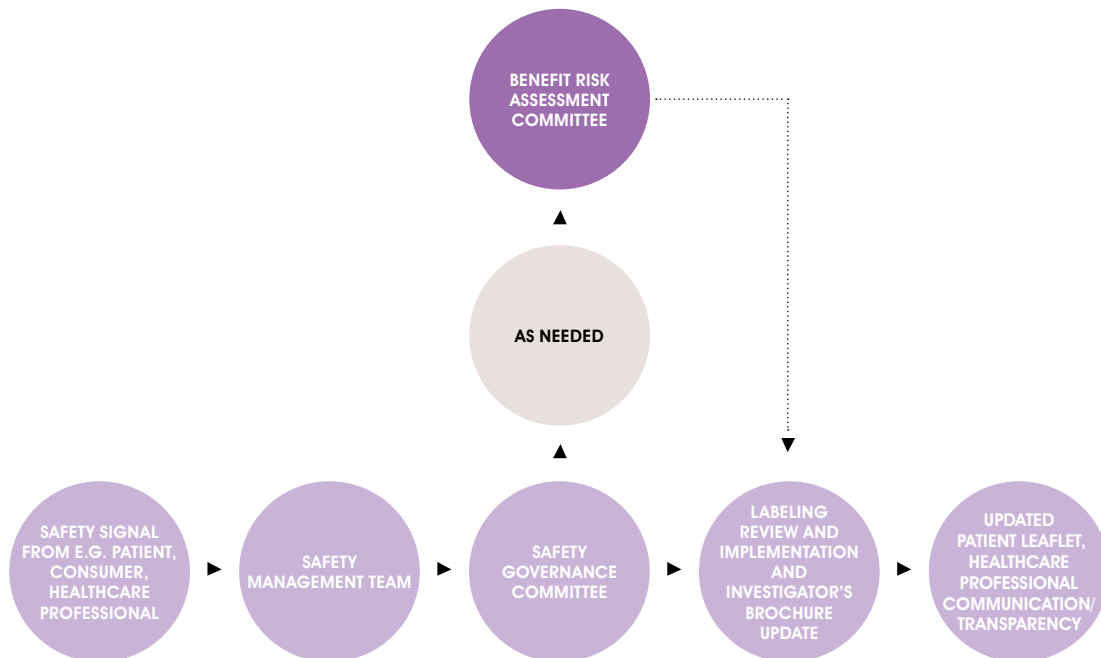
Sanofi has a separate pharmacovigilance system designed to ensure the safety of animal health products.

QUALITY SYSTEMS ENSURE REGULATORY COMPLIANCE

Sanofi's quality approach is designed to ensure that we provide safe and effective products that are developed, manufactured, distributed and marketed in compliance with regulatory requirements and internal company standards worldwide.

Sanofi's quality systems cover our entire product portfolio (prescription medicines, vaccines, consumer health products, generics, medical devices, and animal health products) and all activities governed by health-related regulations throughout the entire life cycle: research and development, manufacturing, marketing and distribution, information to patients, consumers and

SANOFI'S GLOBAL PHARMACOVIGILANCE & EPIDEMIOLOGY (GPE) DEPARTMENT PROCESS



PATIENT SAFETY

healthcare professionals, post-marketing surveillance and pharmacovigilance. Our quality systems are under the responsibility of the Global Chief Quality Officer, who has direct access to the CEO.

MORE in our Download Center

• [Quality Management Systems factsheet](#)

G4-15 **G4-56** **G4-DMA** **G4-PR1**

A revised version of Sanofi's Global Quality Policy was published in 2015. Signed by the Global Chief Quality Officer and our new CEO, it is available in 27 languages and is distributed to employees in every country where we operate. It highlights our commitment to patient safety and product quality worldwide, and supports all Sanofi employees in upholding our Quality Fundamentals.

MORE in our Download Center

• [Quality Policy](#)

Looking to the future, the Global Quality organization's vision includes well-defined targets to ensure effective implementation of all quality principles over the next three to five years. This strategic view encompasses our five key areas: quality systems, inspection readiness, quality risk management, quality performance and quality culture. Each year, the organization tracks progress in the different areas to review and adjust its vision as needed.

Managing quality-related risks

We rely on a mature quality risk management process to enable effective decision making and to build confidence among public authorities in our ability to address any potential issues that may arise.

Sanofi's approach is both reactive and proactive. A well-established and widely-deployed escalation process for quality events and an alert management system are interconnected with the relevant Sanofi functions (R&D, Medical Affairs, Industrial Affairs, Commercial Operations, etc.). This allows us to handle any quality issue in a timely and effective manner in order to mitigate its impact and define and implement any necessary corrective and preventive actions.

Similarly, emerging risks, meaning those that have not yet materialized, can be proactively detected from both internal and external sources through a surveillance process using dedicated resources and the support of a network of experts working in various areas. If a risk is identified as potentially relevant for the company, an in-depth analysis is performed and all necessary measures are taken to help prevent any negative impact on the company or on patient safety.

Data integrity is a topic of growing importance for patients, healthcare professionals and regulatory authorities. We recognize that ensuring data integrity is critical to foster trust and confidence among our stakeholders when it comes to the robustness of our files and the safety of our products. This is why Sanofi is investing substantial efforts to raise awareness among the workforce, in particular employees who work in health-regulated activities, and to ensure the integrity of the data we use and submit to the authorities.

Monitoring our internal quality performance: internal quality audits, management quality reviews, management of complaints, recalls

In 2015, we continued to enhance our manufacturing operations and quality systems in line with health authority requirements and in strict application of Good Manufacturing Practices. Required quality controls are performed and documented at every stage of production, prior to release, and each year, product quality reviews are conducted for each product on the market in order to assess the validity of the manufacturing process, to deliver safe and effective products, and ensure continuous improvement.

As part of our ongoing efforts to instill a sustainable compliance culture in line with regulatory requirements and prepare for regulatory inspections, our internal entities are audited on a regular basis by a dedicated independent audit team against applicable international or local regulations, as well as internal standards. The audit plan is defined using a risk-based approach, adapted to the type of entity audited, and

Facts and figures

QUALITY FUNDAMENTALS: THE 10 PRINCIPLES

1. Be constantly qualified.
2. Follow the rules.
3. Act openly and transparently.
4. Inform and respect patients and consumers.
5. Continuously improve our products, services and processes.
6. Ensure traceability of tasks and steps.
7. Be responsible for what third parties provide.
8. Anticipate, escalate and manage issues.
9. Be rigorous and act responsibly.
10. Say what must be done, do what is planned and document what was done.

The Quality Fundamentals training program is in place in all Sanofi entities. By the end of 2015, 65% of the workforce at every level of the company had taken the program.

E-LEARNING HELPS EXPLAIN DATA INTEGRITY

We have developed and started to deploy an e-learning module covering the requirements for data integrity and ways to monitor and protect it. The module is available to all employees and is being translated into various languages.

A RISK-BASED MODEL TO PLAN INTERNAL QUALITY AUDITS

Each year all manufacturing sites, distribution centers and commercial country organizations are mapped on a color-coded risk grid with two dimensions: intrinsic risk score and compliance risk score. Based on this scoring, the target duration/ frequency of audits is defined for each entity, and an audit plan is established. The compliance risk score is identical for all types of entities, and compiles historical internal quality audit and regulatory inspection performance (number and criticality of observations). The intrinsic risk score is specific to each type of entity. With manufacturing sites, for example, the score is based on number of staff, number of countries served, number of products, technology used, etc.

considering both the specific site characteristics and recent compliance performance. Following audits, corrective and preventive actions (CAPAs) are determined, commensurate to the nature and severity of the audit findings. CAPAs are recorded in a specific quality management tool (CAPA Module, see "Our Progress, p.33") that is progressively deployed to all entities. Regular follow-up ensures that these actions are fully implemented in a timely manner. In 2015, we performed 249 quality audits of internal entities involved in activities governed by health-related regulations.

RELATED CONTENT in this report

- Page 50, Audits of clinical trials

For manufacturing quality, we monitor a number of performance indicators and quality metrics on a regular basis. In addition to regular follow-up at the operational level, a comprehensive report is prepared each quarter and distributed to quality executives.

In addition, reviews are organized periodically by the quality departments with their respective operational management to evaluate quality performance, assess progress against defined action plans, identify critical risks and ensure that appropriate measures are taken.

A dedicated system is in place in all entities to handle complaints received from patients, consumers and healthcare professionals, potentially indicative of quality defects or difficulties in handling or using our products. This system involves commercial affiliates, manufacturing sites, and other functions such as pharmacovigilance as needed, and aims at promptly analyzing the complaints, and defining corrective and preventive actions if needed. Likewise, regulatory authorities are notified in a timely manner about defects, in compliance with regulatory requirements. We seek to learn from complaints to design improvements that will make Sanofi products easier for patients to use, when needed and technically possible.

Providing user-friendly products helps create the conditions for optimal efficacy. In rare cases, it becomes necessary to recall products from the market for various reasons. Sanofi has an established recall process in place, covering all types of products and all types of recalls. This ensures a substantiated decision-making process involving all relevant internal entities, transparent interaction with concerned authorities and rapid communication to the appropriate stakeholders (patients, pharmacists, wholesalers and healthcare professionals), depending on the nature of the recall. In 2015, our rate of batches recalled⁽¹⁾ for quality reasons was less than 0.34%⁽²⁾. In most cases, these recalls were voluntary, i.e., not mandated by the authorities but decided as a precaution, in line with our commitment to put and keep only safe and effective products on the market.

Inspections by regulatory authorities

Our various entities are inspected by health authorities on a regular basis. Following these inspections, corrective and preventive actions are determined as necessary and regular follow up ensures their full implementation. In 2015, Sanofi underwent 335 inspections worldwide, with no resulting regulatory action (such as a warning letter, significant disruption of product supply or regulatory submission, or impact on marketing authorization approval status).

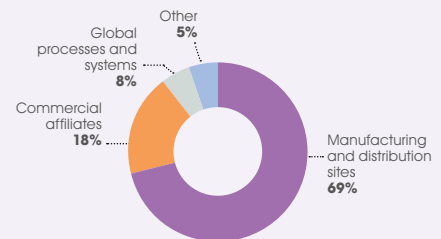
Out of the 219 inspections conducted in manufacturing and distribution sites in 2015, 45% were performed in Europe, where most of the Group's sites are located, and 16% in North America.

(1) Rate of batches recalled = number of batches of commercial products recalled in a given year vs. total number of batches of commercial products released in the same year, expressed as a %.

(2) Our rate of batches recalled in 2015 was higher than in 2014 (less than 0.1%) due in particular to the recall of all Auviq®/Allerject® batches in North America.

Facts and figures

INTERNAL QUALITY AUDITS IN 2015, BY ACTIVITY

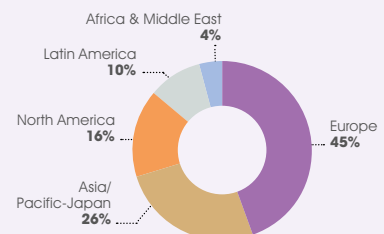


249 audits worldwide

THE "HUMAN ERROR PREVENTION" PROJECT

A Global Quality Strategic Project was conducted in 2015 at various manufacturing sites around the world to investigate the topic of human errors. Multiple interviews were conducted at all levels of the sites, from management to shop floor, to understand the anatomy of human errors, and identify ways to reduce them. The conclusions of the analysis were shared with senior management, and a broad action plan was designed and endorsed. It will be implemented starting in 2016.

REGULATORY INSPECTIONS IN 2015, BY REGION* MANUFACTURING & DISTRIBUTION SITES



219 inspections worldwide

* See definition of regions on Page 107.

PATIENT SAFETY

INSPECTIONS	2014	2015
Number of regulatory inspections	279	335
Pharmacovigilance	5	6
Clinical research (good clinical practices)	82	73
Pre-clinical research	11	21
Manufacturing & distribution sites (good manufacturing practices/good distribution practices)	164	219
Affiliates	17	16
Number of inspections resulting in regulatory actions from health authorities	0	0

SAFETY OF THE END-TO-END SUPPLY CHAIN

Monitoring the quality performance of our suppliers and subcontractors: controls and quality audits

We pay close attention to third parties that provide services, raw materials, and products used for our activities, which are subject to strict guidelines and regulations. All materials, equipment, and services (including transport) that may have an impact on product quality are purchased from approved sources according to pre-defined criteria, and they are tested upon receipt at our plants when applicable. As part of this approach, we audit numerous third parties on a regular basis.

As is our practice for internal entities, we plan audits of third parties using a risk-based approach. One of the key factors in our analysis is the criticality of the service or product supplied or manufactured. Supplying active pharmaceutical ingredients and contracted manufacturing or distribution operations take on particular importance due to their potential impact on the integrity and safety of Sanofi products.

Ensuring optimal transport conditions for our products

For several years, Sanofi has been implementing specific measures and proactively allocating resources to anticipate and take into account changes in the regulations related to Good Distribution Practices, and to reflect them in our internal standards.

We provide expert advice on optimal conditions and means of transport, and we provide support to resolve any difficulties that may arise. We seek to ensure that our products will be transported from production facilities to all intermediaries and end-users in the most efficient way possible, while also safeguarding all properties relating to product quality. Carriers go through a qualification process and are required to sign a quality agreement with the company. Audits of carriers are conducted on a regular basis using a risk-based approach. Sanofi has put in place specific measures designed to ensure the continuity of supplies so that our medicines and vaccines can be delivered to the market without interruption and patients can start or continue their treatments.

MORE in our Download Center

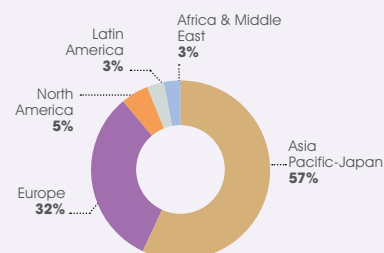
• Continuity of Activities and Supplies factsheet

G4-DMA G4-PR1

AUDITS OF THIRD PARTIES	2014	2015
Suppliers of active pharmaceutical ingredients (API)	262	273
Contract manufacturing organizations	242	288
Distribution subcontractors	56	50
Total number of audits	560	611

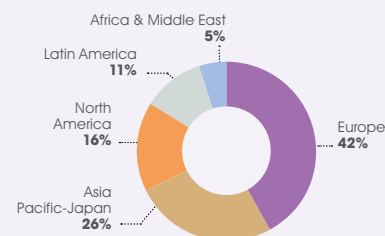
Facts and figures

AUDITS OF API SUPPLIERS IN 2015, BY REGION*



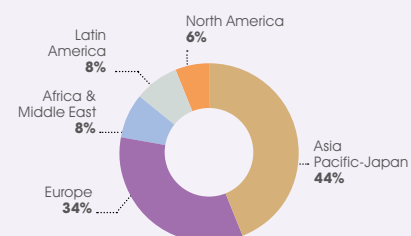
273 audits worldwide

AUDITS OF CONTRACT MANUFACTURING ORGANIZATIONS IN 2015, BY REGION*



288 audits worldwide

AUDITS OF DISTRIBUTION SUBCONTRACTORS IN 2015, BY REGION*



50 audits worldwide

* See definition of regions on Page 107.

PLAYING OUR PART IN THE FIGHT AGAINST COUNTERFEIT DRUGS

According to the U.S. FDA, counterfeit drugs account for more than 10% of the global medicines market. It is estimated that up to 25% of the medicines consumed in developing countries are counterfeit or substandard, and developed countries are not spared by the phenomenon. Counterfeit drugs concern all diseases and therapeutic areas—from cancer to diabetes, malaria and contraceptives, antibiotics, vaccines, etc.

Safeguarding the integrity and traceability of our products and playing our part in the global fight against counterfeit drugs are essential for patient safety. We take a dual approach, cooperating with enforcement authorities and professional organizations in many countries while at the same time operating our own anti-counterfeit laboratory, the Sanofi Central Anti-Counterfeit Laboratory (LCAC).

In 2015 our anti-counterfeiting coordination organization, which operates in the U.S., India and Europe, was expanded to Asia, Africa and Latin America. This structure allows us to pool in-house expertise from many areas (legal, regulatory, security, medical, compliance, communication, industrial and public affairs) and ensures the strategic alignment of all our preventive actions worldwide.

 From drug production to the fight against counterfeit medicines

A wide range of in-house and external initiatives

In the fight against counterfeit drugs, we actively support initiatives by public authorities to promote high standards of drug quality and safety by:

- Working closely with local authorities and professional organizations to educate the public about counterfeiting, especially on the Internet, and the potential risk for people's health;

- Cooperating with police officers, customs officials, health authorities and other pharmaceutical companies to seize potentially harmful products and shut down clandestine production facilities and illegal websites that sell counterfeit drugs;

- Protecting the security of the supply chain and developing innovative, high-tech solutions to safeguard the integrity of our products and to help prevent falsification; and
- Coordinating Sanofi's corporate local actions through a multidisciplinary in-house organization that brings together experts from across the company.

In May 2015, Sanofi was one of the pharmaceutical companies that signed a Memorandum of Understanding with the Armenian Scientific Center of Drug and Medical Technology Expertise. This public-private initiative includes actions and cooperation in Armenia for an awareness campaign on anti-counterfeiting, the exchange of information related to counterfeit medicines, mutual technical support on analysis and counterfeit evidence, sharing best practices, etc.

In October 2015, at the Women's Forum in Deauville, France, Sanofi led a session on the dangers of counterfeit medicines and the essential role women play in improving awareness, with a focus on Nigeria.

 Counterfeit drugs: Information campaign for patients and travelers

MORE in our Download Center

- [Fighting Counterfeit Medicines position paper](#)
- [Fighting Counterfeit Medicines 2015 factsheet](#)
- [G4-DMA](#) [G4-PR3](#)
- [Serialization factsheet](#)

Facts and figures

A SURVEY ON PUBLIC PERCEPTIONS OF COUNTERFEIT MEDICINES

A 2014 survey conducted for Sanofi revealed that 20% of Europeans associate counterfeiting with medicines. In 2015, we conducted a similar survey in the U.S. and Asia (China, Malaysia, the Philippines, Thailand and Vietnam), which showed that 36% of respondents in Asia and 15% in the U.S. linked counterfeiting with pharmaceuticals. Consumers in Asia seem to be aware of the problem, and yet 39% acknowledge buying medicines online (compared to 18% in the U.S.). Overall, these findings indicate that the public does not have an accurate perception of the health issues associated with counterfeit medicines. This clear lack of information makes Sanofi more determined than ever to continue efforts aimed at protecting patients everywhere against counterfeit products.

SANOFI'S ANTI-COUNTERFEIT LABORATORY

At the Sanofi Central Anti-Counterfeit Laboratory (LCAC) in Tours, France, a dedicated team of specialists uses state-of-the-art technologies to analyze suspect product samples found on the market, as well as packaging and product inserts. Since it opened in 2008, the LCAC has recorded more than 30,000 entries in order to analyze potential counterfeit products.

How informed are clinical trial volunteers?

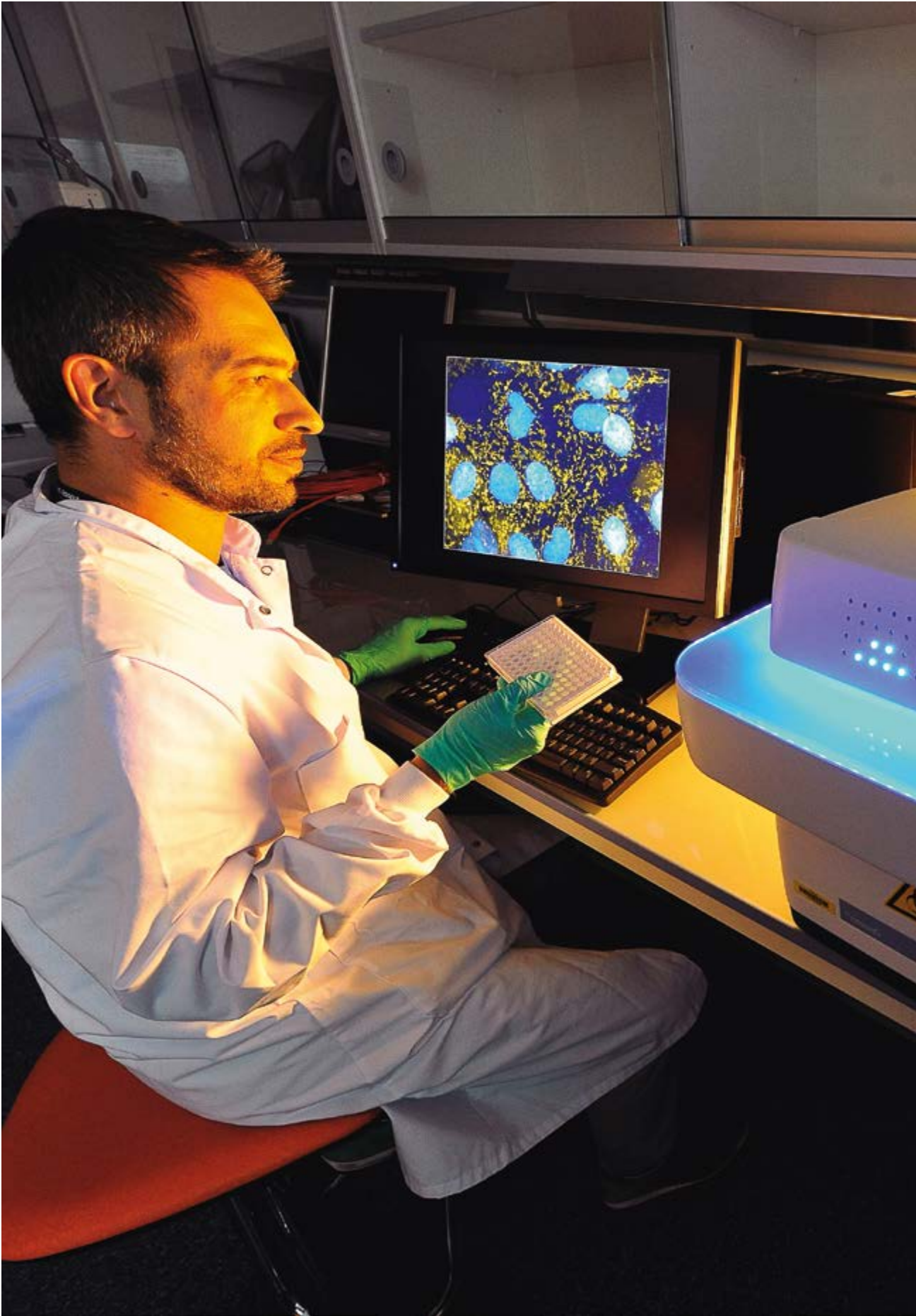
We ensure that individuals who volunteer for clinical trials fully understand the potential benefits and risks, as well as alternatives. This informed consent is the cornerstone of our ethical recruitment of clinical trial participants. However, the process is not just about signing forms: our approach puts the study participant at the center of this process, looking specifically at age, literacy and other factors that may make participants vulnerable.



ETHICS

Because developing new medicines means that we have a responsibility to our patients, Sanofi maintains the highest ethical standards: protecting trial subjects through solid R&D processes and continuously improving the Group's business integrity and transparency.





ETHICS IN R&D

Our R&D practices are continuously challenged by the pace of change in scientific innovation, the increasing globalization of our research activities and the need to comply with constantly-evolving regulatory requirements. Above all, our R&D activities are driven by Sanofi's ambition to meet the growing expectations of patients and communities.

G4-DMA G4-PR1 G4-PR2

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
Ensure the responsible use of animals in our research and production processes	We continued implementation of the 3Rs principles within the Group.	On track
	Mapping the use of animals by third parties was initiated.	On track
Continue to improve information and communication with the patient and healthy subjects as part of the informed consent process	We updated principles and guidelines to be included in existing operating standards.	On track
Address the collection, storage and use of human biological samples for research	Our new policy on the collection, storage and use of human biological samples for research is being implemented.	On track
Improve the management of preventive and corrective action plans resulting from our clinical trials audits	The audit and inspections module became operational in 2015.	Completed

STRATEGIC APPROACH

Through our R&D activities, Sanofi aims to constantly innovate in multiple therapeutic areas while meeting the highest ethical standards. Built on a sound governance system overseen by the Sanofi Bioethics Committee, our strategic approach is designed so that our standards and practices are continuously challenged in response to existing and emerging ethical considerations. We embed this approach in our practices to ensure the responsible use of animals in research and production processes and support ethical conduct in clinical development involving patients and healthy subjects.

FOCUS ON EMERGING CHALLENGES AND STRONGER OVERSIGHT

The Sanofi Bioethics Committee

Created in 2012, the Sanofi Bioethics Committee (BEC) determines the Group's position on bioethics policies that guide the implementation of our R&D strategy. It supports the work of the Sanofi Risk Committee by alerting it to any potential bioethics risks that must be addressed as part of Group's corporate governance responsibility. Ultimately, the BEC is responsible for ensuring that respect for human dignity and human rights are upheld in all our R&D activities.

The Sanofi Group recognizes the importance of defining, respecting and continuously revisiting and improving consistent and transparent bioethical standards during all our research activities involving humans and animals. The Bioethics Committee plays two essential roles:

- It informs internal and external stakeholders about Sanofi's position on the ethical implications of biological research and applications by establishing a common definition and framework for bioethics at Sanofi, promoting a responsible bioethics culture within our R&D organization and increasing the visibility of our bioethics approach; and

- It helps anticipate ethical challenges that may arise at the interface between the life sciences, biotechnology, biodiversity, medicine, politics, law and culture, in particular due to advances in biology and medicine; it fulfills this role by ensuring that our R&D organization continually assesses and apprises emerging bioethics issues, discussing potential issues and findings with relevant stakeholders, working with them to devise mitigation plans, and supporting implementation and monitoring of such plans until issues are resolved.

THE RESPONSIBLE USE OF ANIMALS IN RESEARCH AND PRODUCTION

Research involving animals poses dilemmas not only for scientists who use animals in medical research, but also for society as a whole. The current consensus is that using animals for research is justified when there are clear benefits for human and animal health and when the 3Rs principles (replacement, reduction and refinement) are applied. Animals remain an integral part of a comprehensive research and testing strategy that includes non-animal methods (such as computerized models and *in vitro* testing) and clinical research and animal use is also part of many regulatory requirements. For example, testing vaccines before batch release remains mandatory worldwide for public health reasons and animals are required to ensure the safety and efficacy of commercialized vaccines.

Strongly committed to the 3Rs

For many years, Sanofi has sought to apply the 3Rs when using animals is necessary for our research. Our approach is designed to use animals only when a non-animal method is not suitable for the required use (replacement), in the smallest number necessary for quality science (reduction) and while implementing state-of-the-art practices to promote animal welfare and prevent pain and distress in housing, procedures and treatment (refinement). When animals are required to help ensure the safety or quality of medicines or vaccines,

Facts and figures

REACHING CONSENSUS ON GUIDELINES FOR HUMAN CELLULAR BIOTECHNOLOGY

Sanofi was among the sponsors of the "Biotechnology and the Ethical Imagination Global Summit" held in May 2015 in Atlanta, Georgia. Hosted by Emory University's Center for Ethics, this gathering of thought leaders aimed to reach consensus on reasonable guidelines for cellular biotechnologies such as synthetic biology and stem cell research, as well as animal and human applications of advanced biotechnology.

MORE online

- [BEINGS2015 website](#)

DID YOU KNOW?

The 3Rs stand for :

- **Replacing** animals with any other methods when a non-animal method is feasible
- **Reducing** the number of animals necessary to ensure reliable, quality scientific results
- **Refining** techniques to promote animal welfare and minimize pain and distress

99%

OF THE ANIMALS USED are rodents, rabbits and poultry

Less than

20%

OF THE ANIMALS are used for research

40%

OF THE ANIMALS are used by our Animal Health Division

MORE in our Download Center

- [Animal Protection factsheet](#)
- [Sanofi Policy on the Protection of Animals](#)

procedures are performed in accordance with regulations and involve minimal pain or distress. Ethics committees oversee animal care and use, including active implementation of the 3Rs at the bench level. They confirm that animals are used only when there is an expectation that the results will contribute to the protection and/or improvement of human or animal health. All research and testing protocols must be validated by the ethics committees, and their decision is binding.

Members of the ethics committees include senior animal researchers, staff involved in the care and use of animals, at least one veterinarian and an independent committee member. Whenever possible, a biostatistician sits on the committee to make sure the study uses the smallest number of animals necessary to produce statistically valid results. Good science requires that animals remain in good health, and are subject to minimal pain or distress.

A Group-wide policy on animal protection

We developed a policy on animal protection to promote a shared vision of how animals are considered within the Group. In support of our longstanding commitment to the 3Rs, the policy applies to all animals used by Sanofi for research, testing or production of medicinal products, investigational medicinal products, vaccines, medical devices, veterinary products, nutraceuticals and active pharmaceutical ingredients. It also applies to breeders, suppliers and transporters of animals for research, testing and production purposes, as well as to external partners using animals under Sanofi's sponsorship.

The use of animals is authorized only when regulatory and scientific merit is established, with strict ethical oversight. Our Group-wide policy promotes a culture of care that embraces the responsible use of animals as a primary value so that whenever animals are required, Sanofi and third parties develop quality animal care and use programs.

REPLACE: Promoting alternative *in vitro* testing for the pertussis vaccine

Current regulations worldwide require that every batch of acellular pertussis vaccine

be tested using murine histamine sensitization tests (HIST) to detect residual or reverted pertussis toxin. Originally developed in Japan, HIST tests have been used for many years for quality control safety testing of pertussis combination vaccines, as well as stability testing. They require large numbers of mice, with a lethal endpoint.

Since the early 2000s, considerable research to develop alternative *in vitro* methods has been conducted in close collaboration with official control laboratories, competent authorities and regulators. The biggest hurdle has been reaching a global regulatory agreement for a suitable replacement test. Sanofi has played an active role in the International Working Group for Alternatives to HIST, formed in 2010 to bring together regulators, control laboratories, industry and 3Rs groups. Following six workshops and two collaborative studies, a breakthrough was reached in March 2015 when it was agreed that a modified Chinese hamster ovary (CHO) cell line approach represents an acceptable alternative to HIST tests. This method was recently optimized, and is undergoing international validation. For our worldwide laboratory animal population, this alternative approach will prevent the death of an estimated 22,000 mice each year.

REDUCE: Automating behavioral testing

Behavioral analyzes in animal disease models are a major challenge for the development of new drugs. This type of test is not only time consuming, labor intensive and heavily observer- and environment-dependent, but it also may create stress for the animals. Moreover, results from behavioral analyzes are often inconclusive due to high variability, lack of reproducibility and limited validity for the investigated behavioral phenotype.

To address these difficulties, we adopted a commercial solution known as the Operator-independent Motor analysis System. The "OptiMan" system uses a fully-automated behavioral testing system for rats that combines three manually-operated behavioral tests in a fully automated platform. It

addresses key shortcomings of conventional behavioral readouts in animal research and contributes to improving animal welfare by limiting stress. Moreover, it reduces variability so that fewer animals need to be used.

REFINE: *In vivo* translational models symposium

Our in-house animal science and welfare taskforce organized a global symposium for the broader Sanofi R&D community in 2015. External experts, veterinarians and representatives of Sanofi R&D sites outlined the scientific value and limitations of animal models, with an emphasis on making them more predictive and easily translatable to human diseases. The symposium provided an opportunity for sharing best practices to evaluate the safety and efficacy of novel drugs. Participants looked at applying refinement methods (such as bioimaging techniques) across Sanofi's different therapeutic areas.

Rehoming horses used for plasma production

In line with our commitment to animal welfare and the responsible use of animals, Sanofi seeks to find rehoming opportunities for horses that have been used for plasma production. To conduct a feasibility study, Sanofi collaborated with GRAAL, an organization recognized for its work in the field of animal protection. GRAAL, which is dedicated to finding rehoming opportunities for animals used in biomedical research, now enjoys the support of the pharmaceutical industry. This program makes it possible for young and healthy horses that are accustomed to close contact with people to be adopted and used for recreational riding. To date, 39 horses have been rehomed thanks to this collaboration, and participants' feedback has been very positive.

MORE online

• [GRAAL Animal Protection Association \(website in French\)](#)

A FRAMEWORK TO GUIDE THE CONDUCT OF CLINICAL RESEARCH

G4-DMA G4-PR1 G4-PR2

The ethical challenges in clinical research

As we conduct research designed to develop new healthcare solutions, we must continually examine our practices and processes from an ethical standpoint. Ensuring respect for ethics across our R&D activities requires addressing potential challenges that may arise in response to:

- Social and economic trends;
- New biotechnologies;
- Scientific advances in other fields;
- Public health priorities;
- Specific development needs;
- Public demand for greater transparency and privacy protection.

We must constantly adjust and adapt our practices and processes in light of new developments in all of these areas.

A framework for ethics in clinical trials: 7 key requirements

The purpose of ethical guidelines is to protect patients and healthy volunteers and preserve the integrity of scientific research. The *Journal of the American Medical Association (JAMA)* has published seven ethical requirements⁽¹⁾ to guide the conduct of research. We use these requirements as a framework for evaluating the ethics of our clinical research studies.

MORE online

- [What makes clinical research ethical?](#)

1. Social or scientific value

Sanofi's in-house committees (e.g., the Development Working Group within the R&D organization and Protocol Review Committees) systematically review clinical study protocols, extended synopses and amendments to confirm that the scientific and medical questions the research seeks to address correspond to a clinical need.

2. Scientific validity

To produce rigorous, reliable and valid data, our approach includes a systematic review by Sanofi's internal experts so that the most up-to-date therapeutic guidelines are integrated into our study methodology and evaluation tools. External experts are also consulted when necessary.

3. Fair subject selection

We recruit patients and healthy subjects all over the globe for our clinical trials. In selecting study sites and determining inclusion criteria, we are careful to strike a balance between the quality of local clinical research infrastructures and targeted patient populations to confirm that the disease area and product being investigated correspond to an actual need within the community. As a signatory to the Guiding Principles on Access to Healthcare, our practice is to perform clinical studies in countries where we intend to make the product available, if the development program is successful.

MORE online

- [The Guiding Principles on Access to Healthcare](#)

4. Favorable benefit-risk ratio

Sanofi continuously assesses the benefit-risk profile of all our products in development and marketed products, both prescription medicines and over-the-counter products. To help ensure that healthy subjects and patients are not exposed to a disproportionate risk in relation to the expected benefits of the product being studied, we have a dedicated governance framework that covers all phases of development and commercialization. Several committees and processes are pivotal to this framework, which is overseen by the Benefit-Risk Assessment Committee (BRAC) under the direction of Sanofi's Chief Medical Officer.

RELATED CONTENT in this report

- Page 35, Sanofi's Benefit-Risk Assessment Committee

(1) Emanuel E.J., Wendler D., Grady C. "What makes clinical research ethical?" *JAMA*. 2000; 283: 2701-2711.

Facts and figures

OVERVIEW OF CLINICAL TRIALS IN 2015

For Sanofi Pasteur, our vaccines business, a significant decrease in the number of trial subjects in the Asia Pacific Region was driven by the end of our safety study of our candidate Japanese encephalitis vaccine. For our pharmaceutical activities, a strong pipeline contributed to a significant number of key trials.

In 2015,
197 CLINICAL TRIALS
were conducted by the Group:

150
with Pharmaceuticals

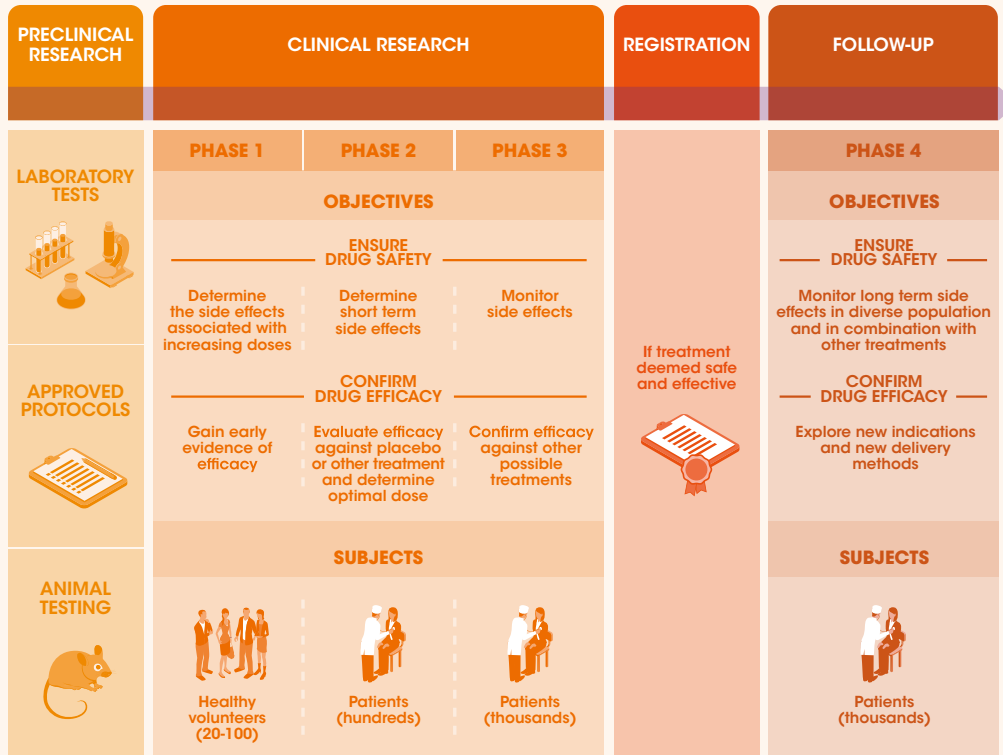
47
with Vaccines

MORE on Sanofi website

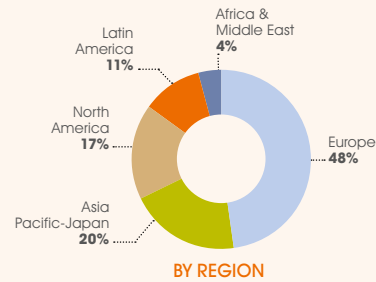
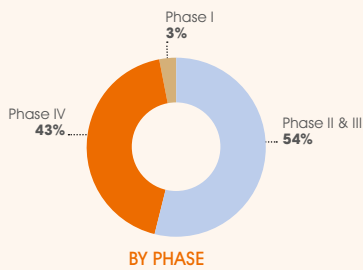
- [Clinical Trials](#)

G4-DMA G4-PR1

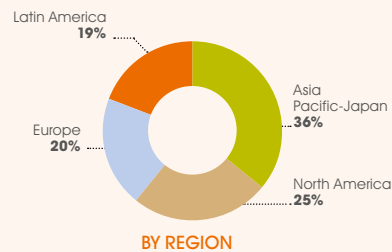
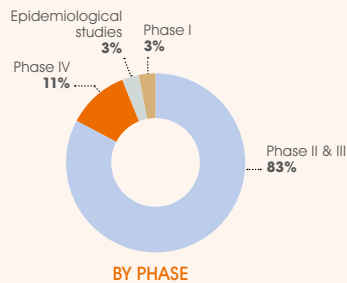
HOW DO CLINICAL TRIALS WORK?



PHARMACEUTICALS
CLINICAL TRIALS 2015,
SUBJECTS ENROLLED
25,064 subjects



VACCINES CLINICAL TRIALS 2015,
SUBJECTS ENROLLED
13,599 subjects



5. Independent review

Sanofi only initiates clinical trials once they have received a favorable assessment by the independent ethics committee and by health authorities to protect participants' safety and welfare. The independent ethics committee and the health authorities are informed of any significant study-related events or issues that arise during the course of the trial.

6. Informed consent

Sanofi processes are designed to assure that all study participants (patients and healthy subjects, or their legal representatives) enrolled in any clinical trial we conduct have given their free and informed consent to participate in the trial. Study participants must be informed about the purpose of the research so that they can understand the information and are able to make a voluntary decision about whether to enroll. Regardless of a trial's objective, it must be designed to protect the safety of participating subjects and guarantee that they give their voluntary consent based on clear, complete information that is expressed in an understandable, non-technical style, especially for trial participants who may be vulnerable for any reason. Informed consent must be obtained prior to any procedure or change in the procedure required by the study protocol and before any data is collected.

The individual informed consent process is the cornerstone of ethical recruitment of participants in clinical trials. The study participant should be the central focus of this process, which is not just about signing forms. Our continuous improvement process looks especially at participants' age, literacy and other factors that may potentially make them vulnerable.

7. Respect for potential and enrolled subjects

Trial sponsors should ensure participants' privacy is appropriately protected. Moreover, enrolled subjects must be properly informed of newly discovered risks or benefits and results and be given the opportunity to withdraw from the trial at any time. Sanofi has organized a number of initiatives to safeguard confidentiality. For example, our Chief Privacy Officer, who is a member of the Bioethics Committee, reviews challenges that may arise in connection with protecting the privacy of persons enrolled in a clinical study. This is especially important with the advent of new technologies, such as electronic forms used to obtain informed consent. The enrollment of potentially vulnerable subjects and patients in a clinical study requires particular attention, especially in pediatric clinical studies or those conducted in countries with fragile health systems.

Facts and figures

INFORMATION THAT MUST BE PROVIDED TO PARTICIPANTS TO HELP ENSURE FREE AND INFORMED CONSENT

1. The purpose and methodology of the study.
2. The difference between participation in a study and medical care.
When the investigator is also a treating physician, he must explain that he is acting not in his capacity as a treating physician, but as an investigator. Explaining the experimental nature of the proposed study will help show how this is different from medical care.
3. Study-specific constraints, which are added to those related to standard care.
4. Potential risks and benefits related to participation in the study.
5. Alternatives to participation in the study (especially important if an individual's decision to participate in the trial may have financial implications such as care provided for free during the study but not under the local health system).
Study participants must be presented with the choice to either participate in the study or to receive care from the local health system. All the pros and cons of participation (financial and non-financial such as study specific constraints) must be clearly presented to the participant to enable an informed decision.
6. Compensation for expenses during the study.
The goal is to fairly compensate participants for expenses without creating a situation where this might constitute an undue financial incentive to participate.
7. Measures in the case of an adverse event.
8. Participant's post-study access to the medicine or vaccine being tested, or alternative treatment.
9. Study interruption and withdrawal of consent.
10. Access to information before, during and after the study.
11. Respect for participants' privacy and confidentiality of individual data.

TRUST project aims to reduce the risk of “ethics dumping”

In 2015, Sanofi committed to be on the advisory board of an initiative called TRUST (creaTing Relationships: eqUitable, reSponsible, inTernational), funded by the European Commission “Horizon 2020” program. This project aims to reduce the risk of “ethics dumping,” namely, exporting to other countries research practices that would not be accepted in Europe on ethical grounds, and to actively address the mechanisms to mitigate such a risk.

Providing access to investigational treatments

Individuals participating in our clinical trials may be provided with the treatment being investigated. The purpose of these trials is to discover whether a treatment is safe and effective. We submit a full dossier of evidence from trials and other data to regulatory authorities, who make the final decision to approve the potential treatment or not. Until the regulatory authority has made this decision, the treatment remains experimental and is not generally available to patients outside of clinical trials. However, patients who are not part of these trials and meet certain criteria can request access, through their physician, to the investigational treatment. In 2015, we created a dedicated website to facilitate access to the compassionate use of our products in development.

MORE online

• [Compassionate access to Sanofi investigational products \(2015\)](#)

ETHICS IN CLINICAL RESEARCH: OVERSIGHT OF CLINICAL TRIAL PRACTICES

G4-DMA **G4-PR1** **G4-PR2**

To ensure respect for ethics across our R&D activities, we monitor and audit our processes as we continuously seek to improve them.

Monitoring quality in clinical trials

Maintaining accuracy and quality throughout a clinical study requires an ongoing, active process based on two complementary systems:

- **Quality control** consists of periodic operational checks within each functional department to make sure that clinical data are generated, collected, handled, analyzed and reported in line with requirements. Each investigating site is monitored by a representative of Sanofi two to eight times a year, and more often if necessary;
- **Quality assurance** involves the systematic and independent examination of all trial-related activities and documents. This includes site audits, vendor audits and system/process audits, as well as inspections and pre-approval inspections.

Limiting the risk of misconduct by a clinical investigator

To limit the risk of potential misconduct by a clinical investigator, we utilize central data surveillance and on-site trial site monitoring that provides early detection of any signals that indicate potential deviations, enabling us to implement corrective and preventive actions. 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), we determine the best course of action according to the severity of the situation. Measures 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.

Facts and figures

CORRECTIVE ACTION IN THE EVENT OF POTENTIAL MISCONDUCT

In the event of a serious deviation, we determine the best course of action according to the severity of the situation. In 2015, for clinical trials sponsored by Sanofi (including Sanofi Pasteur):

- 28 cases of critical and/or major systematic deviations and/or potential misconduct were identified requiring in-depth investigations, thanks to a unique tool that applies a consistent approach to deviation management;

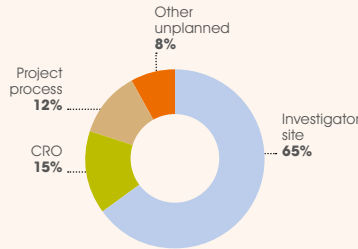
- Of the 28 cases, 5 led to a conclusion of misconduct/serious non-compliance, requiring notification to regulatory agencies;
- Of the 28 cases, 2 were managed via the rapid quality notification/quality alert process in order to notify Global Quality management and support implementation of corrective and preventive actions, thereby avoiding major or critical impact on data integrity and/or patient safety;
- No clinical trials were terminated in 2015 due to misconduct.

Facts and figures

2015 CLINICAL TRIAL AUDITS

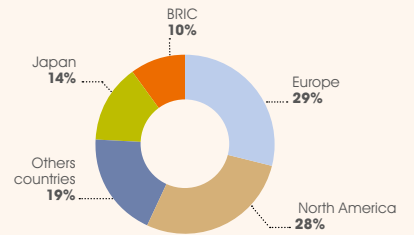
In 2015, Sanofi (including Sanofi Pasteur) conducted 218 audits for our clinical trial activities and related systems and suppliers, with a strong focus on investigator site audits. Approximately 36% of the 142 investigator audits took place in developing countries or emerging markets, in line with the geographical distribution of our clinical trials.

CLINICAL TRIALS AUDITS*, 2015 BY TYPE



218 audits

CLINICAL TRIALS INVESTIGATOR SITE AUDITS*, 2015, BY REGIONS

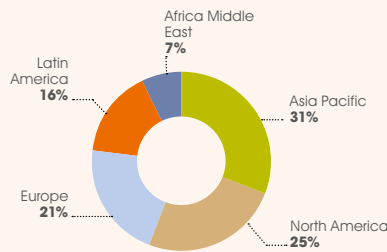


142 investigator site audits

INSPECTIONS IN 2015

Of the 73 inspections by regulatory authorities related to clinical activities carried out in 2015 within the perimeter of Pharmaceuticals and Vaccines, none had critical outcomes resulting in regulatory action from the health authorities (such as a warning letter, significant disruption of product supply or regulatory submission, or impact on marketing authorization approval status).

INSPECTIONS BY REGULATORY HEALTH AUTHORITIES*, 2015, BY REGION



73 inspections

* Includes all Sanofi activities: Pharmaceuticals and Vaccines

Internal clinical audits

We conduct internal audits of our trials, associated systems and contractors to protect participants' safety and ensure continuous improvement and compliance with our quality standards. Our audit strategy relies on a risk-based approach where each trial is assigned a risk level:

- High-risk trials include pivotal trials (i.e., conducted to support the registration dossier) and trials for dose selection. All such studies are included in an audit program with 8-10% of active investigating sites being audited;
- Moderate risk applies to trials to support dossiers, such as proof of concept, safety studies and important post-marketing trials. Between 50% and 75% of these studies are part of an audit program, with 2-5% of active sites being audited;
- Low-risk trials are subject to system audits. Readiness for an inspection by health authorities is another component of our audit strategy. Various criteria are used to select the sites to be audited (e.g., number of patients enrolled, number of protocol deviations, past experience with that site, etc.). In addition, for-cause audits may be carried out in the event of suspected misconduct.

Outsourcing clinical trials

The Quality Management of Outsourcing initiative is a Global Quality initiative implemented to harmonize outsourcing processes across R&D. This initiative pays particular attention to Clinical Research Organizations (CROs). Its continuous improvement objective is to streamline processes across the Group and ensure a strong focus on quality that is consistent with our in-house practices. It addresses CRO selection, qualification and oversight visibility through a central repository for both the corporate and local levels.

Our commitment to share clinical trial data and documents

Sanofi is committed to sharing appropriate patient-level clinical trial data and study reports with qualified researchers. Eligible trials for products that received regulatory approval from US and /or EU agencies as of January 1, 2014 are available upon request. In addition, Sanofi will review *ad hoc* requests for studies that are not currently listed on the data sharing site. Requests for clinical trial data are reviewed and approved based on scientific merit, by an independent panel of experts. All patient-level data remain anonymous to protect the privacy of patients who participated in clinical trials, in compliance with applicable laws and regulations.

MORE online

- [Access to clinical trial data](#)

Facts and figures

DID YOU KNOW?

We recently approved a request for our clinical data on Semuloparin, an investigational low molecular weight heparin. Although we have discontinued further development of this compound, our data can now contribute to a study aimed at providing important evidence for the targeted treatment of patients with solid cancers and at informing recommendations in clinical practice guidelines about the use of heparins in patients with solid cancers. Solid cancers are a common health problem worldwide and cancer-related complications, such as deep venous thrombosis and pulmonary embolism, are a cause of mortality and morbidity.



BUSINESS ETHICS

Today more than ever, we are committed to upholding ethical principles and behaving with integrity in our activities to preserve the trust of the patients and the communities we serve, and to protect Sanofi's image and reputation. Above and beyond respect for principles and compliance with regulations, we want to do what is right.

G4-DMA

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
Deploy a system (4M) for the review and approval of promotional and non-promotional materials	The project was launched in 2014 and deployment of the tool began in 2014.	On track
	We started exploring the integration of 4M with other existing tools (such as digital material).	In development
Maintain a comprehensive and evolving set of policies and standards, aimed at framing sensitive topics and providing guiding principles, as well as raise employee awareness and provide continuous training on business ethics	See Page 58 of the report.	Completed
Implement new transparency requirements in our relationships with healthcare professionals	We deployed a web-based companywide platform in 2015 to allow the tracking, approval and reporting of transfers of value with European HCPs and HCOs as required by the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on Disclosure.	Completed
Deploy our ethical sourcing of promotional items on a worldwide basis	The solution was deployed in 25 countries across Europe, the U.S., Latin America (Argentina, Brazil, Chile, Colombia, Ecuador and Peru) and Asia (China, Hong Kong, Singapore and South Korea).	Completed
	The solution will be deployed in the remaining countries across Africa, the Middle East and Asia Pacific.	On track

STRATEGIC APPROACH

As a leader in our industry, we interact on a daily basis with patients, healthcare professionals, authorities, suppliers, business partners and other stakeholders. Our approach to business ethics is both proactive and preventive: we establish and enforce clear rules in accordance with the legislative framework in each country where we operate, and we implement rigorous in-house systems to prevent violations of internal rules. As our ethics ambassadors, our employees are on the front line, working with integrity each day to ensure our business is run in a way that is ethical, sustainable and creates long-term value.

G4-24 G4-56 G4-PR3 G4-DMA G4-PR7

PATIENTS

Patient advocacy groups play a vital role in making sure that patients' voices are not lost in the complexity of today's increasingly intricate healthcare systems. Sanofi fosters open dialogue with patients because we wish to gain insights into the patient journey, and we want to collaborate in areas of mutual interest: patient engagement, access to treatment, medical innovation, etc. In our interactions with patients and patient associations, we are committed to transparency as a safeguard of their independence. We have established robust in-house policies governing our relations with these key stakeholders—in particular, a policy on interactions with patients, patient advocates and groups.

How do we help protect patients' privacy?

Sanofi receives personal health data from patients all over the world, and we respect the highly confidential character of such information. For example, during the drug development process, we collect anonymized and aggregated medical data from patients enrolled in clinical trials, which we share with the health authorities as part of the drug development and marketing authorization

process. Sanofi's pharmacovigilance organization also closely monitors potential adverse events related to marketed medicines, and once again, we may report anonymized patient health information to document adverse reactions and update a drug's safety profile.

As a worldwide company, we apply the highest standards for the protection of personal data, including the European Personal Data Protection Directive 95/46 EC⁽¹⁾ and the United States HIPAA Privacy Rule in addition to local rules. To implement and enforce these rules, Sanofi's Global Privacy Officer has established a number of policies, procedures and tools. We comply with Good Clinical Practice rules and regulations as well as specific personal data protection laws regulating the collection, handling, storage, transfer and use of personal health information.

MORE in our Download Center

- [Protection of Personal Data factsheet](#)
- [Partnering with Patient Advocates and Groups factsheet](#)
G4-16 G4-24
- [Patient Associations supported by Sanofi 2015 factsheet](#)
G4-DMA G4-SO1
- [Binding Corporate Rules & List of Sanofi affiliates having signed the BCR](#)
- [Sanofi Aventis Group personal data protection charter](#)

OUR BUSINESS ETHICS FRAMEWORK



HEALTHCARE PROFESSIONALS

Relations between our industry and the medical community are often called into question, yet as a pharmaceutical company it is essential for us to interact with healthcare professionals and solicit their expertise in many areas. We also interact with physicians to provide information about our marketed products as well as scientific, medical and educational information.

All these engagements are governed by applicable laws and by the internal policies Sanofi has developed, such as:

- Donations and other contributions to organizations;
- Interacting with External Experts;
- Research Initiated by an Independent Sponsor or Expert;
- Good Scientific Information and Marketing Practices;
- Organization of and Contribution to Events.

Sanofi may enter into compensation-for-services arrangements with external experts to perform meaningful services or activities in medical and scientific fields for which Sanofi has a legitimate need—for example, chairing or speaking at scientific meetings, sitting on advisory boards, and providing training or consulting services. External experts are chosen on the basis of objective criteria such as education, knowledge, expertise and experience in a given therapeutic area. Sanofi determines compensation of external experts according to the fair market value in the experts' country of practice. The engagement is not intended to constitute an inducement to prescribe, purchase, supply, sell, administer or recommend Sanofi products or services.

Promotional practices

G4-DMA G4-PR3 G4-PR7

We are committed to providing accurate, complete and reliable information about our marketed products to physicians, pharmacists and other healthcare professionals. To ensure our promotional practices respect the standards of ethics and comply with

legislation in all countries where we do business, we have established specific measures and systems to support the marketing of our products.

Medical Representatives' Certification in Africa, the Middle East, Eurasia and South Asia

Each day, Sanofi's 7,500 medical representatives are in contact with 85,000 healthcare professionals in the AMESA⁽²⁾ region. Across the more than 80 countries that make up this region, we consider the quality of the call and the customer's satisfaction to be the key indicators of our performance. This is why, starting in 2014, we set up a local Medical Representatives' Certification Process held annually in each country in the region, endorsed by the General Manager and the Management Committee. On the basis of tests and roleplaying, the certification process assesses whether representatives possess the appropriate competencies in terms of knowledge of medicine, our products and our competitors; communication skills and promotional practices; the Sanofi Code of Ethics; pharmacovigilance, compliance and safe driving. All newcomers to the job must obtain certification prior to a probationary period to ensure they meet the company's expectations, and our active representatives must repeat the certification process on an annual basis.

(1) Directive which seeks to strike a balance between a high level of protection for the privacy of individuals and the free movement of personal data within the European Union (EU).

(2) The AMESA region encompasses Africa, the Middle East, Eurasia and South Asia.

Facts and figures

DID YOU KNOW?

Each year, we publicly declare payments or other transfers of value to healthcare professionals in France, the UK, the United States and, as of June 2016, the 33 EFPIA member countries⁽³⁾.

MORE on Sanofi websites

- [Sanofi UK, Public Disclosure of Payments](#)
- [Sanofi France, Publication des Données](#)
- [Sanofi US, Committed to Transparency](#)

(3) Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.

Promotional materials

Sanofi’s foremost concerns are patient safety and the proper use of our products. The promotional materials related to Sanofi products are based on scientifically proven results and undergo an internal review process to ascertain that they are objective and fair before they can be used. Our Medical and/or Regulatory Affairs teams at the global and regional levels and in each country are responsible for reviewing materials and approving them prior to use.

Continued deployment of 4M

In 2015, we continued to roll out our global solution for the review and approval of medical and marketing materials. Known as 4M for “Medico-Marketing Materials Management System,” this solution standardizes the review process while providing a degree of flexibility to improve the workflows for the review and approval of promotional and non-promotional materials worldwide. Deployment started in 2014 and is due to be completed by the end of 2016. In 2016, 4M will be implemented in Asia, Africa and the United States.

For international events (see table below), this review is performed centrally by Medical Expertise & Innovation scientific and promotional reviewers in the Global Medical

Affairs organization, in collaboration with representatives from the country where events take place.

In 2015, Sanofi conducted 30 internal audits of our affiliates’ compliance with the approval procedures for promotional materials (PM). Audit result analysis shows a stable trend in the number of observations related to promotional material management compared to the past two years. In 2015, there were no critical findings and 37% of PM-related findings were rated as major. Our primary action plans have focused on:

- PM review and approval process;
- PM content and quality control;
- Company-sponsored website management.

MORE in the Download Center

- [Sanofi Standards for External Experts’ Participation at Scientific Events \(brochure\)](#)

AUTHORITIES

The pharmaceutical sector is a highly-regulated industry where government and administrative authorities determine the rules governing research, the protection of intellectual property and reimbursement policies, as well as the procedures to obtain marketing authorization. Through

our lobbying and advocacy activities, Sanofi takes part in policy debate affecting the regulatory landscape and our business. We engage in sustainable interactions with governments and other stakeholders to work toward the shared goal of improving access for the greatest number of patients to the best medicines and healthcare products; such interactions also contribute to health information globally while preserving incentives for research and innovation. We are transparent about our lobbying activities, conducted in compliance with the Sanofi Code of Ethics, the Group’s Responsible Lobbying Policy, and applicable lobbying and advocacy laws and regulations where we do business.

MORE in the Download Center

- [Responsible Lobbying factsheet](#)
- [G4-16](#) [G4-24](#) [G4-DMA](#) [G4-SO6](#)

A new external affairs organization

Announced in May 2015, the new external affairs organization encompasses several departments: government affairs, public affairs and advocacy, global policy, global market access, communication, CSR, impact and risk management. It focuses on public affairs activities and interacts with governments and international organizations.

2012-2015: NUMBER OF PROMOTIONAL MATERIALS REVIEWED BY GLOBAL TEAMS PRIOR TO USE

	2012	2013	2014	2015
Promotional materials	1,492	1,860	1,441	1,988
Digital projects	156	164	24	6 ⁽¹⁾
Communication materials	178	235	156	179
Scientific events and materials for booth or symposia in international congresses and events	27	39	51	51

(1) Since 2014, only global websites are reviewed by the global team, while local websites are reviewed by the local team to help ensure alignment with national regulations.

SUPPLIERS AND PARTNERS

G4-DMA G4-EN33 G4-LA15 G4-HR11 G4-SO10

We work with many suppliers worldwide to procure the materials, goods and services that Sanofi requires to manufacture our products, serve patients and supply our facilities. Since 2007, our responsible procurement approach, embedded in our overall procurement strategy, has aimed to ensure that our suppliers uphold high ethical standards and take social and environmental responsibilities seriously. We expect suppliers to meet the standards set out in the Sanofi Suppliers' Code of Conduct. We have developed a risk-based approach to concentrate our efforts on those supplier segments considered to be most at risk in terms of key CSR criteria—for example, human rights, labor and environmental practices, governance and anti-corruption. In 2015, this risk segment, which is updated annually, covered 25 procurement categories and 42 countries. For these suppliers, we conduct an annual targeted evaluation of their CSR performance, which entails identifying shortcomings and gaps in their CSR practices and where relevant working with them to achieve tangible improvements.

Ethical sourcing of promotional items

Supplier-related social and environmental risks are often a concern when it comes to sourcing promotional items. In 2009, the

MedDirect Initiative was launched to address such risks, which are higher when distributors lack visibility and control over the manufacturers of promotional products. Today the initiative is run through InnerWorkings and Staci, two global entities that offer an end-to-end solution, from user requirements to delivery. They conduct audits of factories and implement corrective action plans. Through the collaboration, in 2015 the MedDirect project was introduced in more than 40 countries, covering all our procurement regions worldwide.

Suppliers' Day organized in Asia

G4-EC9

In 2015, Sanofi hosted Suppliers' Days in a number of Asian countries: Vietnam in March, Korea in April, India and Bangladesh in June, and the Philippines in October. Each event was unique, providing an opportunity to build our local suppliers' network to meet Sanofi's strategic and operational objectives while helping to ensure our ethics standards are upheld.

MORE in our Download Center

• **Responsible Procurement factsheet**

G4-DMA G4-EC9 G4-EN33 G4-LA15 G4-HR11
G4-SO10 G4-EN32 G4-LA14 G4-HR10 G4-SO9

• **Suppliers' Code of Conduct**

G4-56 G4-DMA G4-HR11

• **Sanofi Supplier Relationships Charter**

SUPPLIERS EVALUATION IN 2015

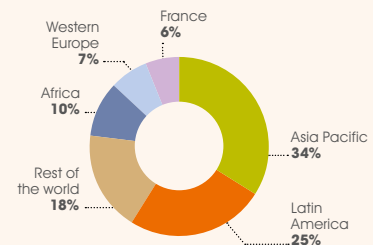
	2011	2012	2013	2014 ⁽¹⁾	2015
Number of suppliers assessed on their CSR performance	45	185	188	128	190
Number of assessed suppliers that met our CSR requirements	30	129	103	64	115
Number of buyers trained to the Responsible Procurement Platform	0	0	106	120	153 ⁽²⁾

(1) Final 2014 campaign figure.

(2) Out of approximately 800 operational procurement staff and 314 users of the evaluation platform.

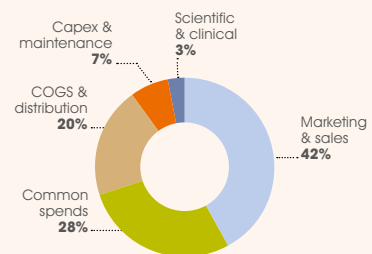
Facts and figures

ASSESSED SUPPLIERS IN 2015, BY REGION*



190 suppliers

ASSESSED SUPPLIERS IN 2015, BY PROCUREMENT ACTIVITY



190 suppliers

Marketing and sales: communication agencies, events and media, market research, promotional items.

Common spends: fleet and travels, energy and waste, IS, real estate and site services, consulting, HR and insurance.

Scientific and clinical: clinical, laboratory equipment, research materials and subcontracting.

Manufacturing Capital Expenditure (Capex) and maintenance: civil works, manufacturing equipment, spare parts and industrial maintenance.

Cost of Goods Sold (COGS) and distribution: raw materials, packaging and devices, subcontracting, licenses and supply chain.

* See definition of regions on Page 107.

ETHICS AND BUSINESS INTEGRITY

G4-DMA G4-56

Our approach to business integrity is focused first and foremost on compliance with applicable laws, regulations and industry standards. In practice, this entails developing internal policies to contextualize and clarify rules and expectations. We also strive to instill an ethical business culture that goes above and beyond following rules and regulations, by encouraging our employees to do what is right.

Our Ethics & Business Integrity Department

In addition to enforcing internal rules, the core mission of the Ethics & Business Integrity Department is to promote a culture of integrity within the Group so that Sanofi's operational objectives can be attained in compliance with the Group's ethics, values and policies. It fulfills this role by providing support to identify, assess and mitigate risks that are potentially associated with the Group's activities.

The Ethics & Business Integrity Department develops a Group-wide compliance program built on a dedicated organizational framework reaching from the global to the local level. To support this framework, a network of more than 100 compliance professionals is in charge of implementing the compliance program. To help meet the day-to-day challenges facing our business operations, they assist in monitoring third parties; support policy development; promote training and awareness; and provide risk assessment, prevention and investigation. The Head of the Ethics & Business Integrity Department and Global Compliance Officer, who has direct access to the Group's CEO, meets periodically with the Audit Committee and/or the Board of Directors and external auditors. The Executive Compliance Committee, chaired by the CEO, sustains the effectiveness of the program.

Working closely with Sanofi's Internal Audit and Internal Control & Processes Departments, the Chief-Anti Fraud Officer implements a comprehensive Fraud Risk Management Program focused on four pillars:

prevention, detection, investigation and reporting. This role contributes to enhancing the capability to prevent and uncover misconduct. A dedicated function is also in charge of supporting internal investigations. The Ethics & Business Integrity Department also runs a secured compliance helpline available 24/7 to all Sanofi employees.

Sanofi's fight against corruption

G4-SO4 G4-SO5

Our commitment to preventing corruption has shaped the Sanofi Anti-Bribery Policy. All employees receive information, guidance and training to comply with anti-bribery regulations. Sanofi has zero tolerance for unethical and illegal conduct by Group employees. In the event of allegations of any wrongdoings, Sanofi conducts an investigation and, where appropriate, notifies and cooperates with the competent authorities. It is equally important to monitor contractual relationships with third parties when a risk of corruption has been identified. To reinforce this capacity, in 2015 we have reshaped and enhanced a standard for conducting anti-bribery due diligence of third parties.

EMPLOYEES

G4-DMA

Our employees are the ambassadors of our ethical standards in their dealings with third parties. Acting with integrity at the individual level means understanding and respecting our Code of Ethics, which sets out the behaviors to adopt in interactions with stakeholders. The Code also provides guidance to employees in dealing with issues that may arise within the scope of their day-to-day responsibilities, and promotes a culture of compliance throughout the Group and beyond.

Policies to guide and support employees

A comprehensive and evolving set of policies and standards is maintained, aimed at framing sensitive topics providing guiding principles:

- Anti-bribery;
- Gifts and reminder items;
- Donations and other contributions to organizations;
- Conflict of interest;
- Interactions with external experts;
- Organizations of and contribution to events;
- Good scientific information and marketing practices;
- Interactions with patients, patient advocates & groups;
- Anti-bribery due diligence on third parties;
- Responsible lobbying;
- Complaints management;
- Corrective and disciplinary actions.

Among the key subjects covered by our policies, conflicts of interest deserve particular attention. A conflict of interest may arise without anyone being at fault, and it is important to recognize and deal with such situations effectively so that our employees are able to perform their duties in a fair and unbiased way.

For a compliance program to be strong, policies must be enforced and, in the event of a violation, corrective and/or disciplinary action must be taken. To ensure such actions are determined in a consistent and harmonized way, in early 2015 the Group introduced a policy formalizing the global framework for corrective and/or disciplinary actions.

E-learning on ethics and business integrity

G4-SO4

Based on the findings of an internal survey and interviews, we updated the offer of our e-learning catalogue in 2014-2015 to focus on essential modules.

The library provides a wide range of materials in up to 19 languages to enhance awareness of specific areas of compliance such as: anti-corruption, anti-money laundering and fraud, conflicts of interest, insider trading, global competition law, ethical decision making and integrity, data and personal information, communication, confidentiality and information security,

understanding lobbying, donations and other contributions to organizations, and interactions with external stakeholders.

Mandatory employee training

G4-SO4

Furthermore, in order to raise employee awareness and provide continuous training on business ethics, a Master Compliance Training Plan is established, encompassing yearly mandatory trainings for all the employees and/or for targeted audience. In 2015, the focus was made on "principle-based decision making" with three e-learning modules made available in 19 different languages.

To foster compliance mindset, a library of e-learning courses is also available to all employees, addressing fundamental ethics and business integrity topics.

A second wave of an awareness campaign already implemented in 2014 and based upon short videos representing "real-life" situations, has been developed to be launched in early 2016. The first wave was dedicated to Fighting Corruption and Prevention of Conflict of Interest, the second wave is addressing Data Privacy and Anti-Fraud.

MANDATORY TRAINING TOPICS	
2013	Fighting bribery and corruption Prevention of conflicts of interest
2014	Anti-fraud <ul style="list-style-type: none"> • Fraud in the workplace • Global financial fraud prevention Communications <ul style="list-style-type: none"> • E-mail: think before you click • Responsible business communication
2015	Ethical decision making and integrity Information security & confidential proprietary information

A dedicated compliance helpline

All Sanofi employees have access to a secured compliance helpline system available 24/7 with a dedicated web page and a toll-free number available in 28 languages. If employees have a concern or if they believe in good faith that a law, a rule or one of the principles in our Code of Ethics has been or is about to be violated, they can inform their manager or the Ethics & Business Integrity Department by using the compliance helpline. Employees will not be disciplined or discriminated against for making any report, even if the facts reported prove to be inaccurate provided that they have acted in good faith. In the United States, a toll-free external compliance helpline has been set up for Sanofi employees in accordance with local regulations and practices.

MORE in our Download Center

- [The Group Internal Audit and Internal Control & Processes factsheet](#)
- [Prevention of Conflicts of Interest factsheet](#)
- [Code of Ethics](#)
- [G4-15](#) [G4-56](#)
- [Anti-Competitive Behavior factsheet](#)
- [G4-DMA](#) [G4-SO7](#)
- [Ethics and Business Integrity factsheet](#)
- [G4-DMA](#) [G4-SO4](#)
- [Anti-Bribery Policy](#)
- [G4-56](#) [G4-SO4](#)
- [Fighting Corruption factsheet](#)
- [G4-DMA](#) [G4-SO4](#) [G4-56](#)

Facts and figures

DID YOU KNOW?

Our compliance helpline covers many areas: health and safety (including discrimination, harassment and violence), freedom of association, the prohibition of child labor and forced labor, the protection of confidentiality and intellectual property, conflicts of interest and asset protection, good promotional and distribution practices, respect for privacy and personal data protection, protection of the environment, respect for human rights and the ten principles of the Global Compact, financial and accounting control rules, fair competition and corruption.



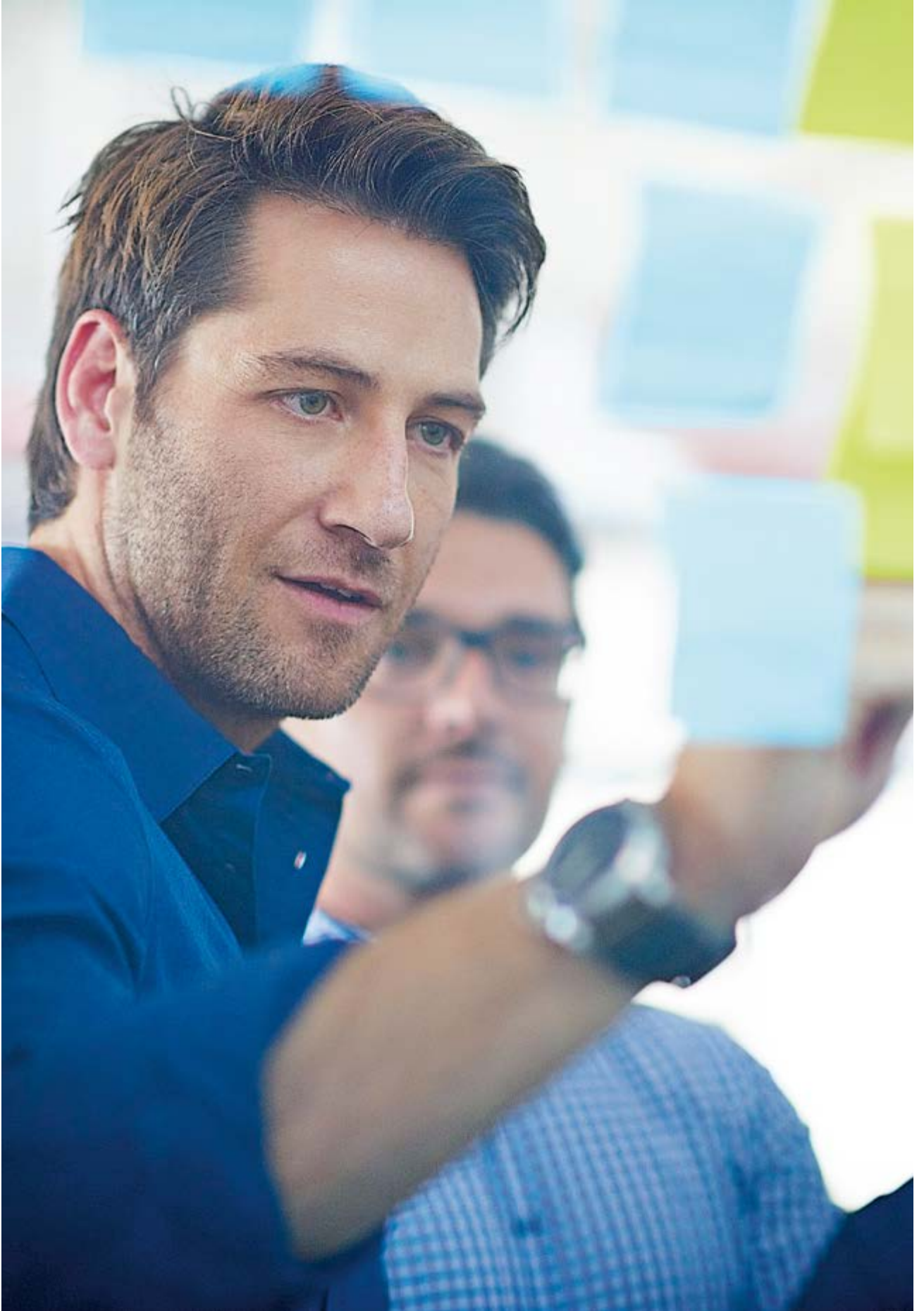
Do women have the same management opportunities?

Over the past several decades, societies have been dealing with the proverbial glass ceiling. However, in the corporate world, the climb to the top is still full of obstacles for many women. Sanofi recognizes that gender-balanced leadership brings about better performance. Over the past few years, the Group has maintained a dedicated focus on female career paths and training. In 2015, Sanofi female managers represent 40 percent of all managers and our 14-member Board of Directors includes five women.

PEOPLE

Because a diverse workforce performs better,
Sanofi commits to diversity, inclusion
and professional development of its employees.





PEOPLE DEVELOPMENT

Sanofi's more than 110,000 employees worldwide are motivated by a sense of purpose and pride, knowing that their work has an impact on patients' lives. In developing our multicultural workforce, we cultivate a rich source of talent, innovation, cooperation and competitive edge.

Our challenge is to successfully prepare each individual for the healthcare sector's rapidly changing and highly competitive environment in a way that is consistent with Sanofi's values and our "People Development Principles."

G4-DMA G4-LA10

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
Attract and retain talents	Sanofi ranked among the Top 100 Most in Demand Employers by LinkedIn: No.48 in Europe, Middle-East and Africa (EMEA) and No.93 in North America.	On track
	Sanofi rated No.1 on Glassdoor 2016 "Best Places to Work" in France.	On track
Develop employees' capabilities at every level of the Sanofi Group	The single learning management system (LMS) is being implemented to provide all employees worldwide with an optimal learning experience and to better pilot workforce development across the Group.	In development
	Launch of the Sanofi Digital Academy.	On track
Assess and reward performance	52.2% ⁽¹⁾ of employees were engaged in our global performance and development planning process.	On track
Build and diversify Career	We scaled up our "People Development Principles" to encourage a diversified career and maximize our employee's potential and performance.	On track
	79.4% of executive vacancies of the Top 400 ⁽²⁾ were filled by internal candidates.	On track
Value and support diversity	"Good Morning Sanofi" videos made by employees: 11 released in 2015 and 16 more planned in 2016.	On track

(1) This percentage corresponds to 60,418 employees out of 115,631 of the total workforce. The total workforce covers more than 97% of the scope of reporting. It doesn't include companies not included in our Human Resources database "Convergence" which data on the performance review is not collected.

(2) The Top 400 is defined as senior executive and management positions considered to be essential for business continuity and workforce planning at the global level.

STRATEGIC APPROACH

WHY IS PEOPLE DEVELOPMENT SO IMPORTANT TO US?

Our vision for Sanofi is to become a magnet for diverse and exceptional talents. We strive to give our employees the opportunity to succeed and develop to their full potential by providing an environment where each of us can grow as a professional while contributing to the success of our company.

Ensuring that every individual across the Group has a chance to develop is the key to building and sustaining the growth of our organization. To realize this ambition, our Human Resources function has adopted the

“One Sanofi, One HR” concept. Designed to harmonize and align our human resources practices across all our business activities and affiliates, “One Sanofi, One HR” holds out a promise of fairness and efficiency for employees and managers. As part of this approach, in 2015 we adopted a holistic people development model based on shared principles and a single framework to be applied consistently at every level of the organization.

This holistic and forward-looking model for talent development across the Group will also allow us to keep pace with emerging developments in the healthcare industry.

Facts and figures



“Sanofi has been known for years to have excellent execution in everything we do and a high level of passion and engagement. This is really a company where people commit themselves. It’s people who have made Sanofi’s success so far—and by growing the talent of our people, we’ll be even more successful in the future, as a company and as individuals.”



Roberto Pucci,
Executive Vice President, Human Resources

THE “ONE SANOFI, ONE HR” MODEL FOCUSES ON FIVE LEVERS:



A SINGLE HR SYSTEM SOLUTION

A new Human Resources information system

In guiding the transformation to “One Sanofi, One HR,” we wanted to give our employees greater opportunities to move across different businesses and different countries. We identified the need for a common denominator that would allow people to improve their capabilities and derive a strong sense of motivation.

In line with our “One Sanofi, One HR” model, we decided to invest in an innovative Human Resources information system, which is currently being rolled out across the entire business and helping us become much faster and more effective in leveraging and unlocking our talents. It empowers employees to take ownership of their career development while providing data for managers to make informed business decisions.

A phased implementation over time

The new system is being phased in gradually and its related harmonized processes will ultimately support every manager and employee to better drive individual development, career management and business performance. First, key HR processes will be put in place. Then additional functionalities (compensation, absence, recruitment...) will be implemented on an *ad hoc* basis by region or by groups of countries.

The choice of one single HR system solution to address Sanofi’s HR needs is tied to the Group’s history of local and global mergers and acquisitions. Since 1973, our highly diversified HR processes were supported by more than 600 information system applications, which were often incompatible and posed substantial global data consolidation challenges.

A radical shift bringing multiple benefits

This single system where employees and managers will be in control of the quality and accuracy of data will reduce the administrative burden in HR and will allow staff to invest more time in value-added tasks, such as supporting managers in managing their talent, and improving organizational effectiveness. It represents a radical shift in the mindset and culture of the Company. The new information system is anticipated to improve interactions between employees and managers on human resources questions and our HR function can be more effective to bring enhanced value to the business.

BOOSTING OUR SOCIAL MEDIA PRESENCE TO ATTRACT AND RETAIN TALENTS

Sanofi doubles number of LinkedIn followers

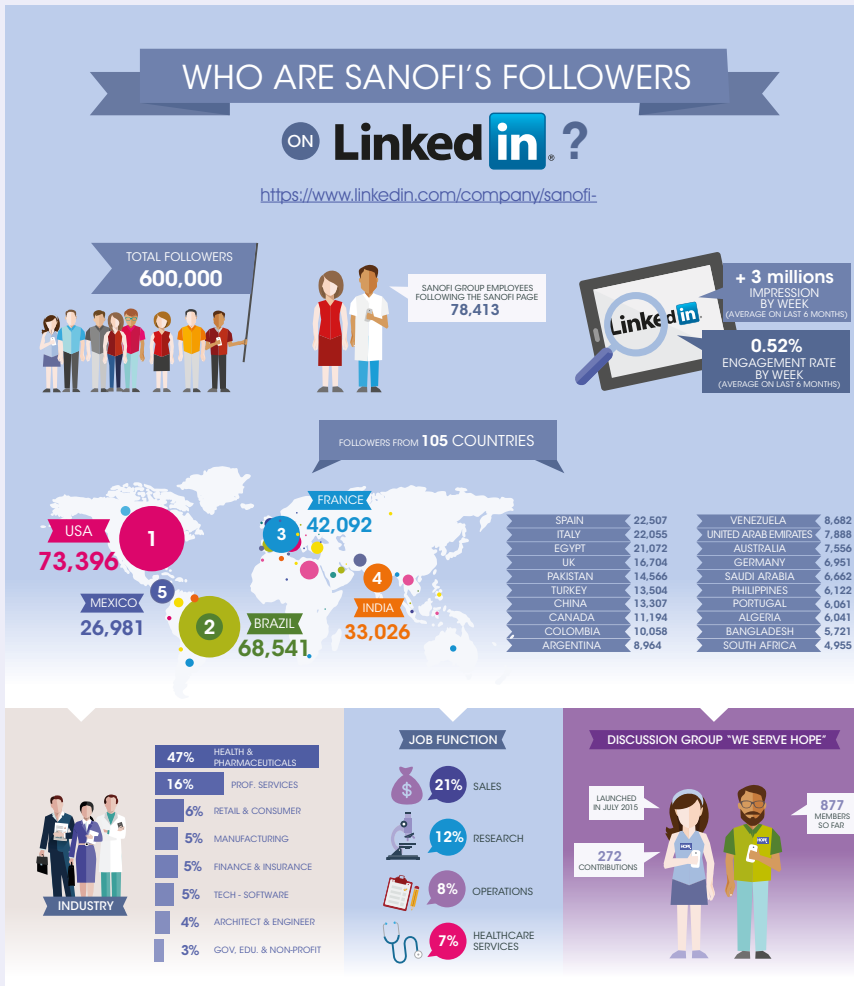
To attract, motivate and retain diverse and exceptional talents, Sanofi constantly onboards and develops talents. In their approach, HR managers and recruiters increasingly use social media for recruitment. Beyond simply utilizing a recruitment tool, Sanofi decided to take a more ambitious approach to LinkedIn with the aim of strengthening the Group’s reputation as an employer and increasing Sanofi’s attractiveness for potential applicants. Thanks to the active management of our presence online, the number of followers on our corporate LinkedIn page has doubled in a short space of time, growing from 300,000 in early 2014 to more than 600,000 by late 2015—of whom nearly 80,000 are Sanofi employees. In 2015, the use of LinkedIn for recruitment impacted 15% of new hires in the Group, mostly in the United States and France. This resounding success drives a weekly average of three million impressions, which corresponds to the number of times each update is shown to LinkedIn members. The average rate of engagement is in the high range for LinkedIn averages (0.52% vs. an average of 0.3 to 0.5% for comparable companies). (See Facts and Figures [page 66](#)).

“We Serve Hope” community is born

Our 600,000 followers represent a genuine strength for our Group as well as an extraordinary opportunity for us to increase our visibility, be recognized as an employer of choice and connect with thousands of talented individuals all around the world. Few companies have achieved such a strong presence on LinkedIn.

In July 2015, when we reached the milestone of half a million followers, we celebrated by creating a unique Sanofi club called “We Serve Hope.” This private group (members are personally invited) has grown to become a community of nearly 1,000 professionals from a wide range of companies, fields and industries. Members have an “open innovation” mindset and are eager to share their wealth of knowledge and career experiences with one another. “We Serve Hope” exemplifies our values and resonates with our followers.

Facts and figures



LINKEDIN IMPACTED 15% OF SANOFI GROUP NEW HIRES IN 2015



PROFILE OF SANOFI GROUP IMPACTED HIRES* (IN %)

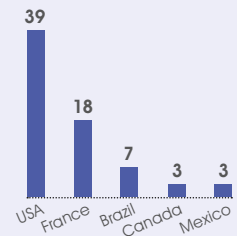
By function (top 5)



By position



By geography (top 5)



DID YOU KNOW?

Measuring LinkedIn Performance

- Impressions: the number of times each update is shown to LinkedIn.
- Interactions: the number of times people have liked, commented on, or shared each update.
- Engagement: the number of interactions plus the number of clicks

- and followers acquired, divided by the number of impressions.
- Average rate of engagement: the percentage of users' interactions with a brand's posts as a percentage of a brand's followers.

In 2015, the use of social media (LinkedIn) for recruitment impacted 15% of new hires in the Group, mostly in the United States and France. The Sales and R&D functions have witnessed the greatest impact.

* All data covered from December 2014 to November 2015.

Best places to work: Sanofi ranks at the top

In 2015, for the first time, Sanofi ranked among the Top 100 Most in Demand Employers by users of LinkedIn. The Group was listed in 48th position of most sought-after Europe, Middle-East and Africa (EMEA) employers, ahead of most of our competitors. Among employers in North America, Sanofi ranked 93rd. These results are based on billions of interactions from LinkedIn's more than 380 million members. Rather than relying on questionnaires, the rating system measures the actual behavior of professionals as they explore their career journey.

Sanofi was also rated #1 on the Glassdoor 2016 "Best Places to Work" in France list. Glassdoor's annual Employees' Choice Awards recognizes the best places to work in North America and parts of Europe. Winners are determined by the people who know the companies best—their employees.

DEVELOP AND GROW EMPLOYEES' CAPABILITIES

G4-LA9

Sanofi is devoted to help patients and improve their lives. We are motivated to be part of an organization with a culture of learning that provides opportunities to hone our talents and potentially develop our careers across a broad range of business areas and functions, where appropriate.

In today's rapidly-changing business environment, the capabilities we need as an organization to deliver on our business strategy are constantly evolving, which is why we must adapt our learning and development approaches. Our programs are designed to keep pace with the needs of our business, through on-the-job, local and global programs, coaching, modular training and digital learning.

With the support and resources provided by the Group, employees can broaden their skills and develop their expertise for a positive impact on our performance and their own. Employees are strongly encouraged to take charge of defining their potential career path.

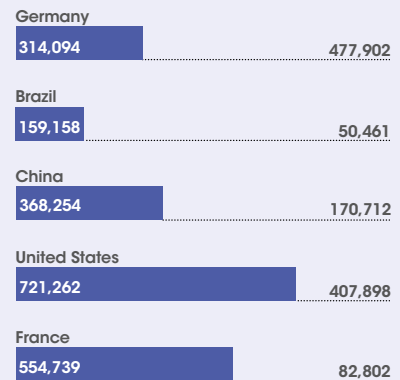
The Sanofi Academies

Sanofi's learning centers and academies help employees develop their expertise and discover new ways of working. In 2011, we founded the first Sanofi Academies covering six areas: Legal, Finance, Human Resources, Information Systems, Procurement and HSE. Since then, we have introduced additional academies to provide training in areas including Quality, Alliance Management, Diabetes Medical Affairs, LEAN, Supply Chain, Launch Excellence and Market Access. To cite two recent examples:

- **The Launch Excellence (LEx) Academy** was established in 2014 to embed launch capabilities within the organization and ensure operational launch excellence, helping to give Sanofi a competitive advantage in the marketplace by teaching employees marketing-savvy skills and capabilities; and
- **The Market Access (MAx) Academy** was created in 2015 with a focus on strategic capability building, collaborative problem solving with MAx colleagues, and knowledge building of Max with our internal colleagues across the Regulatory, Marketing and R&D functions. By late 2015, the MAx Academy had conducted 48 training sessions for more than 800 employees.

Facts and figures

TOTAL NUMBER OF TRAINING HOURS AND NUMBER OF PARTICIPANTS RECEIVING TRAINING



Training data are presented below for five countries (Germany, Brazil, China, the United States and France), which account for 59% of Sanofi's workforce as of January 1, 2016 and can thus be taken as a representative sample.

2015 TRAINING HOURS IN FRANCE

554,739
HOURS OF TRAINING
were provided

82,802
PARTICIPANTS
have received training

24.8
average number of training
hours per trainee

PEOPLE DEVELOPMENT

Strengthening corporate leadership

Two years ago, Sanofi identified the need to reinforce and coordinate new leadership practices for senior leaders in today's business world, where agility and flexibility are more critical than ever. To leverage best practices and build a stronger leadership culture across the Group, we created the Corporate Leadership Development platform. We also established several executive education programs, such as Leading for Tomorrow and Business for Tomorrow. More individualized development training for leaders is available through our Evolution Centers for Excellence and Leadership. These programs contribute to reinforcing our succession plan pipeline and internal recruitment while helping Sanofi leaders expand their networks and gain clarity about their own development goals.

New programs will be launched in 2016 for senior leaders and managers, with a focus on skills such as influencing in a complex environment and building inspirational leadership skills. We will continue to harmonize our leadership development offerings at all management levels to promote a culture of continuous learning and feedback.

A global cloud-based learning management system

Sanofi is convinced that a single, cloud-based learning management system (LMS) is best adapted to our employees' future needs. With the goal of providing state-of-the-art learning technology, we launched the "One LMS" project, is expected to deliver the design and functionality of a robust, flexible and scalable system in line with our business needs going forward. In early 2017, a wide range of

learning activities will be available to Sanofi employees worldwide: regulated and non-regulated activities, face-to-face and digital sessions, online and offline trainings.

Sanofi's new learning management system is expected to bring many benefits: enhance our compliance, ensure standardization of learning processes, ensure learning-related data management is accurate and up-to-date, and drive business decisions through robust learning analytics. "One LMS" will support employee ownership of learning and help make Sanofi's workforce more mobile, international and interconnected.

The Sanofi Digital Academy

Digital technology has already begun to change the world. In the health sector, digital innovations are revolutionizing medical practices and opening up new horizons in prevention, screening and treatment, and helping patients manage day-to-day living with an illness or a disability.

Naturally, the digital revolution also changes our employees' jobs. In 2015, we launched the Sanofi Digital Academy to help familiarize them with innovations and new challenges and equip them to seize new opportunities. The Digital Academy aims to increase awareness, develop skills, build a digital culture and change mindsets. Employees can access the platform anytime and anywhere, including from home, using any device, including their personal devices, enabling them to watch the videos and embark on the digital journeys. We recently developed this Corporate Open Online Course European initiative in collaboration with other large companies and Netexplo, an independent observatory that studies the impact of digital technology on society and business. In September 2015, the Sanofi Digital Academy was opened to all our employees worldwide.

TARGET POPULATION | LEADERSHIP PROGRAMS | DEVELOPMENT CENTERS

DEVELOPING LEADERS AT THE DIFFERENT LEVELS OF THE ORGANIZATION

EXECUTIVES

- LEADING FOR TOMORROW
- BUSINESS FOR TOMORROW
- ECE EVOLUTION CENTER FOR EXCELLENCE

SENIOR LEADERS

- IMPACT Communicate in an impactful way
- INSPIRE Leading Teams Effectively
- INFLUENCE Performing Transversally
- ECL EVOLUTION CENTER FOR LEADERSHIP

MANAGERS OF MANAGERS

- LOCAL PROGRAMS

FRONTLINE MANAGERS

- MANAGEMENT ESSENTIALS
- EVOLVE

INDIVIDUAL CONTRIBUTORS

- LOCAL PROGRAMS
- EVOLVE

SANOFI DIGITAL ACADEMY

FROM 01/10/2015 TO 31/12/2015

161,000
PAGES VIEWED



2,200
DIGITAL PASSPORTS
OBTAINED



4,800
DIGITAL JOURNEYS
COMPLETED



ABOUT 4,000
SINGLE USERS

ABOUT
1,200
FROM SALES FORCE

759
FROM INDIA

1,400
FROM GLOBAL
OPERATIONS



26,250
VIDEOS WATCHED

THE 3 MOST POPULAR VIDEOS ARE:

- MY CONNECTED LIFE
- MY CONNECTED LIFE AS AN EMPLOYEE
- MY CONNECTED LIFE AS A CONSUMER

ASSESS AND REWARD PERFORMANCE

G4-LA11

Introduced in 2010, Sanofi's performance and recognition approach is designed to support a performance culture by recognizing the different levels of contribution of each individual employee, based on delivery priorities (business outcomes) and professional behaviors (competencies).

Periodic talent reviews are designed to identify opportunities for personal development, potential career options and succession plans for key positions. The reviews provide a valuable opportunity for dialogue between

employees, managers and HR directors, typically to assess the fulfillment of job responsibilities, identify skill areas that need to be enhanced, preferred potential career paths and training requirements.

How are performance expectations set?

At Sanofi, we align employees' individual goals with the Group's culture, strategy and priorities. At the beginning of the year, each employee is expected to meet with his or her manager to outline clear expectations and determine:

PERFORMANCE

DEVELOPMENT

PERFORMANCE

1 Begin-Year
SET PERFORMANCE
EXPECTATIONS

2 INDIVIDUAL
DEVELOPMENT

3 Year-End
PERFORMANCE
REVIEW

Ongoing dialogue makes the difference to developing your career!

Facts and figures

DID YOU KNOW?

The Sanofi Digital Academy is hosted on an ATAWAD (AnyTime, AnyWhere, AnyDevice) platform to allow unlimited access for employees.

DIGITAL PASSPORT

The Sanofi Digital Academy issues a "digital passport" to employees who score well on a quiz based on 20+ video clips about digital technology. With their passport, employees embark on a journey to discover advanced innovations from around the world, earning visas along the way and encountering digital experts who provide in-depth information about selected concepts and practices.

In 2015,

52.2%

OF SANOFI EMPLOYEES

were engaged in our global performance and development planning process.

PEOPLE DEVELOPMENT

- Individual priorities in line with his or her role and the team's priorities;
- Competencies needed to achieve these priorities; and
- Relevant performance indicators for each priority and competency.

The expected competencies are based on the LEAD competencies model, which describes the way in which an individual interacts with others, team members, peers and customers and the professional behaviors that contribute to individual success.

How is performance assessed?

The annual performance and rewards review process provides a key opportunity for employees to take stock of their achievements and receive constructive feedback from their managers. The review process gives managers a chance to recognize and reward, if applicable, the employee's performance and results, and discuss how to be even more successful in the future.

How is performance rewarded?

At Sanofi, rewards are strongly connected to business achievement, team success and individual performance. All employees have the opportunity to talk to their managers, agree on performance and development goals, and determine how they can be accomplished. The performance review takes into account not only an employee's short-term performance, but also his or her skills and competencies, potential and commitment in the long term.

Total compensation encompasses the financial rewards, services and benefits an employee may receive. It recognizes individual performance and internal equity, while taking into account local market positioning. Compensation budgets are linked to business performance and market comparison. Individual compensation decisions are linked to the employee's contribution measured through individual and team achievements against pre-set objectives.

THE VALUE OF CONSTRUCTIVE FEEDBACK DURING THE REVIEW PROCESS

In 2015, we created a series of videos about the performance review process to inform employees and explain how the process unfolds. The videos also help managers to develop ways to provide constructive feedback to their team members.



David Loew, Senior Vice-President Global Commercial Operations Sanofi Pasteur

As a manager, how do you think the LEAD model should be used during the year-end period?

I expect leaders to inspire other people. They federate people around a common vision and common goals. They convey a clear strategy. They pick the best talents and develop them.

As an employee, how do you expect the LEAD model to be used?

From my own managers, I expect to get very tangible, concrete and actionable feedback. The more concrete it is, the easier it is for you to know what you need to change. I think the advantage of the LEAD model is that it stresses equally the importance of the 'what' you are doing and the 'how' you are doing it.

Could you share an example of feedback you once received: how did it help you?

During my career, I received feedback from several leaders providing me with better insights on how my actions are being perceived by others. That really helped me to develop myself as a leader, focusing on how I can change my way of interacting with others.

SANOFI LEAD COMPETENCIES MODEL





**Antonio Tataranni, Vice-President
Head of Medical Affairs, Diabetes
and Cardiovascular**

In a matrix organization, how do you think managers should leverage transversality in the evaluation of their employees?

It's extremely important that the evaluation of every single member of the project team is composed of the inputs of all others that contribute to the success of the project.

As an employee, how do you expect to be evaluated in a matrix environment?

As an employee of Sanofi, evidently what I expect of my evaluation is exactly the same as what I expect of the evaluation of the people I supervise.



**Vincent Warnery, Senior VP Global CHC
Business Unit**

What do you expect from your managers when giving the rates to their teams?

I think it's very important to consider this as an exchange. It's not about giving a rating to the employees but it is about having a discussion to see if he or she is surprised, positive or negatively. It's very important that both of you (employees and managers) lead the meeting with a positive feeling, with the feeling that everything was said and said properly.

BUILD AND DIVERSIFY CAREERS

Sanofi seeks to provide a professional environment that challenges, develops and fosters new learning and ideas while motivating all employees to pursue their career ambitions. Cross-functional mobility is strongly encouraged, where appropriate, across a broad spectrum of activities and functions. International mobility opportunities may arise when there is a need to transfer skills or knowledge, or as part of a defined talent development plan. Each employee plays a critical role in exploring potential new opportunities in the company with the support and guidance of their manager.

To promote career development and mobility across the Group, our global talent management process helps us identify, advance and manage relevant talents throughout the organization, ensuring that the right people are in the right positions to help enable us to achieve our business goals.

Through a robust and continuous talent review process, we capitalize on the best talent resources, support our pipeline of potential future leaders, recognize and mobilize key talents as a shared resource across the Group, and ultimately foster and drive our performance culture.

Facts and figures

"Sanofi is a magnet for diverse and exceptional talents, a place where everyone is able to unleash their full potential and grow as professionals while contributing to the growth of our company."



Roberto Pucci,
Executive Vice President,
Human Resources

79.4%

of executive vacancies of Top 400 were filled by internal candidates in 2015

OUR DEVELOPMENT PRINCIPLES

<p>All our people are valued as part of One Sanofi group-wide</p>	<p>We continuously develop our people to support our business and individual's ambitions, both for leadership and specialist careers</p>	<p>Professional development is a shared commitment between our people and Sanofi.</p>
<p>All Sanofi managers are active developers for our people</p>	<p>We are open and clear in our people development principles and practices</p>	<p>A diversified career is key to our people's potential and performance</p>

Our people development principles in action: two employee portraits

In 2015, Sanofi established a common vision and set of principles for people development across the Group and provided a clear definition of each principle for employees and managers. The “People Development Principles” and practices are designed to encourage pursuit of a diversified career and maximize our employees’ potential and performance. The following portraits of two exceptional employees and their career paths provide insight into how the Group can support talented individuals in pursuit of their professional ambitions.



Niven Al-Khoury
General Manager Sanofi Canada

“Diversify your scope of responsibilities”

Over the course of her career, Niven Al-Khoury has gained experience in fields as varied as sales and marketing, public affairs, regulatory and communications. “Working in diversified functions and different countries has greatly contributed to my career and my personality,” she explains. She recommends diversifying one’s scope of responsibilities along the career path, adding: “It’s extremely enriching if you have the flexibility to move to other countries.”

Early in her career, Niven worked as a pharmacist in Canada, where she grew up and completed her studies. When she became General Manager for Sanofi in Egypt and Sudan, she relished the challenge of turning tough situations into opportunities. “Moving to Egypt was one of the biggest challenges of my career. I didn’t even know how to drive there, but I said to myself: ‘Why wouldn’t I make it?’ I feel extremely valued when I drive impact and bring about change. Transforming a crisis into a success story inspires me,” she says. When asked to offer a word of career advice for other women, she is quick to

reply, “Stay in the driver’s seat! Don’t be shy about expressing your dream, but you must be open to acknowledge what’s needed to achieve it. Be adaptable and accept challenges that get you out of your comfort zone to sharpen your skills.” Since September 2015, Niven was appointed General Manager of Sanofi Canada.



Auri Brito,
PCP Sales Prof

From barista to sales professional

Originally from the Dominican Republic, Auri Brito earned a degree in pharmacology and chemistry and landed her first job in a hospital pharmacy. In 2004, she left to join her mother in the United States. “I came to America without being able to speak English and without a job,” said Auri. “Even though it was difficult, I couldn’t let the opportunity pass by.” Along her career path, Auri worked as a barista in the café at Sanofi’s Bridgewater campus. In 2013, while she was making cappuccinos and lattes, Auri queried her customers about their jobs to help her understand where she might someday hope to

fit into the Sanofi organization. Today Auri is part of the Sales Organization, working in a territory in New York City, which is often a first step to full-time employment with Sanofi. One of Auri’s former customer who became a trusted advisor was Lara Jones, Head of U.S. Diversity and Inclusion. She sensed in Auri an innate ability to connect with people. Says Lara, “Auri was passionate about sales, and that she wanted to seize an opportunity to leverage her pharmacy background. I could tell the combination of her ability to build relationships with people and her pharmacy/clinical background were powerful.” Joshua Rodriguez, a Senior Product Manager who comes also from the Dominican Republic, was another of Auri’s mentors. They worked together to prepare for Auri’s current venture. She’s been on the job since January 2015—and is thrilled to be back in healthcare.

VALUE AND SUPPORT DIVERSITY

The HR processes that support Sanofi's people development policy through the "One Sanofi, One HR" holistic model are even more effective because our human resources tap into the rich diversity of our workforce, giving us a remarkable opportunity to develop our creativity and better address the needs of patients all over the world.

By cultivating the diversity of our multicultural workforce, we create a source of talent, innovation, expertise and competitiveness. For employees, working in an environment that supports diversity and inclusion helps each individual thrive and live up to his or her potential while actively contributing to the company's performance in an industry marked by constant change.

Good Morning Sanofi

"Good Morning Sanofi" is a series of videos made by Sanofi employees across the globe, providing personal insights into each individual's professional and personal experiences. The first 11 episodes featured employees from many different countries and a wide range of backgrounds. Another series of 16 videos is in preparation for release in 2016. Sanofi employees worldwide can watch the "Good Morning Sanofi" videos on the Group's intranet, and viewers outside the company have access to the videos via Sanofi.com, Sanofi's YouTube channel and LinkedIn.

This project was rewarded twice in France: Green Awards and a *Trophée de la Diversité* in 2014 and 2015. In 2015, Sanofi was also a double winner at France's *Festival de la Communication Santé*. We received the jury's *Coup de Coeur* prize as well as an award for "Good Morning Sanofi" in the Corporate Communication, Employer Brand & Information category.

The following sampling of four videos demonstrates the power of diversity and how it is embedded into our people development approach.



Virginie, Chief of Staff (CEO Management Office)

[See Virginie's video on YouTube](#)

Virginie's story exemplifies how valuable cross-cultural diversity is for our business strategy. Her career path offers an exciting glimpse into international mobility and the ways it enhances professional development. A sound grasp of multicultural environments and an understanding of the challenges of diversity help us better serve patients.



Yannick, Deputy Director Global Performance & Systems Sanofi Pasteur (Lyon)

[See Yannick's video on YouTube](#)

Yannick is a project manager in the Global Industrial division of Sanofi Pasteur in Lyon, France. His job involves a lot of communication and teamwork. Three years ago he began using the Tadeo system, so that he can make calls and take part in meetings with his coworkers. His hearing disability has turned out to be an opportunity for his entire team to enhance competencies of respect, sharing, people skills and listening skills, all of which are essential to working at Sanofi.



Cherry, Finance Director Vaccines (China)

[See Cherry Liu's video on YouTube](#)

Cherry Liu joined Sanofi Pasteur 13 years ago and today is the Financial Director of the vaccines division in Beijing, China. Employees of many different nationalities work in China, and she notes that more and more foreigners employed by Sanofi China speak Chinese. Cherry enjoys working in a highly international professional environment.



Israel, HSE Coordinator (South Africa)

[See Israel's video on YouTube](#)

Israel and his wife have both worked for Sanofi for 25 years. His first job was as a machine operator. Like some of his coworkers in production or in packaging, he took part in a professional development program and became a supervisor. Today he is a Health, Safety and Environmental Officer.

MORE in our Download Center

- [Diversity brochure](#)
- [Local Social Impact factsheet](#)
- [G4-DMA](#) [G4-EC8](#) [G4-DMA](#) [G4-SO1](#)
- [Chapter 4 of the Registration document - Section 4.1.1 - 1.C. Compensation](#)
- [Social Charter](#)
- [G4-15](#) [G4-56](#)
- [Chapter 4 of the Registration document - Section 4.1.3 Social Dialogue](#)
- [G4-11](#)
- [Employee Volunteering factsheet](#)
- [Working With Schools and Universities factsheet](#)
- [Health and Safety factsheet](#)

How does climate change impact human health?

While changes in our climate create heat waves, droughts, floods and hurricanes, the health issues that accompany these natural disasters also take a toll on people across the world. Rising heat and humidity, for example, cause mosquitos to flourish and extend the geographic reach of diseases such as dengue and malaria. That is why at Sanofi, we are an official sponsor of COP21 and we also support the WHO's call for action to tackle climate change. Additionally, we are determined to raise awareness among the health community of the importance of working together to mitigate the consequences of climate change.



PLANET

Because the environment we live in directly affects our health, Sanofi cares for the planet by reducing its carbon footprint, managing waste and water and anticipating the consequences of climate change.



OVERVIEW OF OUR ENVIRONMENTAL IMPACT

From the raw materials we use in our products to their potential end-of-life impact on human health and the environment, we strive to limit potential negative effects caused by Sanofi's medicines, devices and services. This is only possible by taking into account their full life cycle and involving all our stakeholders in an efficient, holistic approach. As part of this approach, we have developed a new and far-reaching global project, Planet Mobilization, to define the Group's environmental strategy along the entire value chain.

TRANSPORT IMPACTS

MORE in our Download Center

See our Planet factsheet:

- [Transporting Medicines](#)

RELATED CONTENT in this report

- [Page 79](#), Carbon footprint

Promoting maritime transport

- 24% decrease in CO₂ emissions from 2010 to 2015 by using maritime transport
- 86% of our international shipments are by sea

PRODUCTION IMPACTS

MORE in our Download Center

See our Planet factsheet:

- [Protection of the Atmosphere](#)
- [Circular Economy](#)
- [Packaging](#)
- [Biodiversity and Biopiracy](#)
- [Green Chemistry](#)
- [Soil and Groundwater Protection](#)

RELATED CONTENT in this report

- [Page 79](#), Carbon footprint
- [Page 87](#), Water management
- [Page 95](#), Waste management

Water consumption

- 14.8% reduction in Sanofi's overall water withdrawal since 2010
- "B" score obtained on the 2015 CDP Water questionnaire

RAW MATERIALS IMPACTS

MORE in our Download Center

See our Planet factsheet:

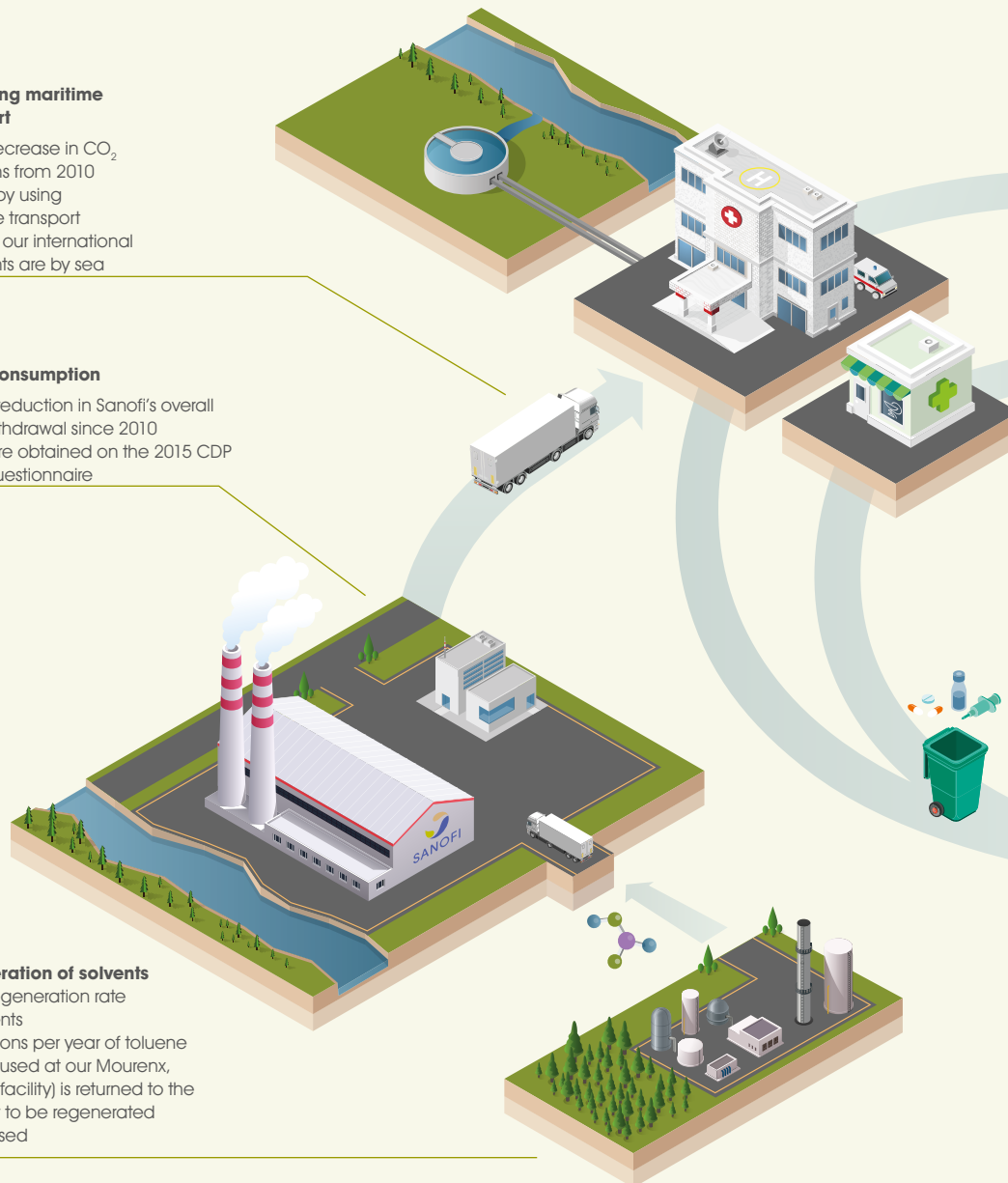
- [Biodiversity and Biopiracy](#)
- [Circular Economy](#)
- [Green Chemistry](#)
- [Implementation of REACH Regulation](#)

RELATED CONTENT in this report

- [Page 87](#), Water management

Regeneration of solvents

- 65% regeneration rate for solvents
- 1,000 tons per year of toluene (solvent used at our Mourenx, France, facility) is returned to the provider to be regenerated and reused

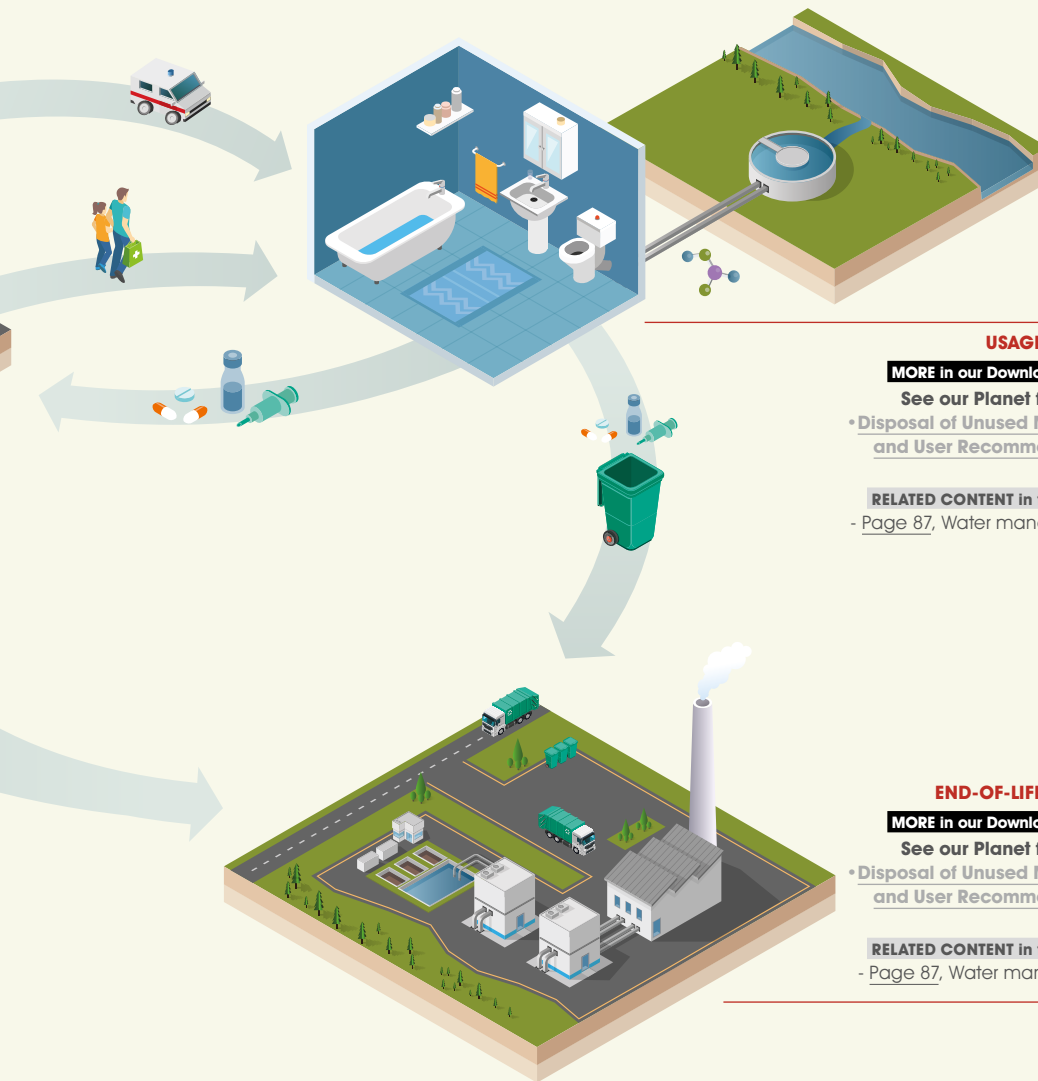


Aware that environmental issues are increasingly important, we are currently designing the Group's 2016-2025 environmental strategy (Planet Mobilization project). Our materiality review of Sanofi's environmental challenges highlighted 3 priorities: carbon emissions, waste, and water management, which are developed in the following pages.



Jean-Christophe Bligny,
Associate Vice President,
Corporate Environment
and Energy, Sanofi

"Planet Mobilization reflects an ambition to integrate environmental criteria across our products' value chain. This represents a great opportunity for innovation, optimization and differentiation of Sanofi's products."



DIRECT IMPACTS

Those on which we can act

INDIRECT IMPACTS

Those on which we cannot act

USAGE IMPACTS

MORE in our Download Center

See our Planet factsheet:

- [Disposal of Unused Medicines and User Recommendations](#)

RELATED CONTENT in this report

- Page 87, Water management

The proper use and disposal of medicines

- Sanofi launched a website (in French) dedicated to the responsible use of antibiotics for healthcare professionals and patients.
- €1.1 million: Sanofi's contribution in 2015 to France's DASTRI program for the safe disposal of medical devices.

END-OF-LIFE IMPACTS

MORE in our Download Center

See our Planet factsheet:

- [Disposal of Unused Medicines and User Recommendations](#)

RELATED CONTENT in this report

- Page 87, Water management

Take-back programs

- More than 11 tons of contaminated plastic have been collected since the inception of the Ivomec® and Eprinex® 4-H BoxBack program in 1998 at our Merial site in Montreal (Canada).



CARBON FOOTPRINT

Climate change is a reality that demands our immediate attention. Projections indicate that if we do not take action now, the future impact on health and the environment will be catastrophic. Sanofi is willing to play a role in the fight against climate change. We are taking steps to do our part—first, through mitigation measures to limit our CO₂ emissions and energy consumption, and second, through adaptation measures designed to help reduce the negative impact of climate change and the consequent burden on human health.

G4-EN19

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
<p>2010-2020: Achieve a 20% reduction in the combined scope 1 and scope 2 CO₂ emissions for industrial and R&D sites, and sales force vehicles</p>	<p>In 2015, we achieved a 15.8% reduction in our scope 1 and scope 2 CO₂ emissions compared to 2010.</p> <ul style="list-style-type: none"> • We signed a new agreement with <i>Suez Environnement</i>. • A waste-to-energy plant and a refrigeration unit were built at our Sisteron (France) site. • We installed cogeneration units at our Origgio (Italy) and Cologne (Germany) sites as well as a trigeneration unit at our Scoppito (Italy) site. • A total of 15 sites obtained ISO 50001 certification and 18 sites underwent energy audits. • We implemented a carbon footprint approach for our Maalox® manufacturing process in Italy. • We made efforts to improve our buildings environmental efficiency. • We reduced CO₂ emissions due to the transport of medicines, resulting in a 24% reduction since 2010 for pharmaceutical manufacturing sites. • We encouraged employees to use car-pooling, electric cars and public transportation. • We took steps to encourage the use of low carbon emitting cars by our medical sales force. • We equipped more telepresence and video-teleconference rooms. 	<p>On track</p>
<p>2013: Publish scope 3 emissions</p>	<p>In 2015, reliable and comprehensive scope 3 CO₂ emissions data were published based on a robust methodology. Sanofi's 2015 scope 3 CO₂ emissions amounted to about 9,855,000 tCO₂e.</p>	<p>Completed</p>

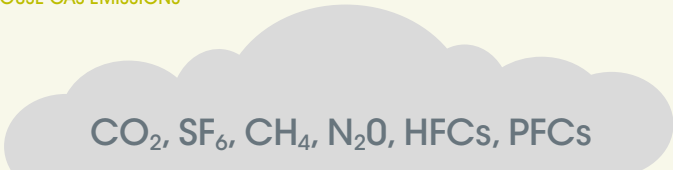
RELATED CONTENT in this report

- Page 24, Climate Change and Health Initiative, Patient section

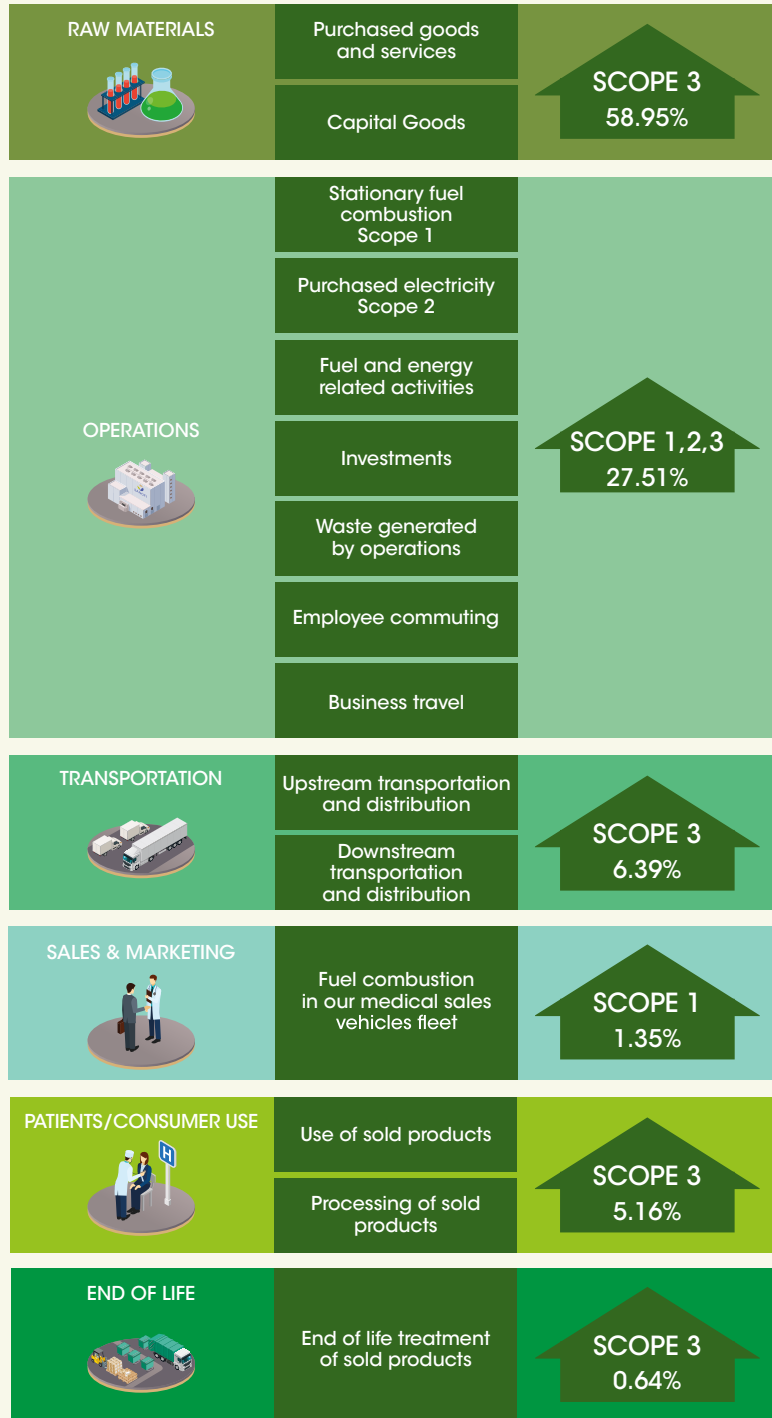
CARBON FOOTPRINT

SOURCES OF OUR TOTAL GREENHOUSE GAS EMISSIONS

G4-EN15 G4-EN16 G4-EN17



Relevant stages of our Value Chain



STRATEGIC APPROACH

The health sector overall contributes between 3% and 5% of OECD countries' CO₂ emissions, and roughly two-thirds of that amount is attributed to consumables (i.e., not energy, building or transport-related emissions). Of these consumables, two-thirds are medicines⁽¹⁾. As a global pharmaceutical company, we feel that we have a responsibility to reduce our own carbon footprint and to contribute to decreasing a significant portion of the health sector's footprint. Sanofi made a commitment to achieve a 20% reduction in CO₂ emissions from our industrial and R&D sites by 2020, in comparison to 2010.

G4-DMA

(1) NHS England Carbon Emissions: Carbon Footprint Report, May 2008, p.10.

Since energy constitutes the main source of our CO₂ emissions, we seek to optimize energy consumption and energy security for all our business activities.

Our responsible energy approach focuses on the three pillars of the energy/climate challenge, expressed by the E3 model: energy usage, energy spending and emissions of greenhouse gases. The strategy we adopt is developed in close cooperation with Sanofi's HSE and Procurement departments, as well as energy management specialists from Industrial Affairs, R&D and other operational units.

We consume ready-to-use sources of energy (petrol for cars, natural gas, etc.) as well as transformed purchased energy (electricity, steam, etc.), required primarily for:

- The production of active ingredients;
- Formulation, filling and packaging of pharmaceuticals and vaccines;

- Heating and air conditioning for pharmaceutical plants;
- Transporting medicines;
- Business travel by sales representatives and other employees.

We have implemented a range of initiatives targeting the responsible use of energy, such as:

- Improving energy efficiency and yields of equipment and facilities;
- Relying on alternative sources of energy;
- Incorporating environmentally-conscious design in buildings and facilities;
- Limiting CO₂ emissions from the transport of medicines;
- Reducing the environmental impact of business travel and employee commuting by encouraging the use of eco-friendlier means of transportation, developing car policies and promoting telepresence or videoconference meetings.

HIGHLIGHTS

Thanks to our efforts to limit CO₂ emissions, since 2010 we have reduced our combined scope 1 and scope 2 CO₂ emissions by 15.8% and our energy consumption by 11%.

The share of renewable energies represents 8.4% of the Group's global energy consumption and remained stable compared to 2014 (8%).

G4-EN19

IMPROVING ENERGY EFFICIENCY AT OUR SITES

G4-EN15 G4-EN16

Working with energy sector leaders: a new strategic partnership in 2015

Since 2013, to improve the energy efficiency of facilities at our sites, specific partnerships with Schneider Electric and ENGIE/Cofely have been set up by our Global Industrial Affairs Department in close collaboration with the

sites, procurement and HSE teams. Because our approach considers energy, water and waste to be interconnected challenges, we established a global EWW (Energy, Water and Waste) program centralized by Industrial Affairs and cascaded to Sanofi's business units and sites worldwide.

In 2015, Sanofi took an important step when we signed a global agreement with *Suez Environnement* aimed at optimizing the economic and environmental performance of Sanofi's manufacturing sites worldwide. Among its main objectives, *Suez Environnement* will develop tailor-made solutions designed to:

- Improve the environmental efficiency of our sites by optimizing the operation of water and wastewater treatment systems and recovering energy from waste;
- Preserve water resources, in particular by optimizing water management, wastewater treatment and recycling at production sites,

as well as enhancing control of emissions and their treatment (e.g., VOCs).

Within the framework of this agreement, a new project is underway at our Sisteron (France) site to build a waste-to-energy plant. This new unit will treat liquid waste (solvents and aqueous phase), which represents 40% of the Sisteron site's total waste. The steam produced will be used for two purposes: to heat processes for chemical synthesis, and for Heat, Ventilation and Air-Conditioning (HVAC) systems and air treatment.

Within the framework of these partnerships, numerous studies are ongoing and many action plans are being implemented.

RELATED CONTENT in this report

- Page 87, Water management
- Page 95, Waste management

CARBON FOOTPRINT

Cogeneration and trigeneration units in Italy and Germany

In 2015, thanks to the Cofely partnership and following initiatives carried out in Italy—at Anagni in 2014 and Brindisi in 2013—we invested about €10 million to set up two new cogeneration units (combining heat and power) at our Cologne (Germany) and Origio (Italy) sites.

Also in Italy, we are building a trigeneration unit at our Scoppito site. The term trigeneration refers to the simultaneous production of three forms of energy: electricity, hot water and cold water. The new plant will provide a major opportunity to reduce energy costs in Italy, where there is a significant gap between electricity prices and natural gas prices. The performance of this new trigeneration plant is expected to reduce the site's energy costs by 36% and CO₂ emissions by 12%, which will

enhance our competitiveness and bring us closer to achieving our environmental and sustainable production targets.

Trigeneration represents an important milestone for the Scoppito site. This new plant is just one of four such facilities being built in Italy, and exemplifies the Group's efforts to preserve the environment and have a positive impact on local communities.

A new refrigeration unit for our Sisteron site

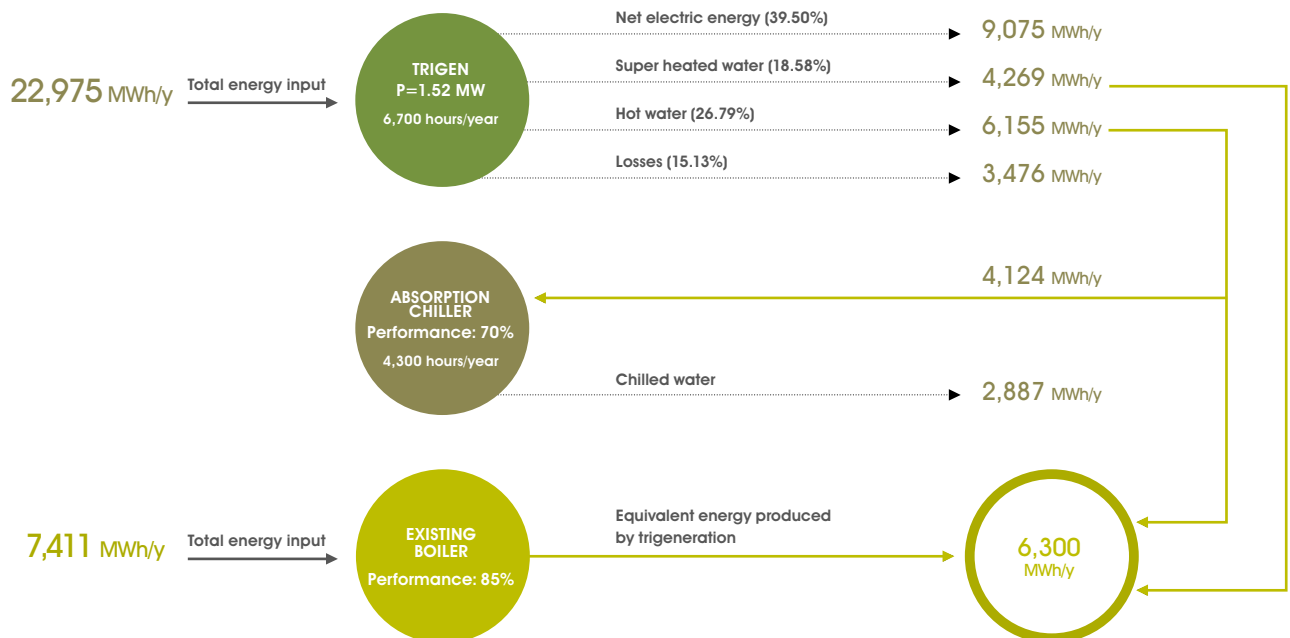
Within the scope of the Sanofi-Cofely partnership, we have begun installation of a centralized refrigeration unit at our Sisteron (France) site using the most advanced techniques. This new unit is expected to reduce electricity consumption by 7.6 GWh annually as of mid-2016, which represents around 15% of the site's electricity consumption.

Energy audits and ISO 50001 certifications

Sanofi has expanded our program with Schneider Electric to help improve energy performance—which to date has focused on research for energy efficiency opportunities like cogeneration and refrigeration units—to include wide-ranging audits of energy and management systems at our sites.

In 2015, 18 energy audits were performed worldwide. In addition to the seven sites that already received certification in 2013 in Germany and France, an additional eight sites received ISO 50001 certification: Compiègne (France), Cairo (Egypt), Zenata (Morocco), Le Trait (France), Bucharest (Romania), Prague (Czech Republic), Geel (Belgium) and Csanyikvölgy (Hungary). Such certification attests to the efficiency of our sites' energy management systems.

TRIGENERATION PLANT AT SCOPPITO (ITALY) SITE



ON TARGET TO PROVIDE ROBUST SCOPE 3 CO₂ EMISSIONS DATA

G4-EN17

We are on target to provide our comprehensive scope 3 CO₂ emissions results based on 2015 data, thanks to close cooperation between many Sanofi business units and functions. With the assistance of an outside expert, we have analyzed and disclosed data in each of the 15 categories of the Greenhouse Gas Protocol, with the exception of those that do not apply to our activities. In 2015, our total scope 3 CO₂ emissions amounted to 9,854,914 tCO₂e at the Group level.

MORE in our Download Center

• [CO₂ Emissions – Scope 3 factsheet](#)

G4-DMA G4-EN17

REDUCING OUR CARBON FOOTPRINT: THE MAALOX® CASE STUDY

At our Scoppito site, we carried out a carbon footprint analysis of the production of Maalox® 400 mg tablets for sale on the Italian market. This study was designed to identify activities that could be modified to reduce energy consumption and CO₂ emissions. Sanofi received a carbon footprint certification following this study, conducted in compliance with the ISO/TS 14067 standard. This is the first time this type of certification has been granted for a pharmaceutical product—indeed, no similar studies have been conducted in the pharmaceutical industry to date. The findings are expected to help us lower production costs and thereby enhance the Group's competitiveness.

MAKING OUR BUILDINGS AND FACILITIES MORE ENVIRONMENTALLY FRIENDLY

G4-DMA

Sanofi introduced our Sustainable Building Charter in 2013 with the aim of making our tertiary buildings more eco-friendly. To date, a total of 15 administrative buildings for our R&D and production activities have received LEED (Leadership in Energy and Environmental Design) certification, and four administrative buildings in France are HQE-certified (HQE, *Haute Qualité*

Environnementale), located at the Campus Sanofi Val de Bièvre (CSVb), Lyon Carteret, Toulouse and La Boétie sites.

In 2015, we inaugurated our new administrative site at the Campus Sanofi Val de Bièvre near Paris. To ensure high-energy performance as part of an eco-responsible approach, the new building is bioclimatic* (see "Did you know?" in the Facts and figures) in design. At the site, a specific energy policy supports this approach by strongly encouraging the control of energy consumption, energy-efficient purchasing and the replacement of equipment by identical energy-performing equipment. In addition, the CSVb site received 2 certifications:

- BREEAM (Building Research Establishment Environmental Assessment Method), with a rating of "very good";
- High Environmental Quality with a rating of "exceptional".

LIMITING CO₂ EMISSIONS DUE TO THE TRANSPORT OF MEDICINES

G4-EN17

CO₂ emissions from the transport of medicines are part of scope 3 emissions and are reported in the scope 3 table in the "downstream transportation and distribution" category in the "Transporting medicines and vaccines" factsheet (see link below). In 2015, thanks to a new methodology developed by an expert third party, we determined that CO₂ emissions related to the transport of medicines amounted to 444,777 tCO₂e for the Group's overall perimeter. For the strict perimeter of pharmaceutical manufacturing sites, CO₂ emissions accounted for 57,899 tCO₂e and 87kg CO₂ per pallet (stable compared to 2014). These results reflect our continuous efforts to reduce the environmental impact due to the transport of our medicines, by preferring maritime shipping for all intercontinental product flows. In 2015, the quantity of medicines transported by barge represented 86% of our international shipments, reducing thereby CO₂ emissions.

MORE in our Download Center

• [Transporting Medicines and Vaccines factsheet](#)

G4-DMA G4-EN17

Facts and figures

DID YOU KNOW?

* **Bioclimatic** indicates that a building's location and design take into account the local climate and environment to reduce energy required for heating, cooling and lighting. The design of a bioclimatic building is based in particular on selecting suitable materials and using air circulation, solar radiation and geothermal recovery techniques, as well as rainwater recovery.

MORE in our Download Center

• [Sustainable Building charter](#)

G4-DMA G4-15

CARBON FOOTPRINT

REDUCING CO₂ EMISSIONS DUE TO BUSINESS TRAVEL AND EMPLOYEE COMMUTING

CO₂ emissions from business travel and employee commuting are part of our scope 3 CO₂ emissions.

MORE in our Download Center

- [CO₂ Emissions – Scope 3 factsheet](#)

G4-DMA G4-EN17

Encouraging lower-carbon commuting

As part of our commitment to reduce our CO₂ emissions, Sanofi has taken steps to encourage employees to use lower-carbon means of transportation. For example, at our Campus Sanofi Val de Bièvre site, electric buses are provided to take employees from the site to the subway. Employees are strongly encouraged to choose public transportation and the site is equipped with a room for bikes and spaces reserved for electric vehicles. To promote carpooling, a mobile application called “Smart Autostop” makes it easy for employees to locate nearby passengers and drivers for the work-home commute.

Our medical sales vehicles fleet

In 2015 the progressive renewal of the Group’s fleet was carried out with a focus on improving the fuel efficiency of our fleet and bringing it into line with the limit set at 120g CO₂/km. So far, around 57.2% of our total vehicle fleet is compliant with this limit, including two wheel vehicles in several Asian countries (India, Indonesia, Vietnam, etc.). These results have been achieved in part thanks to the “eco-driving” technique promoted among our affiliates, which helps limit fuel consumption. Eco-driving techniques are part of road safety training in 57% of the countries where we operate (including Australia, Brazil, Egypt and France). In addition, Sanofi continues to promote the use of low-carbon cars and now owns a total of nearly 3,000 such cars worldwide: 1,713 cars running on biofuel (mostly in Brazil); 1,159 hybrid cars (mostly in Japan); and 12 fully electric cars.

Promoting green meetings

In 2015, Sanofi continued to install telepresence and high-definition video-teleconference (HD VTC) equipment at several of our sites. New telepresence rooms were added in France at our Campus Val de Bièvre, Lyon Carteret and Marcy-l’Étoile sites, and in Singapore. There are now 22 telepresence rooms in progress. In addition, 76 HD VTC rooms were installed in 2015, bringing the total number of equipped rooms to 452. Virtual meetings allow participants to avoid traveling and significantly reduce travel-related CO₂ emissions.

MORE in our Download Center

- [CO₂ Emissions – Scope 3 factsheet](#)

G4-DMA G4-EN17

- [Transporting Medicines and Vaccines factsheet](#)

G4-DMA G4-EN17

- [Sustainable Building charter](#)

G4-DMA G4-15

- [HSE policy](#)

G4-15 G4-56

- [HSE Management System factsheet](#)

G4-56 G4-DMA G4-SO1

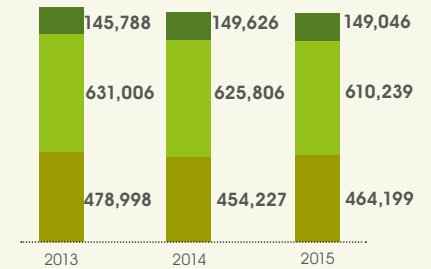
- [Circular Economy factsheet](#)

G4-DMA G4-EN23 G4-EN25 G4-EN27

Facts and figures

SCOPE 1 AND 2 CO₂ EMISSIONS (IN tCO₂e)

G4-EN15 G4-EN16

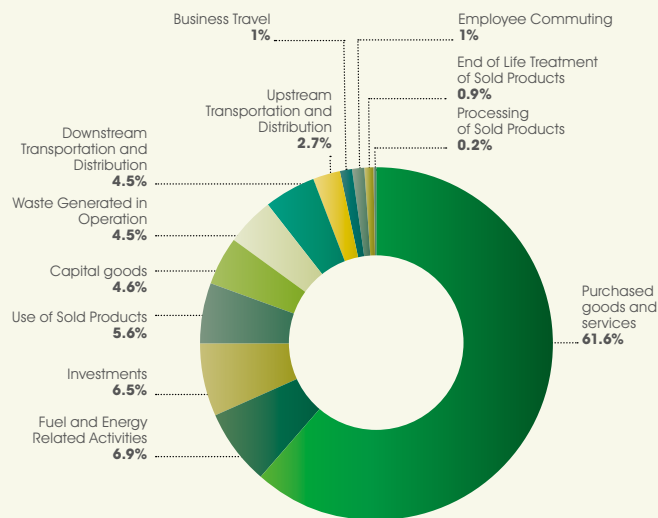


■ Medical sales fleet vehicles (estimated)
 ■ Production of electricity and steam (indirect CO₂ – scope 2)
 ■ Fossil fuel (direct CO₂ – scope 1)

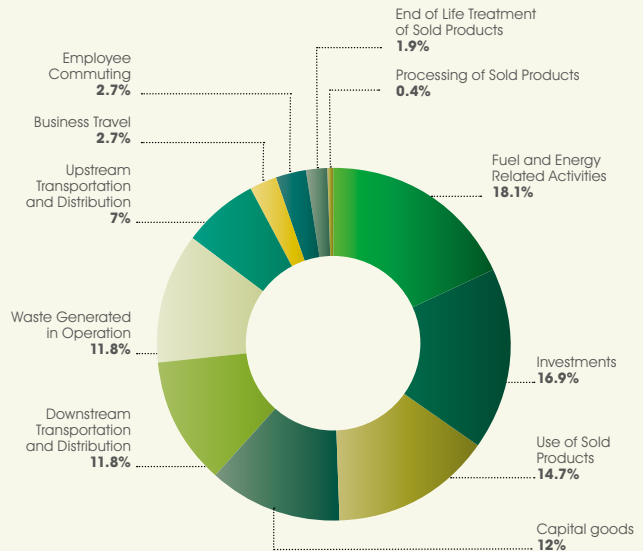
SCOPE 3 CO₂ EMISSIONS

G4-EN17

**SCOPE 3 CO₂ EMISSIONS
(INCLUDING PURCHASED GOODS AND SERVICES)**
TOTAL = 9,854,914 tCO₂e

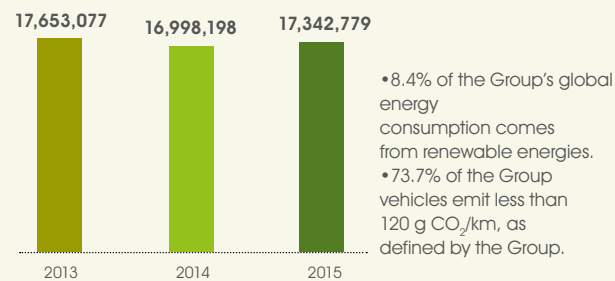


**SCOPE 3 CO₂ EMISSIONS
(EXCLUDING PURCHASED GOODS AND SERVICES)**
TOTAL = 3,780,082 tCO₂e



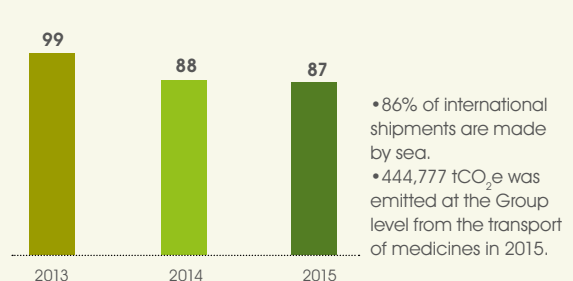
**GROUP ENERGY (IN GJ) CONSUMPTION
(EXCLUDING ENERGY USED BY CARS)**

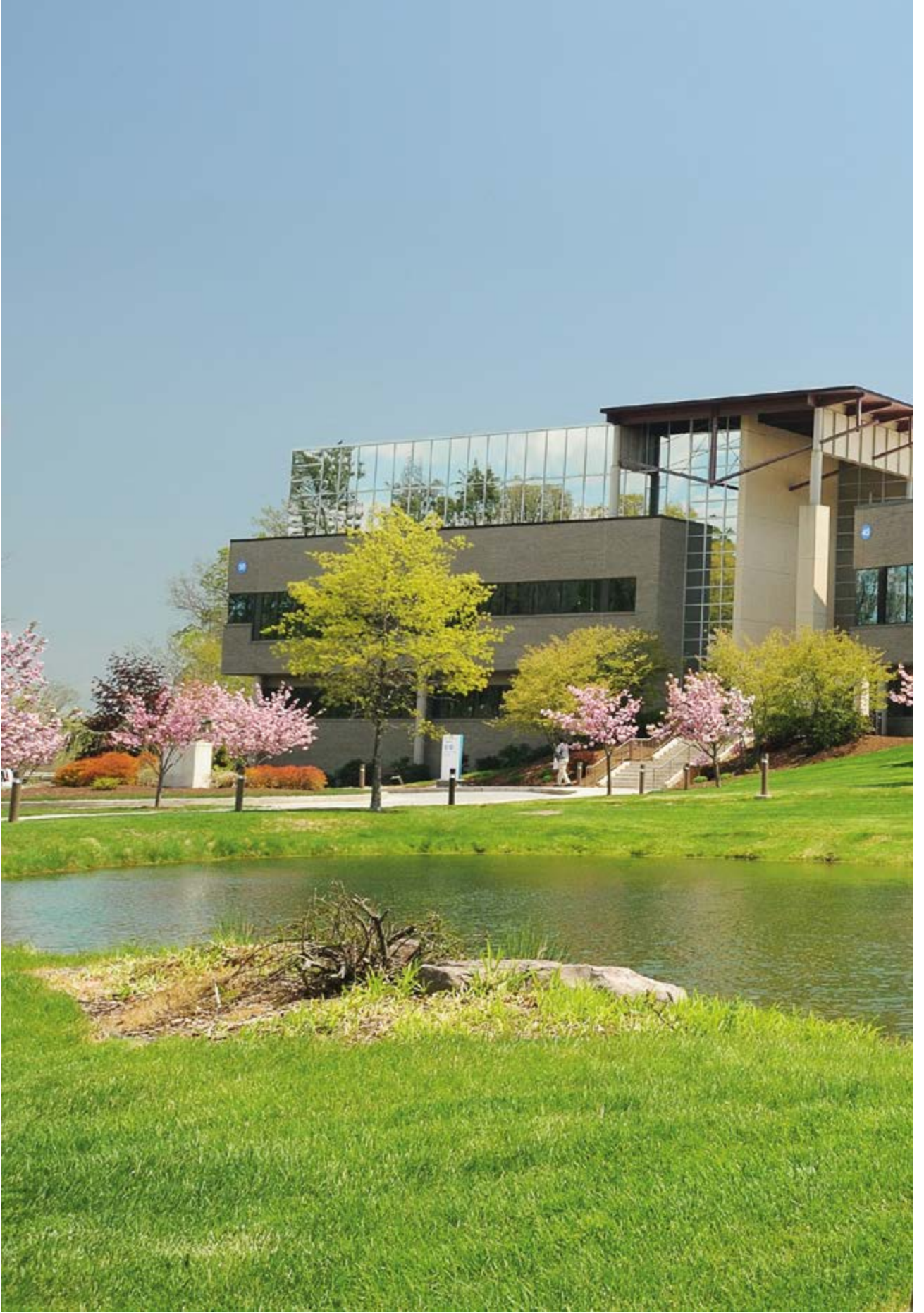
G4-EN15



**KG CO₂ EMITTED PER PALLET TRANSPORTED
(FOR PHARMACEUTICAL MANUFACTURING SITES)**

G4-EN17





WATER MANAGEMENT

At Sanofi, we require clean water in sufficient amounts for our production activities, and we are well aware of the critical challenge posed by the dwindling availability of vital freshwater resources. We also focus particular attention on the challenge of preventing pharmaceuticals from entering the aquatic environment. Pharmaceuticals may end up in the environment due to effluents from manufacturing facilities, medicines consumed by patients and then excreted, and the improper disposal of unused and expired medicines.

G4-DMA G4-EN8 G4-EN9 G4-EN22 G4-EN27

Our Progress

OBJECTIVES	2015 PROGRESS AND ACTIONS	STATUS
REDUCING OUR WATER CONSUMPTION		
2010-2020: Achieve a 25% reduction in water consumption	• In 2015, we achieved a 14.8% reduction in our water consumption compared to our 2010 baseline year.	On track
ASSESSING THE ENVIRONMENTAL IMPACT OF EFFLUENTS FROM OUR MANUFACTURING SITES		
By 2015: Implement an effluent assessment plan at 100% of chemistry sites ⁽¹⁾ that manufacture 30 selected active pharmaceutical ingredients (APIs)	• We completed the review of the effluents of 100% of our chemical manufacturing sites ⁽¹⁾ that manufacture the 30 selected APIs.	Completed
By 2015: Define environmental target values for the 30 selected APIs	• Target environmental values have been assigned to 100% of APIs found in effluents from our chemical manufacturing sites to date.	Completed
Implement an effluent assessment plan at dosage form manufacturing facilities	• We began implementing an effluent assessment program for a first series of 5 facilities.	On track
MEASURING THE POTENTIAL ENVIRONMENTAL IMPACT OF OUR MEDICINES		
Conduct voluntary environmental hazard and risk assessments for APIs in drugs already on the market	• We completed voluntary assessments for 42 APIs in marketed drugs.	On track
CONTRIBUTING TO RESEARCH TO LEARN MORE ABOUT PHARMACEUTICALS IN THE ENVIRONMENT (PIE)		
Develop and share our knowledge about pharmaceuticals in the environment	• We co-funded a research project at the University of Montpellier (France) on the use of an emerging approach to study the environmental effects of pharmaceuticals. • We partnered with the Paris Sud University to study how the issue of PIE is managed in French healthcare facilities.	On track
ENCOURAGING THE PROPER USE OF MEDICINES		
Support targeted programs to take back unused and expired medicines	• We have contributed to the implementation of take-back programs in 13 countries to date. • We supported the first-ever take-back program in Japan and launched a recycling program of empty antiparasitic jugs at our Meril Canada site.	On track
Develop programs to promote the proper use of medicines	• We launched a platform for healthcare professionals and patients about the responsible use of antibiotics.	On track

(1) Chemical manufacturing sites: industrial sites where Sanofi manufactures the active ingredients in medicines marketed by the Group or by third parties.

STRATEGIC APPROACH

Sanofi is committed to managing water responsibly to safeguard the health of individuals and communities.

Our proactive approach, which spans the entire life cycle of our products, seeks to reduce our water footprint while limiting potential risks in relation to pharmaceuticals that may enter the aquatic environment.

The responsible management of water resources touches upon key aspects of our business, such as our license to operate, ensuring business continuity, and our relations with stakeholders.

G4-DMA

REDUCING OUR WATER CONSUMPTION

Sanofi uses water for many of its industrial processes—in cooling systems during manufacturing, for fermentation and vaccine manufacturing, and in production operations and cleaning processes at all our manufacturing sites which is a key quality concern. In terms of our overall consumption, water used for cooling purposes and at chemistry and biochemistry sites accounts for the greatest share by far. The option of cooling with water, as a trade-off with energy requirements, is always fully assessed considering local availability of water, the absence of impact and acceptance by local communities, with regulatory approval. In line with our commitment to decrease our water consumption by 25% between 2010 and 2020, we organize many different initiatives to help the Group use less water. For example, we ask our sites to implement and review water management measures on a regular basis and to organize systematic assessments of any areas where water may potentially be saved. Additionally, we pay particular attention to Sanofi sites located in areas of potential water stress and water scarcity, in order to define specific action plans designed to reduce water consumption and develop appropriate ways to address any risks at these sites.

CONTRIBUTING TO PRESERVING WATER QUALITY

We strive to limit any contamination of water resources by implementing an effective wastewater discharge management strategy, which also includes active pharmaceutical ingredients as part of our activities. Furthermore, we promote the proper disposal of unused and expired medicines by patients.

Managing wastewater discharge responsibly

Industrial wastewater discharged as liquid effluents includes pharmaceuticals from:

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

Each site designs its own wastewater effluent management program based on environmental impact assessments and applicable statutory and regulatory requirements. These programs include characterizing potential pollutants and the implementation of processes to treat, monitor and control such pollutants. We also focus on improving discharge treatment systems and implementing systematic quality controls for effluents to help preserve the quality of surface water and prevent sub-soil and groundwater contamination.

Sanofi's management of wastewater effluents is covered by our Health, Safety and Environment (HSE) policy and falls within the scope of our HSE management system.

Water quality may be impacted by pharmaceuticals in the environment

Following the remarkable advances made in analytical methods, today it is possible to detect the presence of an increasing number of pharmaceutical residues in the environment. Depending on the substances and where they are found, they may be present at very low concentrations—measured in nanograms or micrograms per liter. A major study by the World Health Organization (WHO) concluded that at current levels of exposure in drinking water, adverse impacts on human health are very unlikely⁽¹⁾. Nevertheless, further

Facts and figures

“When you look at water use, the pharma sector's consumption is relatively limited, but given the types of compounds, which are by definition very active, the quality aspect is critical. This is particularly true with respect to downstream impacts on ecosystems and the question of micropollutants.”



Professor Suren Erkman,
Head of Industrial Ecology Group,
Institute of Earth Surface Dynamics (IDYST),
Faculty of Geosciences and Environment,
University of Lausanne (Switzerland)

research into the potential impact of combinations of pharmaceuticals, metabolites and other chemicals that may be present in low concentrations in the environment is necessary to improve our understanding of the potential long-term effects on the environment and human health.

How may pharmaceuticals end up in drinking water?

Trace amounts of pharmaceuticals may end up in the environment in various ways. When patients use medicines, pharmaceuticals may be excreted unchanged or as transformation products called metabolites. These pharmaceutical residues may be released into the environment through sewers and sewage treatment plants.

Other sources of discharge include emissions from manufacturing plants and the inappropriate disposal of unused medicines (e.g., by an end-user disposing of unused medicine directly into a sewage system).

Sanofi's position on pharmaceuticals in the environment

In view of growing public concern about pharmaceuticals in the environment and the limited body of knowledge on the subject, Sanofi has developed a multifaceted approach in line with the Group's policy and HSE requirements, which consists of:

- Analyzing wastewater effluents at our manufacturing sites and assessing their potential impact on the environment;
- Using state-of-the-art technologies to treat wastewater discharge from our sites;
- Contributing to advancing scientific research on this topic;
- Increasing knowledge of our products' environmental impacts by carrying out environmental hazard and risk assessments;
- Encouraging and supporting the proper use of medicines; and
- Contributing to targeted take-back programs for the collection and safe disposal of unused medicines.

Today an increasing number of Sanofi products, both on the market and in development, are produced using biotechnology, such as therapeutic proteins. These products are considered unlikely to have significant environmental effects and are potentially less harmful to the environment after use by patients.

RELATED CONTENT in this report

- Page 95, Waste management section

MORE in our Download Center

• [Disposal of unused medicines and user recommendations factsheet](#)

G4-EN27

• [Sanofi position on biodiversity and biopiracy](#)

G4-DMA G4-56

• [Biodiversity and biopiracy factsheet](#)

G4-DMA G4-EN26

• [CSR biodiversity guide](#)

G4-15 G4-56

• [Green Chemistry factsheet](#)

G4-EN27

• [Implementation of REACH regulation](#)

• [Soil and Ground Water Protection factsheet](#)

G4-EN26

• [HSE Management System factsheet](#)

G4-56 G4-DMA G4-SO1

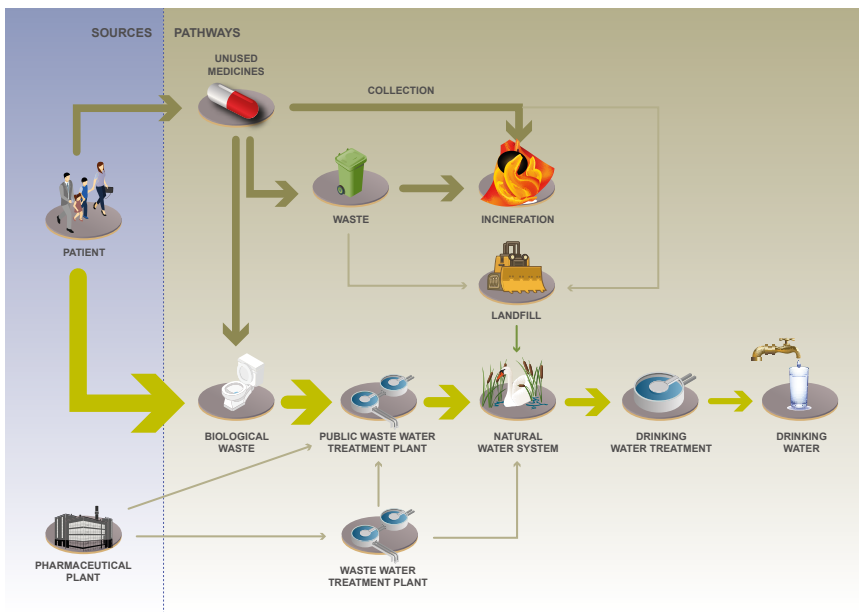
• [HSE Policy](#)

G4-15 G4-56

• [Human Rights in our activities \(guide\)](#)

G4-15 G4-DMA G4-HR11

MAIN SOURCES AND PATHWAYS OF PHARMACEUTICAL RESIDUES IN ENVIRONMENT



(1) "Targeted investigations conducted in the UK, the USA and Australia found that pharmaceuticals are largely present in drinking water at concentrations several orders of magnitude (more than 1,000-fold) below the lowest therapeutic dose and largely below the calculated acceptable daily intakes. The substantial margins of safety for individual compounds suggest that appreciable adverse impacts on human health are very unlikely at current levels of exposure in drinking water." Conclusions of WHO Pharmaceuticals in Drinking Water report 2012.

HIGHLIGHTS

REDUCING OUR WATER CONSUMPTION

G4-EN8 G4-EN9

By 2015, we reduced our water consumption by 14.8% compared to 2010 (reference year), thanks to targeted initiatives in all our activities to reduce water use, including programs to generate savings and recycling programs. The Group's water withdrawal increased by 8.8% between 2014 and 2015. This is mainly due to growing water needs at our Elbeuf (France) site for cooling purposes in fermentation processes. This fully authorized open-loop cooling system limits the impact linked to bodies of water, since water goes back into the river.

Within the framework of our global water management approach at the site level, several initiatives focusing on water consumption were organized by Sanofi sites in 2015.

Our Toronto site takes a comprehensive approach to reducing water consumption

The campus of our Sanofi Pasteur site in Toronto (Canada) spans 55 acres with 35 buildings dedicated to vaccine manufacturing, R&D operations and administrative offices. Some 1,900 employees and contractors work here. In 2010, this site used a great deal of water (1.4 million cubic meters) compared to the annual water consumption of similar-sized facilities. As a result, the site energy team, made up of experts in HSE, engineering and maintenance, came together to devise a comprehensive approach to reduce water consumption. An audit was conducted in 2014 to obtain a complete mapping of water use per building, and findings were combined with information about consumption rates of other utilities, such as steam and electricity. In 2015, a more in-depth analysis examined the factors driving the site's high water consumption and identified ways to optimize water usage and reduce consumption, including options for reuse. The energy team's findings pinpointed the need to optimize water-cooling strategies and review trade-offs with other energy sources.

At Frankfurt's R&D center, making the switch from open-loop to closed-loop water cooling

Our R&D facilities in Frankfurt (Germany), require water for cooling purposes, primarily air conditioning. Until recently, cooling relied on a rather old open-loop system connected to the nearby Main river. In 2015, the site switched to a closed-loop system at two of its R&D buildings. This improvement is anticipated to lead to a 50% reduction in annual water usage for the R&D center while it also generates operational cost savings.

Water-related risks areas: Sanofi sites in water scarcity and water stress areas

As part of our global water management strategy, we focus particular attention on Sanofi sites located in areas of water stress and water scarcity. In such areas, we can develop action plans to reduce water consumption, thus addressing any potential risks. Since 2014, the Group has fine-tuned its methods of determining locations where activities may be impacted by water-related risks. Our approach looks firstly at absolute water usage at the site's level, and secondly at absolute local water stress risk and regional relative water usage levels. In 2015, we completed our analysis with input from an outside consultant, and we defined three categories for Sanofi facilities:

- Sites with very low (or nonexistent) potential water concerns;
- Sites with high potential water-related risk (13 sites), representing 20.5% of Group's water withdrawal; and
- Sites for which further investigations are necessary to determine whether they are affected by water-related risk (13 sites), representing 7.4% of the Group's water withdrawal.

We also ask facilities that consume more than 1 million m³ per year to assess whether their water consumption represents a potential risk as described above in relation to the regional global water context. This applies to an additional three locations, representing 24% of Sanofi's annual water withdrawal. For all 29 impacted facilities, a working program was established in 2015 to cover a four-year period. Facilities with high potential risk as describe above are required to define an action plan to reduce water usage on site, including relevant targets and appropriate follow-up.

In 2015, studies and actions were initiated at facilities located in areas of potential water scarcity in Brazil, France, India, Italy notably.

MANAGING WASTEWATER DISCHARGE

G4-EN22

Chemical Oxygen Demand (COD) concerns final water pollutant content after various treatment steps.

In 2015, pollutant wastewater discharge for chemical oxygen demand decreased by 1.5% compared to 2014 despite an increase in production, thanks to our experts' assessment of the best techniques to be applied in order to maintain the treatment facilities' compliance.

Depending on the type of production activities and also on available facilities, Sanofi sites discharge their water effluents into municipal WasteWater Treatment Plants (WWTP) or treat their effluents on site before discharge into the environment. Most of our chemistry sites have their own WWTP since they require dedicated technical treatment solutions. In other cases, chemistry sites that do not have their own WWTP are connected to a shared industrial WWTP, or to a large city WWTP. Most of our facilities from other businesses are connected to neighboring municipal WWTP, which typically are able to handle our rather small effluent flows and loads. A very few have their own wastewater treatment facility, often due to the fact that they are not close to a city WWTP.

Analyzing wastewater effluents at Sanofi sites

At eight Sanofi chemical manufacturing sites⁽¹⁾, we have introduced a program for detecting and quantifying pharmaceutical substances in wastewater from our treatment plants. Within the scope of the program, environmental target concentrations are established for active pharmaceutical ingredients (APIs) quantified in the effluents. In addition to the chemical analysis, biomonitoring tools have been tested and included in the program.

We identified 30 APIs from Sanofi's product portfolio based on the potential environmental impact of our products (tonnage, toxicity, bioaccumulation and persistence) and quantified their trace amounts in wastewater effluents. Specific analytical methods were developed and applied to wastewater effluents by the Sanofi Chemistry & Biotechnology Development Laboratory. Located in Aramon (France), this internal reference laboratory for the analysis of effluents from industrial sites has received NF EN ISO/CEI 17025 accreditation. Environmental target concentrations have been established for 100% of the selected APIs quantified in the effluents. Additional environmental fate and effects studies have been conducted when available data in terms of ecotoxicity was not sufficient.

In line with these environmental target concentrations, emission reduction measures have been implemented where we considered it necessary.

We initiated a new program for our pharmaceutical manufacturing sites, which is designed to characterize the emissions of APIs from these manufacturing sites and assess related environmental risks. Following a prioritization exercise carried out in 2015, a first group of five sites in Europe and India will start to implement this pilot program in 2016 and 2017. It will be rolled out gradually at the other sites in the coming years.

Limiting API discharge from our manufacturing sites

G4-EN27

At Sanofi we are committed to continuously striving to make our processes safer and more environmentally friendly by adopting best practices. Industrial effluents (wastewater) are treated either at the sites' wastewater treatment facilities and/or at municipal treatment stations in accordance with operating permits. The choice and performance of technologies for effluent treatments are adapted to site-specific conditions. Effluents may undergo additional treatments at the factory level or upon exit from the site, when required and appropriate.

Sanofi invests in technologies to improve WWTP and minimize APIs in effluents, but also seeks to limit effluent discharge upstream of the WWTP in order to reduce effluents at the source (i.e., upon exit from the factory). A good example of this strategy in action is the furosemide project at our chemistry site in Frankfurt, Germany, which discharges wastewater into a treatment plant managed independently of Sanofi. The site set up a filtration process to eliminate furosemide from its effluents. Processes were optimized to extract and recover furosemide from the filtrate rinsing solutions. This technique reduced furosemide losses in wastewater by more than 90%, and the project achieved its initial goal of limiting effluent discharge upstream of the WWTP.

Improving knowledge of our products thanks to environmental risk assessments

Sanofi's commitment to prevent and mitigate environmental risks is central to our CSR and HSE policies. Guided by our Ecoval committee of in-house experts, we have established a sound governance system for assessing the potential impact of our products on the environment. The committee coordinates our Environmental Risk Assessments (ERA) in line with regulations for all new drugs in the United States, Europe and other countries. It also oversees the voluntary environmental studies of APIs used in Sanofi products already on the market.

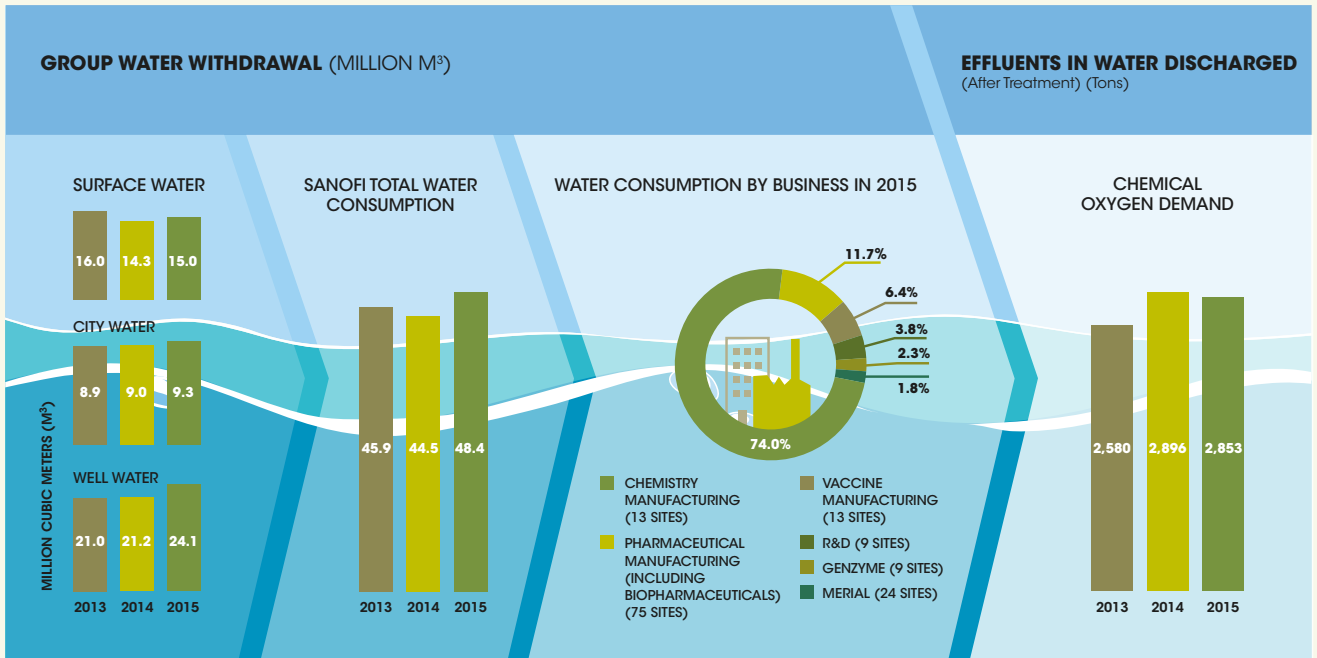
To date, voluntary environmental assessments have been conducted for 42 compounds at Sanofi. These compounds are selected for evaluation on the basis of several criteria, including their environmental fate and ecotoxicity.

(1) Chemical manufacturing sites: industrial sites where Sanofi manufactures the active ingredients in medicines marketed by the Group or by third parties.

Facts and figures

G4-EN8 G4-EN9 G4-EN22

SANOFI WATER MANAGEMENT



42

NUMBER OF COMPOUNDS

subject to a voluntary environmental risk assessment by Sanofi.

100%

OF OUR CHEMISTRY SITES

have undergone a review of their effluents to detect 30 preselected compounds.

Advancing scientific research by collaborating with universities

As part of our commitment to advancing knowledge about the potential impact of Sanofi products, we have formed research collaborations with academia and work closely with pharmaceutical associations. We also share this knowledge with other stakeholders as appropriate.

In 2015, we forged a new scientific collaboration with a university in Montpellier (France), within the scope of a three-year scientific project using molecular biology tools to characterize the biological response of aquatic organisms exposed to pharmaceuticals.

In addition, Sanofi has joined with the Public Health & Environment Group of the Paris Sud University to carry out a preliminary study on how the issue of pharmaceuticals in the environment is managed within French healthcare facilities. Various facilities have participated in this study, which could provide the basis for future collaboration between Sanofi and involved stakeholders to collectively address the challenges relating to PIE.

The responsible use of antibiotics

Medicines are not ordinary consumer goods. At each link in the healthcare chain, professionals, public authorities, patients and the public must be informed about the proper use of medicines, to ensure they are safe and effective.

Each year in France, nearly 160,000 people contract infections caused by bacteria that are multidrug-resistant to a range of antibiotics. Among these patients, 12,500 die⁽¹⁾ from a multidrug-resistant bacterial infection. From 30 to 50% of antibiotic prescriptions in France are inappropriate⁽²⁾, which exacerbates the emergence of resistant bacteria. The massive consumption and, at times, unjustified use of antibiotics over decades has

contributed to this situation. Moreover, antibiotics are the focus of growing concern due to their potential impact on human health and the environment, which needs to be studied and assessed. Sanofi is committed to supporting the responsible prescription and use of antibiotics, and supports healthcare professionals and patients through a dedicated website about the appropriate use of antibiotics: www.antibio-responsable.fr (in French only)

MORE in our Download Center

• [Disposal of Unused Medicines and User Recommendations factsheet](#)

G4-EN27

MORE online

• medsdisposal.eu

Take-back programs for unused medicines

We support targeted take-back programs that collect unused drugs from patients and inform consumers about their safe disposal. Sanofi has supported such programs in Belgium, Brazil, Colombia, France, Japan, Mexico, Portugal, Saudi Arabia, Spain, Taiwan, North America and Venezuela.

In Japan, regulations to prevent the release of pharmaceuticals into the environment are still in the preparatory phase and take-back schemes are voluntary. Our affiliate took the lead by introducing the country's first program for unused and expired medicines in 2014, targeting members of the Sanofi Health Insurance Society (SHIS). Employee households now return unused medicines by mail to our partner, Shiraishi Yakuhin K.K., which oversees their safe disposal. In its first year, the program reported a 60% participation rate among employees. In 2015, the affiliate organized initiatives to build awareness. Leaflets on pharmaceuticals in the environment were sent to all SHIS members and information sessions led by an outside facilitator were held at the Sanofi headquarters.

Another example concerns drug packaging, which may contain residues and therefore represent a source of pharmaceuticals in

the environment, if not properly collected and disposed of. To promote recycling, our Merial Canada site, leader in antiparasitic solutions for cattle, launched the 4-H BoxBack & Recycling program. This initiative is designed to encourage farmers to return empty and clean jugs of Ivomec® and Eprinex® products with respect to a dedicated protocol. Merial donates \$10 to a local 4-H Club (a national Canadian club to educate youth about natural resource conservation and environmental protection) for each label cut out from the product packaging and returned to the company. The jugs are then collected, shredded and used by a Canadian manufacturer to make molded plastic fence posts that are used on farms across the country. Since the program was introduced, a total of 11 tons of plastic has been collected. It benefits the environment by promoting the safe disposal of animal health products while it also supports the clubs. It has provided more than \$100,000 to local 4-H Clubs since its inception in 1998.

MORE online

• [Chapter 4 of the Registration document - Section 4.2.3 - 3.C. Pollution and waste management](#)

(1) Report of the Special Working Group for the Preservation of Antibiotics. Jean Carlet, Pierre Le Coz – June 2015 (in French).

(2) CMIT. *Bon usage des anti-infectieux en ville et à l'hôpital*. In E.Pilly: Vivactis Plus Ed; 2014, pp. 597-602. (in French).



WASTE MANAGEMENT

Waste has an enormous impact on the environment, causing pollution and greenhouse gas emissions that contribute to climate change and resource depletion. Industrial waste management generates substantial costs to the environment and to our business, since waste must be collected, sorted and transported before being treated. Proper waste management including appropriate reuse, recycling and energy recovery is a key factor in optimizing resource efficiency.

G4-EN23 G4-DMA G4-EN27 G4-EN28

STRATEGIC APPROACH

Sanofi takes a multifaceted approach to waste management, designed to limit the quantities of waste generated by our activities and encourage appropriate sorting, reuse and recycling to minimize the need to extract additional natural resources. As a pharmaceutical company, we view as important efforts to both reduce the environmental and health impacts of waste as well as improving resource efficiency.

G4-DMA

Our direct waste stream generally includes:

- Hazardous waste (including solvents), solid and liquid residues mainly from the chemical synthesis of active pharmaceutical ingredients and other production and research activities; and
- Non-hazardous waste generated by production (industrial) and administrative activities.

One of our indirect waste streams consists of unused and expired medicines, which contain active pharmaceutical ingredients with potential environmental impact.

Each Sanofi site is in charge of its own waste management initiatives based on the following waste hierarchy:

- Avoid waste production and reduce waste flow at the source;
- Reuse, recycle and recover on-site or with selected validated providers;
- Incinerate, with energy recovery wherever possible; and

• Send waste to authorized landfills as a solution of last resort, provided that the landfill complies with local regulations and control systems. Landfills should be audited on a yearly basis for hazardous waste landfilling, and audited every three years for non-hazardous waste landfilling. We have designed a waste management program with procedures to characterize process streams and identify, organize, collect, sort, treat, store, transport and dispose of different types of waste as appropriate, and in compliance with applicable laws. In addition, we keep records to ensure the traceability of disposed waste. Before engaging a new waste contractor, Sanofi sets up a purchase agreement that includes a preliminary control to ensure that the contractor has the necessary qualifications, competence and compliance for the type of waste to be handled.

MORE in our Download Center

• [HSE Policy](#)

G4-15 G4-56

• [HSE Management System factsheet](#)

G4-56 G4-DMA G4-SO1

OPTIMIZING SOLVENT USE FOR BETTER WASTE MANAGEMENT

At different steps of manufacturing our products we use solvents, which may contribute to emissions of volatile organic compounds (VOCs) and result in the output of hazardous waste. Sanofi has developed tools and performance indicators to optimize the use of solvents in our industrial processes (chemical synthesis, cleaning equipment, etc.) and to minimize their environmental impact. It is crucial to make sound choices at the earliest stages of product development, since it is often difficult to change them later. To help our teams make decisions on a daily basis,

we updated our internal standards in 2013 with the aim of providing guidance to choose the most appropriate solvents:

- Selecting the least toxic solvents;
- Reducing the quantities of solvents used; and
- Promoting the use of recycled solvents whenever possible.

MORE in our Download Center

• [Green Chemistry factsheet](#)

G4-EN27

• [Protection of the atmosphere factsheet](#)

G4-EN20 G4-EN21

NORTH AMERICA: THE BENEFITS OF STREAMLINING WASTE MANAGEMENT

In North America, Sanofi has streamlined waste management throughout all facilities in the U.S., Canada, Puerto Rico and activities (Meril, Genzyme, Chattem, Pasteur and Sanofi) to only two providers, one for hazardous waste and the other for non-hazardous waste. One exception concerns our Northpoint Lynwood site where vendor changes presented difficulties and no major benefits.

This program includes, but is not limited to, transport, storage, treatment, reuse, recycling, reclamation and/or disposal of all by-products generated by Sanofi.

The consolidation of our waste requirements and the standardization of practices in North America are expected to result in overall savings of U.S.\$1 million within a three-year term and a target of 30% landfilling reduction from 2014. These actions will contribute to achieving the company's goals by harmonizing best practices on waste management, minimizing waste generation, maximizing reuse, recycling and material recovery, recovering energy from the waste stream after material is recycled, and decreasing the amount of waste disposed in landfills.

Facts and figures

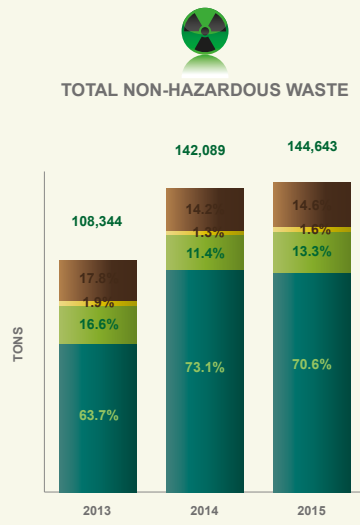
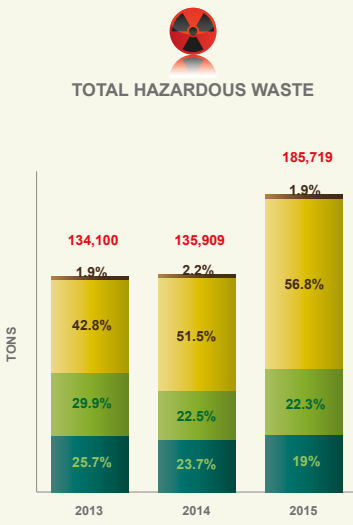
OUR RESULTS IN 2015

G4-EN23 G4-EN25

An increase in hazardous waste (+38.5%) was observed from 2013 to 2015, and may be explained mainly by an increase in the production of sludge at our Elbeuf (France) site, which intensified its activity after taking over the platform's treatment plant. Changes at other sites were related primarily to growth in production (Germany, Italy) or specific operations (France, Brazil). These types of waste generally are incinerated, with a recovery rate of 41%. Hazardous waste disposed of in landfill sites represents 1.9% of the Group total hazardous waste. This solution of last resort is used only when local incineration treatment infrastructures are not available. The volume of non-hazardous waste produced in 2015 increased by 33.5% compared to 2013. However, during the same period of time, the recycling rate rose by 48% in line with our strategy focused on recycling whenever possible.

SANOI WASTE MANAGEMENT

G4-EN23 G4-EN25



■ Recycled
 ■ Incinerated (with thermal recovery)
 ■ Incinerated (without thermal recovery)
 ■ Sent to authorized landfill

DID YOU KNOW?

Resource efficiency is about doing more with less. This concept aims to optimize processes while limiting the consumption of energy, water and materials and the output of waste, thus helping reduce our environmental footprint.

At each of our facilities, Sanofi oversees the recycling of many different types of waste—from solvents to batteries, paper, plastic, ink cartridges, biological waste, etc. For example, we have developed a printing policy to facilitate the responsible management of printing for our administrative activities.

MORE in our Download Center

- [Office printing factsheet](#)
- [Packaging factsheet](#)

G4-EN27 G4-EN28



Julia Vol,
Managing Director,
World Watch Institute Europe

"Sanofi will reach environmental excellence if it manages to work its business case according to the principles of the circular economy: target the most closed loop possible, knowing that the pharma industry is facing some very difficult challenges along the way, and that the possibility of a complete closed loop business model is in the distant future."

"The lifecycle approach is interesting. More than 90% of waste from medicines comes from the consumer usage phase. Sanofi needs to define what it can do to mitigate those impacts. This is challenging and ambitious."

MOVING TOWARDS THE CIRCULAR ECONOMY

The circular economy includes, among others, taking a new approach to developing solutions for managing specific types of waste. In certain cases, we can recover by-products or waste from chemical synthesis in short, and even very short, loops. Recovered waste can be re-processed into raw materials or reused as chemicals. In other cases and for other production needs, specific recovery programs are set up at various Sanofi sites. Here are some examples:

Regeneration and recovery

- Our Aramon (France) factory washes acidic fumes from incinerators that generate hydrochloric acid (2 m³/h), which are used on site to neutralize liquid effluents at the site's own wastewater treatment facility.
- At our Mourenx (France) facility, toluene is provided by a neighboring factory and used as a solvent; 1,000 tons per year of toluene is returned to the provider to be regenerated and reused.
- In mid-2014, Sanofi's Frankfurt (Germany) site began to reuse polystyrene tray carriers for insulin cartridges during production, rather than discarding them after a single use. From inception to today, this has led to a 38% decrease in waste quantities. When combined with an increase in production, it represents an overall 16% reduction in waste output.

Custom-designed waste treatment programs

- Our Aramon (France) site extracts opium derivatives from plants, producing more than 10,000 tons of organic waste each year, which goes to nearby facilities to produce compost that is used by local farmers.
- Sanofi's Ploermel (France) site is specialized in the production of heparins (injectable anti-coagulant) made from pork mucosa collected in France (mainly from nearby slaughterhouses in Brittany). Following the extraction process, the remaining material is used to produce methane gas, which is then used for energy production.

MAKING THE BEST USE OF BLISTER PACKAGING MATERIALS

To reduce waste at the source, we seek to optimize the utilization of blisters made of PVC/aluminum and aluminum/aluminum, which provide the packaging for many of our products. This optimization initiative concerns 46 Sanofi production sites. We carry out studies to limit package sizes in order to decrease the consumption of cardboard, PVC and aluminum. Another aspect of our optimization approach involves increasing the number of boxes per pallet transported and filling trucks, barges and other means of transportation to maximize occupancy.

We also perform life cycle analysis of packaging approaches using specially-designed software. An expert third party reviews the resulting analysis to help quantify the environmental impact of our packaging materials.

MORE in our Download Center

- [Packaging factsheet](#)
G4-EN27 G4-EN28
- [Circular Economy factsheet](#)
G4-DMA G4-EN23 G4-EN25 G4-EN27

SUPPORTING MEDICINES TAKE-BACK PROGRAMS

If unused medicines are not disposed of properly, they may potentially be found in the environment. Sanofi considers it to be our responsibility to contribute to the protection of natural resources and local ecosystems by providing support for targeted local take-back programs to collect unused medicines. We encourage the use of incineration instead of landfilling to dispose of our products. Sanofi supports take-back programs in many countries and issues recommendations for consumers about what to do with their unused medicines.

MORE in our Download Center

- [Green Chemistry factsheet](#)
G4-EN27
- [Packaging factsheet](#)
G4-EN27 G4-EN28
- [Protection of the Atmosphere factsheet](#)
G4-EN20 G4-EN21
- [Disposal of Unused Medicines and User Recommendations factsheet](#)
G4-EN27

RELATED CONTENT in this report

- Page 87, Water management

OUR CSR PERFORMANCE

Sanofi's commitment to Corporate Social Responsibility is a documented strategy, backed by hard metrics. We use a wide range of indicators to measure our performance on a continuous basis in our four CSR areas: Patient, Ethics, People and Planet.

OUR INDICATORS

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
PATIENT						
Access to healthcare						
Total number of ongoing access to healthcare programs (worldwide)	G4-SO1	G4-SO2	Number	261	303	283*
Estimated number of beneficiaries of above programs, which included:	G4-SO1	G4-SO2	Number	177,274,753	190,013,914	325,308,554*
- Number of healthcare professionals trained	G4-SO1	G4-SO2	Number	163,505	273,283	569,751*
- Number of individuals targeted by awareness campaigns	G4-SO1	G4-SO2	Number	79,148,558	100,101,301	268,791,753*
- Number of patients receiving diagnosis, vaccination or treatment	G4-SO1	G4-SO2	Number	97,963,690	89,639,330	55,947,050*
Innovation						
Research and Development (in our portfolio)						
Number of new molecular entities (NME) and vaccine candidates in clinical development			Number	49	43	46
Number of NME projects or vaccine candidates that are in Phase III studies or have been submitted to the health authorities for potential marketing approval			Number	12	14	14
Approximate percentage of projects coming from collaborations and partnerships			%	50	50	50
Product quality and safety						
Number of internal quality audits			Number	235	236	249*
Rate of batches recalled for quality reasons (number of batches of commercial products recalled in a given year vs. total number of batches of commercial products released in the same year)			%	-	< 0.1	< 0.34 [1]
Fight against counterfeit drugs						
Number of seizures			Number	10,100,000	9,600,000	20,700,000
Number of websites shut down			Number	13,700	11,800	2,410
Number of people arrested or under investigation			Number	213	434	156
Number of entries recorded by the Sanofi Central Anti-Counterfeit Laboratory in order to detect counterfeit products since 2008			Number	-	30,000	>30,000
Number of people Sanofi has trained about counterfeit drugs			Number	17,000	20,000	15,000
- Number of employees			Number	9,000	12,700	15,000
- Public health agents, customs officials and police officers from around the world			Number	8,000	7,300	0 [2]

[1] Our rate of batches recalled in 2015 was higher than in 2014 (less than 0.1%) due in particular to the recall of all Auviq/Allerject batches in North America.

[2] With a focus on internal awareness to sales forces, quality and supply chain representatives to better detect malicious acts on products (theft, counterfeit, diversion) and put in place mitigation measures within the scope of the end-to-end product security program.

* Indicators identified by an asterisk (*) were the focus of an in-depth review by one of our statutory auditors, as part of their review of the present 2015 CSR report. Their report describing the work they performed as well as their comments and conclusions is available at the end of this report.

OUR CSR PERFORMANCE

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
ETHICS						
Human rights						
Employees trained to human rights since 2010 [3]	G4-EC9	3.E	Number	84	104	147
Supplier-related risks						
Number of suppliers assessed on their CSR performance	G4-EN32 G4-LA14 G4-HR10 G4-SO9	3.C, 3.E	Number	188	128	190*
Number of assessed suppliers that met our CSR requirements	G4-EN32 G4-LA14 G4-HR10 G4-SO9	3.C, 3.E	Number	103	64	115*
% of assessed suppliers that met our CSR requirements	G4-EN32 G4-LA14 G4-HR10 G4-SO9	3.C, 3.E	%	55	50	61*
Number of buyers trained to the Responsible Procurement Platform	G4-HR2	3.C, 3.E	Number	106	120	153*
Corruption						
Total number of people trained through e-learning courses [4]	G4-SO4	3.D	Number	97,000 [5]	96,663 [6]	96,663 [7]
Clinical trials						
Total number of clinical trials	G4-PR1 / G4-PR2		Number	271	227	197
by Pharmaceuticals			Number	200	171	150*
by Vaccines [8]			Number	71	56	47
Number of subjects enrolled	G4-PR1 / G4-PR2		Number	62,022	62,627 [9]	38,663
with Pharmaceuticals			Number	38,960	26,906 [9]	25,064*
with Vaccines [8]			Number	23,062	35,721	13,599

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
PEOPLE						
Workforce						
Employees under contract [10] Employees under contract include all employees who have a contract with Sanofi, including interns and apprentices	G4-10 G4-LA1	1.A	Number	112,128	113,496	115,631*
Part time	G4-10/G4-LA1	1.B	Number	4,510	4,522	4,429
Temporary employees	G4-10/G4-LA1	1.B	Number	5,448	5,951	5,725
Workforce by employment type						
Permanent contract (PC)	G4-10/G4-LA1	1.B	%	90.0	89.1	89.2
Fixed-term contract (FTC)	G4-10/G4-LA1	1.B	%	10.0	10.9	10.8

[3] Cumulative 2009-2015.

[4] Training to the Code of Ethics, which includes sections about corruption. Cumulative since 2011.

[5] Cumulative 2011-2013.

[6] Cumulative 2013-2014.

[7] Cumulative 2013-2015. The global campaign was completed in 2014: only newcomers and *ad hoc* employees are now trained.

[8] Includes only trials where Sanofi Pasteur was the lead sponsor.

[9] Does not include Genzyme.

[10] The total number of employees contributing to business activity of Sanofi is 123,500 in 2015 including employees under contract, temporary employees, and third-party outside sales forces.

* Indicators identified by an asterisk (*) were the focus of an in-depth review by one of our statutory auditors, as part of their review of the present 2015 CSR report. Their report describing the work they performed as well as their comments and conclusions is available at the end of this report.

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
Workforce by region						
Europe	G4-10/G4-LA1	1.A	%	48.1	47.0	47.0
Including France	G4-10/G4-LA1	1.A	%	24.6	23.7	23.7
North America	G4-10/G4-LA1	1.A	%	16.8	16.4	16.7
Other countries	G4-10/G4-LA1	1.A	%	35.2	36.6	36.3
Workforce by function						
Sales force	G4-10/G4-LA1		%	29.9	30.1	29.5
R&D	G4-10/G4-LA1		%	14.9	14.3	14.1
Production	G4-10/G4-LA1		%	39.2	39.1	39.6
Marketing and support functions	G4-10/G4-LA1		%	16.0	16.5	16.8
Workforce by activity						
Pharmaceuticals	G4-10/G4-LA1		%	82.8	82.3	81.2
Vaccines	G4-10/G4-LA1		%	11.6	12.3	13.1
Animal health	G4-10/G4-LA1		%	5.6	5.4	5.7
New hires/departures						
Total number of hires	G4-10/G4-LA1	1.A	Number	13,145	15,915	15,856*
Total number of departures	G4-10/G4-LA1	1.A	Number	14,191	14,769	14,070*
Resignations	G4-10/G4-LA1	1.A	%	40	41	46
Terminations	G4-10/G4-LA1	1.A	%	26	30	31
End of fixed-term contracts	G4-10/G4-LA1	1.A	%	17	19	19
Retirement	G4-10/G4-LA1	1.A	%	5	5	5
Training						
Total number of hours of training in the 5 countries which account for 59% of Group employees [11]						
Total number of hours of training, Germany	G4-LA9		Number	N/A	321,327	314,094*
Total number of hours of training, Brazil	G4-LA9		Number	N/A	132,930	159,158*
Total number of hours of training, China	G4-LA9		Number	N/A	258,195	368,254
Total number of hours of training, United States	G4-LA9		Number	N/A	125,700	721,262
Total number of hours of training, France	G4-LA9		Number	591,931	423,130	554,739*
Percentage of employees receiving at least one session of training during the year, France	G4-LA9		%	82	74	82
Number of people trained, France	G4-LA9		Number	22,540	19,962	22,357
Average hours of training per year per trained employee, France	G4-LA9	1.E	Hours	26.3	21.2	24.8
Absenteeism [12]						
Number of days absent, France	G4-LA6	1.B	Number	278,969	255,029	248,465
Illness (France)	G4-LA6	1.B	Number	214,777	197,917	190,135
Occupational and commute-related injuries (France)	G4-LA6	1.B	Number	10,368	10,213	9,498
Maternity and/or paternity (France)	G4-LA6	1.B	Number	53,824	46,899	48,832
Number of days absent, Germany	G4-LA6	1.B	Number	N/A	89,157	124,020
Illness (Germany)	G4-LA6	1.B	Number	N/A	81,024	114,840
Occupational and commute-related injuries (Germany)	G4-LA6	1.B	Number	N/A	678	915
Maternity and/or paternity (Germany)	G4-LA6	1.B	Number	N/A	7,455	8,265

[11] These data take into account entities of Sanofi in the five following countries (Brazil, China, France, Germany, United States) excepted in Brazil which the activities of Meril are excluded. For more information, please refer to the *Document de Référence 2015*, page 362.

[12] Days of absence correspond to the length of absences, expressed as a number of business days, recorded by each human resources system in five major countries (France, Germany, the United States, Brazil and China) in accordance with local regulations. The length of absence beyond which employees are considered "inactive" instead of "absent" thus varies from one country to another the next. The scope of this indicator includes actively working permanent employees but excludes temporary staff, interns, apprentices, summer job staff and inactive employees. Absenteeism data do not include absences authorized by the company: paid leave, holidays, unpaid leave, parental leave, sabbatical leave, business creation leave, leave for family-related responsibilities and unworked notice periods. For more information, see the *Document de Référence 2015*, page 358.

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OUR CSR PERFORMANCE

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
Number of days absent, Brazil	G4-LA6	1.B	Number	N/A	34,904	56,301
Illness (Brazil)	G4-LA6	1.B	Number	N/A	21,935	36,580
Occupational and commute-related injuries (Brazil)	G4-LA6	1.B	Number	N/A	729	1,685
Maternity and/or paternity (Brazil)	G4-LA6	1.B	Number	N/A	12,240	18,036
Number of days absent, China	G4-LA6	1.B	Number	N/A	39,536	28,657
Illness (China)	G4-LA6	1.B	Number	N/A	8,767	8,669
Occupational and commute-related injuries (China)	G4-LA6	1.B	Number	N/A	151	25
Maternity and/or paternity (China)	G4-LA6	1.B	Number	N/A	30,618	19,963
Number of days absent, United States	G4-LA6	1.B	Number	N/A	36,523	38,713
Illness (United States)	G4-LA6	1.B	Number	N/A	32,433	34,270
Occupational and commute-related injuries (United States)	G4-LA6	1.B	Number	N/A	269	197
Maternity and/or paternity (United States)	G4-LA6	1.B	Number	N/A	3,821	4,246
Occupational health-safety						
Lost time injury frequency rate [13] (LTI-FR)						
LTI-FR worldwide	G4-LA6	1.D	Number	1.6	1.9	1.7*
LTI-FR France	G4-LA6	1.D	Number	2.9	4.2	3.7*
LTI-FR for temporary employees	G4-LA6	1.D	Number	1.2	1.6	1.7
LTI-FR for independent contractors	G4-LA6	1.D	Number	2.8	3.0	2.7*
LTI -FR by function						
Research and Development	G4-LA6	1.D	Number	1.1	1.7	1.4
Industrial Affairs	G4-LA6	1.D	Number	1.4	1.9	1.5
Global Operations	G4-LA6	1.D	Number	1.6	1.6	1.5
Vaccines	G4-LA6	1.D	Number	2.1	3.2	2.7
Support functions	G4-LA6	1.D	Number	0.7	0.8	1.7
Genzyme	G4-LA6	1.D	Number	1.4	1.3	1.3
Meril	G4-LA6	1.D	Number	2.2	3.1	3.0
Total reportable injury frequency rate (TRI-FR) worldwide (Sanofi employees) [14]	G4-LA6	1.D	Number	2.9	3.1	2.8*
Motor vehicle accidents (MVA)						
Number of MVA	G4-LA6	1.D	Number	4,931	4,194	4,095
Total number of medical sales representatives vehicles	G4-LA6	1.D	Number	24,266	24,436	24,767
- including total number of motorcycles	G4-LA6	1.D	Number	3,837	4,101	4,437
Motor vehicle accidents (MVA) rate	G4-LA6	1.D	%	20.3	17.2	16.5
Motor vehicle-related LTI-FR	G4-LA6	1.D	Number	1.2	1.1	1.2
Fatalities	G4-LA6	1.D	Number	0	1	1

[13] The lost time injury frequency rate (LTI-FR) 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 stationary 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. Frequency rates of previous years have been adjusted in 2015 based on the following factors: eliminating injuries dismissed by regulatory authorities, including injuries reported late, and changes in the scope of reporting.

[14] The total reportable injury frequency rate (TRI-FR) is defined as the number of LTI (see previous definition) plus the number of injuries without lost time (IWLT) within a 12-month period, per million hours worked. IWLT fulfill certain severity criteria defined by the Group to segregate them from simple first aid cases which are not counted as reportable injuries. Frequency rates of previous years have been adjusted the same way as described under the previous definition.

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Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
Total occupational diseases recognized [15]						
Occupational diseases recognized by type	G4-LA6	1.D	Number	38	44	14
Total by chemical agent	G4-LA6	1.D	Number	6	1	0
- respiratory disease	G4-LA6	1.D	Number	2	1	0
- skin disease	G4-LA6	1.D	Number	1	0	0
- cancer or malignant blood disease	G4-LA6	1.D	Number	3	0	0
- other illnesses caused by chemical agents	G4-LA6	1.D	Number	0	0	0
Total by physical agent	G4-LA6	1.D	Number	32	40	12
- upper limb disorder [16]	G4-LA6	1.D	Number	27	40	11
- neck, back, lower limb disorder [16]	G4-LA6	1.D	Number	4	0	0
- ear disorder	G4-LA6	1.D	Number	1	0	0
- other diseases caused by a physical agent	G4-LA6	1.D	Number	0	0	1
Disease caused by a biological agent	G4-LA6	1.D	Number	0	3	2
Others (including nervous breakdown and anxiety)	G4-LA6	1.D	Number	0	0	0
Social dialogue						
Percentage of employees covered by collective bargaining agreements [17]						
Germany	G4-11	1.C	%	N/A	62	62
Brazil	G4-11	1.C	%	N/A	100	100
China	G4-11	1.C	%	N/A	10	20
France	G4-11	1.C	%	N/A	100	100
Diversity						
Proportion of female employees in the total workforce	G4-LA12	1.A	%	45	45	46
People Managers [18]	G4-LA12		%	39	40	40
Executive Committee	G4-LA12		%	17	18	14
Board of Directors	G4-LA12		%	25	33	36
Workforce by age						
Less than 21 years	G4-LA12	1.A	%	0.3	0.3	0.3
21 to 30 years	G4-LA12	1.A	%	18.1	18.8	18.4
31 to 40 years	G4-LA12	1.A	%	33.1	32.6	32.4
41 to 50 years	G4-LA12	1.A	%	30.1	29.8	29.5
51 to 60 years	G4-LA12	1.A	%	16.8	16.8	17.6
Over 60 years	G4-LA12	1.A	%	1.7	1.7	1.8

[15] Occupational diseases presented here refer to recognized cases by regulatory authorities each year. The 2013 and 2014 figures were updated according to the files received after December 31st of the respective year.

[16] Musculoskeletal disorders.

[17] Collective bargaining agreements include those signed by the organization itself or by employer organizations of which it is a member. For more information, see the *Document de Référence 2015*, page 359.

[18] The definition of the term "manager" corresponds to every person who have one or more direct reports.

OUR CSR PERFORMANCE

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
Distribution of employees under contract worldwide based on seniority						
> 35 years of seniority	G4-LA12		%	1.5	1.3	1.4
31 to 35 years	G4-LA12		%	3.0	2.9	2.9
26 to 30 years	G4-LA12		%	4.4	4.4	4.8
21 to 25 years	G4-LA12		%	7.9	7.4	6.7
16 to 20 years	G4-LA12		%	8.6	8.8	9.0
11 to 15 years	G4-LA12		%	15.1	14.6	14.0
6 to 10 years	G4-LA12		%	21.6	21.3	20.1
1 to 5 years	G4-LA12		%	27.9	27.0	29.3
< 1 year	G4-LA12		%	10.1	12.2	11.8
Employees with disabilities in the workforce	G4-LA12		Number	2,058	2,038	2,252

Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
PLANET						
Materials						
Solvents used	G4-EN1	2.C	Tons	169,234	178,483	190,016*
- including % regenerated	G4-EN2	2.B, 2.C	%	60	65.45	65.32
Energy						
Total energy consumption [19]	G4-EN3	2.C	GJ	17,653,077	16,998,198	17,342,779*
- Natural gas/liquefied petroleum gas	G4-EN3	2.C	GJ	8,639,273	8,516,725	8,707,641
- Electricity	G4-EN3	2.C	GJ	6,906,563	6,764,148	6,840,753
- Liquid hydrocarbon (fuel)	G4-EN3	2.C	GJ	465,531	264,259	288,097
- Coal	G4-EN3	2.C	GJ	58,018	64,476	38,700
- Other (steam, thermal fluids, etc.)	G4-EN3	2.C	GJ	1,565,455	1,317,069	1,390,911
- Renewable Fuels [20]	G4-EN3	2.C	GJ	18,237	71,521	76,677
Total fuel consumption from medical sales fleet vehicles	G4-EN3	2.C	GJ HHV	2,200,978	2,253,489	2,173,294
- Total number of medical sales representatives vehicles including motorcycles	G4-EN3	2.C	Number	25,309	24,877	18,568
- Distance traveled	G4-EN3	2.C	Km	744,306,479	747,154,757	794,528,026
- Normalized consumption	G4-EN3	2.C	Liters per 100 km	8.1	8.2	7.7
Water						
Total water consumption	G4-EN8	2.C	m³	45,979,062	44,507,485	48,420,118*
- Surface water	G4-EN8	2.C	m ³	16,037,989	14,277,192	15,011,962
- Well water	G4-EN8	2.C	m ³	21,049,842	21,241,291	24,085,427
- City water	G4-EN8	2.C	m ³	8,891,231	8,989,002	9,322,729
Percentage reduction (baseline year: 2010)	G4-EN8	2.C	%	-17.4	-20.1	-14.8
Percentage of water consumed by sites located in water scarcity and water stress areas [21]	G4-EN9	2.C	%	56	54.4	52.1

[19] These figures do not include energy used by cars.

[20] Renewable fuels are only relevant for biomass, hydrogen, and other renewable fuels purchased and burnt on-site.

[21] Following the implementation of a new methodology in 2015 to assess our water stress and water scarcity locations in collaboration with an expert third-party, the 2013 and 2014 figures have been recalculated for the same perimeter.

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Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
Biodiversity						
Plants and animals appearing on the CITES lists	G4-EN14	2.E	%	Based on available information to date, no vegetal or animal listed in the CITES lists (appendix I, II and III) are used in our production	Based on available information to date, no vegetal or animal listed in the CITES lists (appendix I, II and III) are used in our production	Based on available information to date, no vegetal or animal listed in the CITES lists (appendix I, II and III) are used in our production
CO₂ emissions						
- Fossil fuel (direct CO ₂) medical sales car fleet not included	G4-EN15	2.D	tCO ₂ e	478,998	454,227	464,199*
- Production of electricity and steam (indirect CO ₂)	G4-EN16	2.D	tCO ₂ e	631,006	625,806	610,239*
Total scope 1 and 2	G4-EN15	2.D	tCO ₂ e	1,110,004	1,080,033	1,074,438*
Estimated CO₂ emissions from medical sales fleet vehicles	G4-EN15	2.D	tCO₂e	145,788	149,626	149,046
Percentage of the Group vehicles compliant with the 120g CO₂/km maximum defined by Sanofi [22]	G4-EN16	2.D	%	46	50.2	57.2
Transporting medicines [23]						
CO ₂ emissions related to the transport and distribution of medicines	G4-EN30 G4-EN16	2.D	tCO ₂ e	59,701	54,992	57,899
CO ₂ emitted by pallet transported	G4-EN18 G4-EN16	2.D	kg of CO ₂	99	88	87
Scope 3 CO₂ emissions (estimate) [24]						
- 1 Purchased goods and services [25]	G4-EN4 G4-EN27		tCO ₂ e	460,000	449,179	6,074,832
- 2 Capital goods	G4-EN4 G4-EN27		tCO ₂ e	300,000	223,016	455,357
- 3 Fuel and energy related activities	G4-EN4 G4-EN27		tCO ₂ e	140,000	236,569	682,512
- 4 Upstream transportation and distribution	G4-EN4 G4-EN27		tCO ₂ e	N/A	N/A	263,743
- 5 Waste generated by operations	G4-EN4 G4-EN27		tCO ₂ e	170,000	162,079	445,898
- 6 Business travel	G4-EN4 G4-EN27		tCO ₂ e	99,000	104,398	101,809
- 7 Employee commuting	G4-EN4 G4-EN27		tCO ₂ e	70,000	84,034	103,264
- 8 Upstream leased assets	G4-EN4 G4-EN27		tCO ₂ e	N/A	N/A	N/A
- 9 Downstream transportation and distribution [26]	G4-EN4 G4-EN27		tCO ₂ e	210,000	54,992	444,777
- 10 Processing of sold products	G4-EN4 G4-EN27		tCO ₂ e	51,000	45,990	15,502

[22] This figure has been adjusted to include two-wheelers.

[23] Those figures only refer to the pharmaceutical manufacturing sites.

[24] In 2015, the scope 3 emissions have been subject to an in-depth and comprehensive analysis based on a new methodology developed by an expert third party. Those figures cover now the overall Group perimeter and integrate additional elements to consider for each category, which explains the significant changes between 2014 and 2015. The 2013 and 2014 data have not been recalculated with the new methodology applied in 2015.

[25] The 2013 and 2014 data were limited to solvents and packaging materials.

[26] The 2013 and 2014 data only refers to the pharmaceutical manufacturing sites perimeter. The significant decrease between 2013 and 2014 is due to emission factors corrections. The 2015 data covers the Group overall perimeter.

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Definition	GRI 4	Reference Grenelle II (French law)	Unit	2013	2014	2015
- 11 Use of sold products [27]	G4-EN4 G4-EN27		tCO ₂ e	6,300	99,164	555,944
- 12 End of life treatment of sold products	G4-EN4 G4-EN27		tCO ₂ e	100,000	123,524	71,275
- 13 Downstream leased assets	G4-EN4 G4-EN27		tCO ₂ e	N/A	N/A	N/A
- 14 Franchises	G4-EN4 G4-EN27		tCO ₂ e	8,600	9,284	N/A
- 15 Investments	G4-EN4 G4-EN27		tCO ₂ e	N/A	N/A	640,000
Emissions to air						
- VOC emissions [28]	G4-EN21	2.B	Tons	2,801	3,336*	N/A
- NOx emissions	G4-EN21	2.B	Tons	343	303	308*
- SOx emissions	G4-EN21	2.B	Tons	249	264	284*
- ODS emissions	G4-EN20	2.B	TCFC-11 eq	<1	<1	<1
Waste water discharge						
- Chemical oxygen demand (COD)	G4-EN22	2.B	Tons	2,580	2,896	2,853*
Product impact assessment						
Percentage of chemical sites manufacturing active ingredients for which effluents have been reviewed against a list of 30 chemicals that was defined based on environmental hazard criteria	G4-EN26		%	75	75	100*
Percentage of APIs for which a target value has been defined	G4-EN26		%	23	44	100*
Number of molecules assessed voluntarily to date (cumulative)	G4-EN26		Number	26	34	42*
Waste						
Total hazardous waste	G4-EN23	2.B	Tons	134,100	135,909	185,719*
- Recycled	G4-EN23	2.B	Tons	34,437	32,251	35,325
- Incinerated (with thermal recovery)	G4-EN23	2.B	Tons	39,758	30,615	41,325
- Incinerated (without thermal recovery)	G4-EN23	2.B	Tons	57,420	70,023	105,508
- Sent to authorized landfill	G4-EN23	2.B	Tons	2,485	3,020	3,561
Total non-hazardous waste	G4-EN23	2.B	Tons	108,344	142,089	144,643*
- Recycled	G4-EN23	2.B	Tons	68,970	103,820	102,090
- incinerated (with thermal recovery)	G4-EN23	2.B	Tons	17,997	16,255	19,239
- incinerated (without thermal recovery)	G4-EN23	2.B	Tons	2,100	1,908	2,254
- sent to authorized landfill	G4-EN23	2.B	Tons	19,277	20,106	21,060
Expenditure/investment						
Total remediation cost	G4-EN31	2.A	Euros	52,000,000	58,000,000	63,000,000
Provisions for environmental risks and remediation	G4-EN31	2.A	Euros	698,000,000	697,000,000	720,000,000*

[27] The 2013 and 2014 data were limited to packaging materials.

[28] In 2015, in order to ensure the reliability of our VOC emissions data, we now report VOC emissions of year Y-1. Thereby, in 2015, we collected 2014 VOC emissions data by sending a specific questionnaire to sites consuming more than 5 tons of solvents as reported in 2014 (representing 68 sites).

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Definitions of regions of quality inspections and audits

Europe: Aland Islands, Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Isle of Man, Italy, Jersey, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Scotland, Serbia and Montenegro, Slovakia, Slovenia, Spain, Svalbard and Jan Mayen, Sweden, Switzerland, Turkey, Ukraine, United Kingdom

Latin America: Antigua and Barbuda, Argentina, Aruba, Bahamas, Barbados, Belize, Bolivia, Brazil, Cayman Islands, Chile, Colombia, Costa Rica, Cuba, Curaçao, Dominica, Dominican Republic, Ecuador, El Salvador, Falkland Islands, French Guiana, Greenland, Grenada, Guadeloupe, Guatemala, Guyana, Haiti, Honduras, Jamaica, Martinique, Mexico, Montserrat, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Barthélemy, Saint Kitts and Nevis, Saint Lucia, Saint Martin, Saint Vincent and the Grenadines, South Georgia and the South Sandwich Islands, Suriname, Trinidad and Tobago, Turks and Caicos Islands, Uruguay, Venezuela, Virgin Islands, Bermuda

North America: Canada, Saint Pierre and Miquelon, United States

Asia Pacific-Japan: Afghanistan, American Samoa, Anguilla, Antarctica, Australia, Bangladesh, Bhutan, British Indian Ocean Territory, Brunei Darussalam, Cambodia, China, Christmas Island, Cocos (Keeling) Islands, Cook Islands, Fiji, French Polynesia, Gambia, Guam, India, Indonesia, Japan, Kazakhstan, Kiribati, Korea (North), Korea (South), Kuwait, Kyrgyzstan, Republic Of Lao, Macao, Malaysia, Maldives, Marshall Islands, Mauritius, Micronesia, Mongolia, Myanmar, Nauru, Nepal, New Caledonia, New Zealand, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Papua New Guinea, Philippines, Pitcairn, Samoa, Singapore, Solomon Islands, Sri Lanka, Tajikistan, Thailand, Timor-Leste, Tokelau, Tonga, Turkmenistan, Tuvalu, United States Minor Outlying Islands, Uzbekistan, Vanuatu, Vietnam, Wallis and Futuna

Africa-Middle East: Algeria, Angola, Bahrain, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Djibouti, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Iran, Iraq, Israel, Ivory Coast, Jordan, Kenya, Lebanon, Lesotho, Liberia, Libyan, Madagascar, Malawi, Mali, Mauritania, Mayotte, Morocco, Mozambique, Namibia, Niger, Nigeria, Oman, Qatar, Reunion, Rwanda, Saint Helena, Sao Tome and Principe, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Syrian Arab Republic, Tanzania, United Republic of Togo, Tunisia, Uganda, United Arab Emirates, Western Sahara, Yemen, Zambia, Zimbabwe

Definition of procurement regions

North America: Canada, Puerto Rico and USA

Asia Pacific: Australia, Bangladesh, Cambodia, China, Hong Kong, India, Indonesia, Japan, Korea, Malaysia, New Zealand, Pakistan, Philippines, Singapore, Taiwan, Thailand, and Vietnam

Latin America: Argentina, Brazil, Chile, Colombia, Dominican Republic, Equator, Guatemala, Mexico, Paraguay, Peru, Uruguay, and Venezuela

Africa: Algeria, Cameroun, Egypt, Morocco, Nigeria, Senegal, South Africa, and Tunisia

Western Europe: Austria, Belgium, Bosnia, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Portugal, Serbia, Slovenia, Spain, Sweden, Switzerland, and UK

Rest of the world: Belarus, Bulgaria, Czech Republic, Hungary, Iran, Israel, Kazakhstan, Lebanon, Poland, Romania, Saudi Arabia, Slovakia, UAE, and Ukraine

GRI INDEX REPORTING 2015

INDICATORS SELECTED BASED ON SANOFI MATERIALITY ANALYSIS 2013+ UPDATE PLANET 2015

GENERAL STANDARD DISCLOSURES		
Profile disclosure	Disclosure	Location of the information
STRATEGY AND ANALYSIS		
G4-1	Statement from the most senior decision-maker of the organization	On this report p.2 , p.3
ORGANIZATIONAL PROFILE		
G4-3	Name of the organization	Front cover
G4-4	Primary brands, products, and services	Form 20-F 2015 - Item 4
G4-5	Location of the organization's headquarters	Paris
G4-6	Number of countries where the organization operates	On this report p.I , p.II , p.III
G4-7	Nature of ownership and legal form	Form 20-F 2015 - Item 4
G4-8	Markets served	Form 20-F 2015 - Item 4
G4-9	Scale of the organization	Form 20-F 2015 - Item 4
G4-10	Total workforce by employment type, contract, region, gender	On this report p.100 Chapter 4 French Registration Document 2015 - Section 4.1.1 Employment
G4-11	Percentage of employees covered by collective bargaining agreements	On this report p.73 , p.103 Chapter 4 French Registration Document 2014 - Section 4.1.3 - Social Dialogue
G4-12	The organization's supply chain	On this report p.6 Sanofi Suppliers
G4-13	Significant changes during the reporting period	On this report p.112
G4-14	The precautionary approach	On this report p.14 , p.15
G4-15	Charters, principles,... to which the organization subscribes or endorses	On this report p.11 , p.14 , p.33 , p.36 , p.59 , p.73 , p.84 , p.89 , p.95
G4-16	Memberships of associations & organizations	On this report p.10 , p.54 , p.56
IDENTIFIED MATERIAL ASPECTS AND BOUNDARIES		
G4-17	Entities in financial statements covered by the report	Form 20-F 2015 - F105 to F108
G4-18	Process for defining the report content and the Aspect Boundaries	On this report p.5 , p.9 , p.112
G4-19	Material Aspects identified in the process for defining report content	On this report p.5 , p.8 , p.9 , p.10
G4-20	For each material Aspect, report the Aspect Boundary within the organization	On this report p.5 , p.112
G4-21	For each material Aspect, report the Aspect Boundary outside the organization	On this report p.5 , p.112
G4-22	Effect of any restatements of information provided in previous reports	On this report p.112
G4-23	Significant changes from previous reporting periods	On this report p.112
STAKEHOLDER ENGAGEMENT		
G4-24	List of stakeholder groups engaged by the organization	On this report p.10 , p.22 , p.54 , p.56
G4-25	Basis for identification and selection of stakeholders with whom to engage	On this report p.10
G4-26	Approach to stakeholder engagement	On this report p.10
G4-27	Key topics and concerns raised through stakeholder engagement	On this report p.5 , p.9 , p.10
REPORT PROFILE		
G4-28	Reporting period	On this report p.112
G4-29	Date of most recent previous report (if any)	2014
G4-30	Reporting cycle (such as annual, biennial)	Annually
G4-31	Contact point for questions regarding the report or its contents	corporate-responsibility@sanofi.com
G4-32	GRI Content Index, chosen option & reference to the External Assurance	On this report p.108
G4-33	External assurance for the report	On this report p.114
GOVERNANCE		
G4-34	Governance structure of the organization	On this report p.14 , p.16 , p.17 Form 20-F 2015 - Item 6
ETHICS AND INTEGRITY		
G4-56	Organization's values, principles, standards such as codes of ethics	On this report p.11 , p.14 , p.17 , p.36 , p.54 , p.57 , p.58 , p.59 , p.73 , p.84 , p.89 , p.95

SPECIFIC STANDARD DISCLOSURES

Profile disclosure	Disclosure	Location of the information
CATEGORY: ECONOMIC		
MATERIAL ASPECT: INDIRECT ECONOMIC IMPACTS		
G4-DMA	Generic Disclosures on Management Approach	On this report p.73 Chapter 4 French Registration Document 2015 – Section 4.3.1 – Local economic and social impact of Sanofi's activities
G4-EC7	Development and impact of Infrastructure investments and services supported	On this report p.21, Chapter 4 French Registration Document 2015 – Section 4.3.1 – Local economic and social impact of Sanofi's activities
G4-EC8	Significant indirect economic impacts, including the extent of impacts	On this report p.21, p.73
MATERIAL ASPECT: PROCUREMENT PRACTICES		
G4-DMA	Generic Disclosures on Management Approach	On this report p.57 Chapter 4 French Registration Document 2015 – Section 4.3.3 – Subcontracting and suppliers
G4-EC9	Proportion of spending on local suppliers at significant locations of operation	On this report p.57, p.100 Chapter 4 French Registration Document 2015 – Section 4.3.3 – Subcontracting and suppliers
CATEGORY: ENVIRONMENTAL		
MATERIAL ASPECT: WATER		
G4-DMA	Generic Disclosures on Management Approach	On this report p.87, p.88
G4-EN8	Total water withdrawal by source	On this report p.87, p.90, p.92, p.104
G4-EN9	Water sources significantly affected by withdrawal of water	On this report p.87, p.90, p.92, p.104
MATERIAL ASPECT: EMISSIONS		
G4-DMA	Generic Disclosures on Management Approach	On this report p.81, p.83, p.84
G4-EN15	Direct greenhouse gas (GHG) emissions (Scope 1)	On this report p.80, p.81, p.83, p.84, p.85, p.105
G4-EN16	Energy indirect greenhouse gas (GHG) emissions (Scope 2)	On this report p.80, p.81, p.84, p.105
G4-EN17	Other indirect greenhouse gas (GHG) emissions (Scope 3)	On this report p.80, p.83, p.84, p.85
G4-EN18	Greenhouse gas (GHG) emissions intensity	On this report p.105
G4-EN19	Reduction of greenhouse gas (GHG) emissions	On this report p.79, p.81
G4-EN20	Emissions of ozone-depleting substances (ODS)	On this report p.95, p.97, p.106
G4-EN21	NOX, SOX, and other significant air emissions	On this report p.95, p.97, p.106
MATERIAL ASPECT: EFFLUENTS AND WASTE		
G4-DMA	Generic Disclosures on Management Approach	On this report p.84, p.89, p.95, p.97 Chapter 4 French Registration Document 2015 – Section 4.2.3 – Environmental information (3.A.a Water consumption and 3.A.b Water supplies and local constraints)
G4-EN22	Total water discharge by quality and destination	On this report p.87, p.91, p.92, p.106 Chapter 4 French Registration Document 2015 – Section 4.2.3 – Environmental information (3.A.a Water consumption and 3.A.b Water supplies and local constraints)
G4-EN23	Total weight of waste by type and disposal method	On this report p.84, p.95, p.96, p.97, p.106 Chapter 4 French Registration Document 2015 – Section 4.2.3 – Environmental information (3.C – Pollution and waste management)
G4-EN25	Weight of transported, imported, exported, or treated hazardous waste	On this report p.84, p.96, p.97 Chapter 4 French Registration Document 2015 – Section 4.2.3 – Environmental information (3.C – Pollution and waste management)
G4-EN26	Biodiversity value of water bodies affected by the organization's discharges	On this report p.89, p.106 Chapter 4 French Registration Document 2015 – Section 4.2.3 – Environmental information (3.D – Protecting Biodiversity)

OUR CSR PERFORMANCE

SPECIFIC STANDARD DISCLOSURES		
Profile disclosure	Disclosure	Location of the information
CATEGORY: ENVIRONMENTAL		
MATERIAL ASPECT: PRODUCTS AND SERVICES		
G4-DMA	Generic Disclosures on Management Approach	On this report p.89 , p.95
G4-EN27	Extent of impact mitigation of environmental impacts of products and services	On this report p.84 , p.87 , p.89 , p.91 , p.93 , p.95 , p.96 , p.97 , p.105 , p.106
G4-EN28	Percentage of products sold and their packaging materials that are reclaimed	On this report p.95 , p.96 , p.97
MATERIAL ASPECT: SUPPLIER ENVIRONMENTAL ASSESSMENT		
G4-DMA	Generic Disclosures on Management Approach	On this report p.57
G4-EN32	Percentage of new suppliers that were screened using environmental criteria	On this report p.57 , p.100
G4-EN33	Significant environmental impacts in the supply chain and actions taken	On this report p.57
CATEGORY: SOCIAL		
SUB-CATEGORY: LABOR PRACTICES AND DECENT WORK		
MATERIAL ASPECT: TRAINING AND EDUCATION		
G4-DMA	Generic Disclosures on Management Approach	On this report p.63
G4-LA9	Average hours of training per year per employee by gender, and by employee category	On this report p.67 , p.101
G4-LA10	Programs for skills management and lifelong learning	On this report p.63
G4-LA11	Percentage of employees receiving regular performance and career development reviews	On this report p.62
MATERIAL ASPECT: SUPPLIER ASSESSMENT FOR LABOR PRACTICES		
G4-DMA	Generic Disclosures on Management Approach	On this report p.57
G4-LA14	Percentage of new suppliers that were screened using labor practices criteria	On this report p.57 , p.100
G4-LA15	Significant impacts for labor practices in the supply chain and actions taken	On this report p.57
SUB-CATEGORY: HUMAN RIGHTS		
MATERIAL ASPECT: SUPPLIER HUMAN RIGHTS ASSESSMENT		
G4-DMA	Generic Disclosures on Management Approach	On this report p.11 , p.57 , p.89
G4-HR10	Percentage of new suppliers that were screened using human rights criteria	On this report p.57 , p.100
G4-HR11	Significant human rights impacts in the supply chain and actions taken	On this report p.11 , p.57 , p.89
SUB-CATEGORY: SOCIETY		
MATERIAL ASPECT: LOCAL COMMUNITIES		
G4-DMA	Generic Disclosures on Management Approach	On this report p.14 , p.17 , p.21 , p.22 , p.54 , p.73 , p.84 , p.89 , p.95
G4-SO1	Local community engagement, impact assessments, and development programs	On this report p.14 , p.17 , p.21 , p.22 , p.54 , p.73 , p.84 , p.89 , p.95 , p.99
G4-SO2	Operations with significant negative impacts on local communities	On this report p.92
MATERIAL ASPECT: ANTI-CORRUPTION		
G4-DMA	Generic Disclosures on Management Approach	On this report p.53 , p.58 , p.59 Form 20-F 2015 - Item 3
G4-SO4	Communication and training on anti-corruption policies and procedures	On this report p.58 , p.59 , p.100
G4-SO5	Confirmed incidents of corruption and actions taken	On this report p.58 Form 20-F 2015 - Item 8
MATERIAL ASPECT: PUBLIC POLICY		
G4-DMA	Generic Disclosures on Management Approach	On this report p.56
G4-SO6	Total value of political contributions by country and recipient/beneficiary	On this report p.56
MATERIAL ASPECT: ANTI-COMPETITIVE BEHAVIOR		
G4-DMA	Generic Disclosures on Management Approach	On this report p.59 Form 20-F 2015 - Item 8
G4-SO7	Number of legal actions for anti-competitive behavior, anti-trust,... and their outcomes	On this report p.59 Form 20-F 2015 - Item 8

Profile disclosure	Disclosure	Location of the information
MATERIAL ASPECT: COMPLIANCE		
G4-DMA	Generic Disclosures on Management Approach	Form 20-F 2015 - Item 8
G4-SO8	Significant fines and sanctions for non-compliance with laws and regulations	Form 20-F 2015 - Item 8
MATERIAL ASPECT: SUPPLIER ASSESSMENT FOR IMPACTS ON SOCIETY		
G4-DMA	Generic Disclosures on Management Approach	On this report p.57
G4-SO9	New suppliers that were screened using criteria for impacts on society	On this report p.57, p.100
G4-SO10	Significant negative impacts on society in the supply chain and actions taken	On this report p.57
SUB-CATEGORY: PRODUCT RESPONSIBILITY		
MATERIAL ASPECT: CUSTOMER HEALTH AND SAFETY		
G4-DMA	Generic Disclosures on Management Approach	On this report p.14, p.33, p.36, p.38, p.43, p.46, p.49
G4-PR1	Products for which health and safety impacts are assessed for improvement	On this report p.14, p.33, p.36, p.38, p.43, p.46, p.49, p.100
G4-PR2	Incidents of non-compliance on health and safety impacts of products	On this report p.43, p.46, p.49, p.100
MATERIAL ASPECT: PRODUCT AND SERVICE LABELING		
G4-DMA	Generic Disclosures on Management Approach	On this report p.39, p.55
G4-PR3	Product and service subject to information and labeling requirements	On this report p.33, p.39, p.54, p.55
G4-PR4	Non-compliance concerning product and service information and labeling	Form 20-F 2015 - Item 8
MATERIAL ASPECT: MARKETING COMMUNICATIONS		
G4-DMA	Generic Disclosures on Management Approach	On this report p.54 Form 20-F 2015 - Item 8
G4-PR7	Incidents of non-compliance concerning marketing communications	On this report p.54, p.55 Form 20-F 2015 - Item 8

REPORTING METHODOLOGY

How corporate social responsibility information is reported in CSR report: methodological note

G4-13 G4-18 G4-20 G4-21 G4-22 G4-23 G4-28

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 or administrative headquarters);
- Health and safety data (occupational accidents and injuries) are consolidated at the global level for all Group companies, including joint ventures and consolidated companies included in the Group's financial results; and
- Environmental data (including spending and investments) are consolidated for all industrial sites (the Fawdon site was not taken into account for reporting purposes due to the cessation of its activity in the second quarter of 2015) and research sites. The environmental impact measured as CO₂ emissions from all company vehicles includes all Pharmaceutical Operations affiliates. The environmental impact of administrative headquarters locations is not included within this scope.

CHANGES IN SCOPE

Within the Group, changes in scope (new sites, site closings, transfers of activity) between 2014 and 2015 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 formulas and emission factors. In addition, Sanofi has adopted standard data collection tools:

- Social data: As of 2015, Convergence (Sanofi's global HR data platform) covers almost all of Sanofi's workforce (97.3%). The platform was launched in 2011 to facilitate personnel management and process implementation, and to provide managers and employees with access to a wide array of HR information and tools. The Convergence data quality controls that were bolstered in 2013 were continued at the global level and within Group entities in 2014 and 2015;
- Safety data: The MSRS system was used to collect and consolidate safety data for Sanofi's entire scope in 2015; and

- Environmental data: The GREEN tool was used to consolidate all 2015 Sanofi data contained in the report. This tool and the guidelines are updated and improved on a regular basis. In particular, the Group carried out a hard close in 2015 for the indicators included in this report.

The reporting period for 2015 environmental indicators from 2015 begins October 1, 2014 and ends October 31, 2015.

Energy, greenhouse gas and water indicators are estimated for the last quarter of 2014 using average amounts based on real data from the first three quarters of 2014.

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;
- The practical methods used for data collection and entry; and
- The fact that HSE operating expenses are extracted from the GREEN reporting tool and entered by the HSE representatives for each site. 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 the home-workplace commute are not included in this indicator. However, they are included for medical sales representatives, in accordance with the reporting rules defined by the Group.

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

Total occupational injury frequency rate

Sanofi decided not to publish the severity rate calculated according to the criteria defined by French regulations. Because this rate is calculated solely on the basis of the number of days of lost time, it does not reflect the actual severity of injuries from an international standpoint.

In other words, for a given injury, the number of days of lost time may vary considerably from one country to another depending on the applicable regulations and compensation systems. As a result, Sanofi has decided to publish the total occupational injury frequency rate.

The total occupational injury frequency rate is defined as the number of occupational injuries with or without lost time, per million hours worked.

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

Environmental indicators are collected during an annual campaign. Indicators relating to energy and water consumption, however, are collected during quarterly campaigns.

CO₂ 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: Emission factors are obtained from the report entitled "CO₂ Emissions from Fuel Combustion 2015 – Highlights," published by the International Energy Agency (IEA). Emissions in 2015 were estimated on the basis of the most recent emission factors (end of 2013). For the preceding years, emissions for the year "Y" were calculated on the basis of the emission factor for the year "Y-2";
- Emissions in connection with the production of steam are calculated on the basis of site-specific factors or estimations set forth in the Group's standards; and
- Emissions from vehicles used by medical sales representatives are not included.

The reliable levels of the data and of the used methodology within the framework of the calculation of the indirect CO₂ emissions (scope 3) are described in details in the [CO₂ Emissions-Scope 3 factsheet](#) available in our download center.

Percentage of renewable electricity

The percentage of renewable electricity compared to total electricity purchased is calculated using real data when such information is specified in electricity supply contracts. In other cases, it is calculated on the basis of International Energy Agency (IEA) data.

Volatile Organic Compound emissions (VOCs)

VOCs are estimated on the basis of mass balance. The classification of volatile organic compounds is based on EU regulations.

Following the action plan implemented by the HSE Department to analyze VOC emissions and the modification to the 2015 reporting period, reported VOC values correspond to values from the 2014 calendar year for 66 sites that used more than five tons of solvents during the year 2014 (the Ocoyoacac site [solid form products] and the Toronto site,

not significant, were not included). The information was collected using a dedicated questionnaire.

Wastewater discharge

The data presented correspond to effluents after internal and/or external treatment. In the absence of information on external treatment, a purification rate of 50% is assumed for the COD.

For sites using solvents, we proceeded from the assumption that the volume of solvent present in the effluents could not exceed 5% of the total volume of solvent used.

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 soil remediation operations is not included in the published operational total. Recovery refers to recycling and incineration with energy recovery.

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 year. Employees under contract are measured in terms of headcount, irrespective of hours worked or their date of hiring during the month.

Worldwide new hires and departures

New hires do not include movements within the Group, such as international, inter-company or inter-site transfers.

Departures do not include movements within the Group, such as international, inter-company or inter-site transfers.

For 2015, we applied a specific methodology to exclude all intra-Group movements. Moreover, we took steps to enhance the reliability of movement-related data from the Convergence platform. Data on movements (new hires and departures), rate of internal candidates for executive vacancies of the Top 400, and rate of employees were engaged in our global performance and development planning process, cover more than 97% of the scope of reporting. They do not include companies that were consolidated or acquired during the year or movements relating to companies not included in Convergence, for which data on new hires and departures are not collected.

Fixed-term contracts that were converted into permanent contracts were not taken into account for either new hires or departures.

Lowest average wages

In 2015, the average of the lowest 15% of wages was compared to the minimum wage provided for by law or collective agreement in five countries that are representative of the diverse locations of Sanofi's worldwide sites (Brazil, China, France, Germany and the United States).

Data on wages were specifically extracted from

Sanofi's payroll systems in the countries in question. Gross annual base pay excludes variable compensation (collective and individual), team bonuses and exceptional bonuses paid in addition to wages. In France, average wages were calculated solely on the basis of wages paid under permanent contracts. Additional methodological information on the components of compensation that were taken into account for calculations and the minimum wages applicable in the different countries is available from Sanofi upon request.

Absenteeism

Days of absence correspond to the length of absences, expressed as a number of business days, recorded by each human resources system in five major countries (Brazil, China, France, Germany and the United States) in accordance with local regulations. The length of absence beyond which employees are considered "inactive" instead of "absent" thus varies from one country to the next. In 2014, in addition to France, the Group decided to add four major countries that account for a large portion of the workforce. The scope of this indicator includes actively working permanent employees but excludes temporary staff, interns, apprentices, summer job staff and inactive employees. Absenteeism data do not include absences authorized by the company: paid leave, holidays, unpaid leave, parental leave, sabbatical leave, business creation leave, leave for family-related responsibilities and unworked notice periods.

Social dialogue

Social dialogue data are provided by the human resources departments in each of five major countries (Brazil, China, France, Germany and the United States). Collective bargaining agreements are defined as those that have been signed by the company itself or the employers' organizations to which it belongs. Where a specific agreement has been signed by several sites or entities, it is taken into account only once.

Hours of training

Reporting on hours of training was introduced in 2014 in four of the five major countries where the Group operates (Brazil, China, Germany and the United States), representing 59% of employees worldwide (including France, which has a special reporting mechanism; see below). Because this reporting is based solely on data recorded in local databases, the relevant indicator may be underestimated.

Data on hours of training collected for reporting purposes correspond to:

- Mandatory training, particularly regulated training; and
- Training organized by Sanofi (in-person or e-learning training) and provided by in-house or external trainers.

In Brazil, China, Germany and the United States, quantitative training data (total number of hours provided) are consolidated on the basis of reports from each Sanofi entity in each of these countries, with the exception of Brazil where Animal Health activities are excluded.

In France, quantitative training data (number of hours of training and number of participants in 2015) are consolidated on the basis of reports from each Group company (including Merial and Genzyme). In the future, reporting on training will be enhanced through the use of a tracking and reporting tool shared across all Group companies in France. The number of participants was estimated.

Percentage of women in the Top 400

The Top 400 are defined as senior executive and management positions considered to be essential for business continuity and workforce planning at the global level. These positions are identified by the heads of global operations and the human resources departments of the relevant divisions, and the corresponding data are entered in the Convergence platform. Managers are defined as individuals with one or more direct subordinates.

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, environmental impact is either attributed to the one with the greatest impact or 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 accordance with the provisions of the French "Grenelle II" decree of April 24, 2012 and the French Ministerial order of May 13, 2013 on the verification of CSR data, Sanofi has designated one of its statutory auditors as the independent third party (Organisme Tiers Indépendant, or OTI) responsible for verifying the disclosure and fair presentation of its CSR information. The OTI's statement certifying the disclosure and fair presentation of CSR information, included in Section 4.5 of our Document de Référence, details the work carried out by the OTI, as well as its comments and conclusions.

STATUTORY AUDITORS' REPORT

G4-33

Limited assurance report by one of the Statutory Auditors on a selection of labor, environmental and social information included in the CSR report.

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

For the year ended December 31, 2015

To the Chief Executive Officer,

In compliance with the assignment entrusted to us and in our capacity as Statutory Auditor of Sanofi, we have performed a review allowing us to express limited assurance on a selection of labor, environmental and social information (hereafter referred to as the "CSR Information") included in Sanofi's CSR report for the year ended December 31, 2015.

The CSR Information selected by Sanofi and subject to our review is listed in the appendix to this report. The CSR Information was prepared under the responsibility of Sanofi's CSR Excellence Department in accordance with the guidelines used by the Company (hereinafter the "Guidelines").

Our responsibility is to express a limited assurance conclusion on the selected CSR Information based on our review. Our findings set out below relate to the selected CSR Information and not to all the CSR information contained in the CSR report.

Nature and scope of the work

We performed our work in accordance with the French professional auditing standards related to labor and environmental information falling within the scope of procedures directly related to the statutory audit engagement (NEP 9090) and with ISAE 3000⁽¹⁾.

We performed the procedures set out below to obtain limited assurance that the selected CSR information, taken as whole, is, in all material aspects, fairly presented in accordance with the Guidelines.

At Group level:

- we assessed the suitability of the Guidelines in terms of their relevance, completeness, reliability, impartiality and comprehensibility, and taking into account best practices where appropriate;
- we verified that a data collection, compilation, processing and control procedure has been implemented to ensure the completeness and consistency of the CSR Information and reviewed the internal control and risk management procedures used to prepare this information.

At the level of the selected entities:

- we conducted interviews with the persons responsible for preparing the data to ensure that procedures are followed correctly;
- we performed tests of detail, using sampling techniques, in order to verify the calculations made and

reconcile the data with the supporting documents. The samples selected therefore represented on average 34% of the headcount and 25% of the quantitative environmental data tested.

We were assisted in our work by our specialists in corporate social responsibility.

Conclusion

Based on our work, nothing has come to our attention that causes us to believe that the selected CSR Information was not prepared, in all material respects, in accordance with Sanofi's Guidelines applicable in 2015.

Neully-sur-Seine, May 4th, 2016

One of the Statutory Auditors
PricewaterhouseCoopers Audit:

Philippe Vogt
Partner

Sylvain Lambert
Sustainable Development partner

Appendix – List of CSR information selected by Sanofi and covered by our limited assurance report

- Labor Information:**
- total headcount and breakdown by activity, age, gender, seniority in the Group and geographic area;
 - number of new hires and departures;
 - number of training hours in France, the US, Germany, Brazil and China;
 - percentage of women in the Top 400;
 - lost time injury frequency rate worldwide (Sanofi and subcontractors);
 - total accident frequency rate;
 - 2015 internal recruitment rate to vacant positions (Top 400);
 - share of employees engaged in the global performance and development planning process;
 - health and safety conditions in the workplace;
 - respect of ILO conventions;
 - implementation of human rights policies.

Environmental information

- air emissions (COV, SOx and NOx);
- wastewater discharge (COD);
- total quantities of hazardous and non-hazardous waste;
- total water consumption;
- environmental policy;
- total energy consumption;
- direct and indirect greenhouse gas emissions (scopes 1, 2 and 3);
- percentage of products found in effluents of industrial sites having been assigned an environmental target value;
- percentage of chemical sites manufacturing active ingredients for which effluents have been reviewed against a list of 30 chemicals that was defined based on environmental hazard criteria;
- number of drugs on the market for which a voluntary environmental toxicity assessment has been completed.

Social Information (relating to commitments to promote sustainability)

- Access to Healthcare :
Partnerships and alliances formed by the Group:
 - diabetes: KIDS program: number of schools and children, and number of teachers involved in the program; AllStar® program: number of pens distributed and new countries where AllStar® was launched;
 - malaria: School children against Malaria program and partnership with Drugs for Neglected Diseases initiative (DNDi) foundation on the development of ArteSunate AmodiaQuine Winthrop®;
 - polio: partnership with the Bill & Melinda Gates foundation on the supply of inactivated polio vaccines; dosage/number of vaccinated children;
 - dengue: development of the dengue vaccine;

Indicators related to programs promoting access to healthcare:

- number of patients treated;
 - number of persons aware of these programs;
 - number of trained professionals.
- Responsible procurement:
 - procurement risk assessment process;
 - share of purchases from SMEs among the total purchases of Sanofi France;
 - number of buyers trained to use the Responsible Procurement Platform;
 - share of CSR-evaluated suppliers;
 - share of suppliers who met Sanofi's CSR requirements.

- Patient health and safety:
 - number of internal quality audits by business sector;
 - number of audits of API suppliers by geographical area;
 - number of audits of subcontractors by geographical area;
 - convergence of all pharmacovigilance systems into the Application for Worldwide Adverse Reaction Evaluation (AWARE);
 - implementation of methods to assess contents of digital media.

- Ethics in R&D:
 - number of inspections by regulatory health authorities by geographical area;
 - governance put in place by the Bioethics Committee;
 - number of clinical trial internal audits;
 - number of clinical trials conducted in 2015 by business sector and geographical area;
 - number of persons participating in clinical trials in 2015.

- Business ethics:
 - review of Group policies on anti-corruption, conflict of interest and data privacy.

(1) ISAE 3000: Assurance engagements other than audits or reviews of historical financial information

FORWARD-LOOKING STATEMENTS

This 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 labelling 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, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment initiatives 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, 2015. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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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.

