2015 CORPORATE SOCIAL RESPONSIBILITY REPORT
PARTNERING TO PROMOTE ACCESS TO HEALTHCARE
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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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.theirc.org
INNOVATIVE HEALTHCARE SOLUTIONS

6 MAJOR LAUNCHES

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

More than 100 INDUSTRIAL SITES ACROSS THE GLOBE

2015 GEOGRAPHIC BREAKDOWN OF SALES

EUROPE
- 41 Manufacturing sites
- 4 Development centers
- 33 Distribution hubs

AMERICA
- 17 Manufacturing sites
- 2 Development centers
- 8 Distribution hubs

ASIA
- 15 Manufacturing sites
- 3 Development centers
- 30 Distribution hubs

AFRICA MIDDLE EAST & SOUTH ASIA
- 16 Manufacturing sites
- 2 Development centers
- 58 Distribution hubs

LATIN AMERICA
- 11 Manufacturing sites
- 3 Development centers
- 30 Distribution hubs

THE NORTH
- 37 Manufacturing sites
- 2 Development centers
- 8 Distribution hubs

NORTH AMERICA
- 32.4% Emerging markets
- 36.2% Western Europe
- 9.7% Rest of the World
- 21.7% USA

2015 KEY RESEARCH & DEVELOPMENT FIGURES

More than 45 MOLECULES AND VACCINES IN THE DEVELOPMENT PORTFOLIO (16 in Phase III or currently registrating)

14% OF SALES INVESTED IN R&D
Increasing annual R&D investments up to €8bn by 2020

More than 16,000 R&D EMPLOYEES

MORE THAN 100 INDUSTRIAL SITES ACROSS THE GLOBE
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

GLOBAL BUSINESS UNITS*

*DIEBETES & CARDIOVASCULAR

GENERAL MEDICINES & EMERGING MARKETS
- Consumer healthcare
- Generics

SANOFI PASTEUR
- Vaccines

SANOFI GENZYME
- Rare diseases
- Multiple sclerosis
- Oncology
- Immunology

MERIAL
- Animal health

*This new organization has been effective since January 1, 2016.
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.

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

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. II - III).

RELATED CONTENT in this report

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

MORE in our Download Center

- Materiality Analysis factsheet
- Updating our Materiality Analysis factsheet

G4-18 G4-19 G4-20 G4-21 G4-27
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.

**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.

**TAX POLICY**

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. 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 €2.187 billion. The effective tax rate based on our business net income was 23.0% in 2015.

**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**
  - USA: 15%
  - Western Europe: 42%
  - Other countries: 1%

The long history of Sanofi reveals 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 sites and more than half our Research and Development sites are located in Western Europe.

**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 department 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 Organisation for Economic Co-operation and Development (OECD) and country-specific rules.

**RELATED LINKS**

- **INTERNATIONAL MULTIJURISDICTIONAL TAX ENVIRONMENT**
- **MULTINATIONAL ORGANIZATION**
- **TAX POLICY**

**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 of 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.

**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.

**OUR CSR PERFORMANCE**

- **PLANT**
- **PEOPLE**
- **ETHICS"PEOPLE"
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.

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Build CSR awareness among employees worldwide</td>
<td>Mergers and acquisitions completed</td>
<td>Completed</td>
</tr>
<tr>
<td>Integrate human rights into our operations</td>
<td>Local implementation of materiality: • Local materiality toolkit finalized</td>
<td>Completed</td>
</tr>
<tr>
<td>OUR CSR APPROACH</td>
<td>Role out of the materiality test in 4 pilot countries: Japan, Canada, Germany and Brazil</td>
<td>Completed</td>
</tr>
<tr>
<td>CSR quick newsletter distributed to 1200 external stakeholders and published on sanofi.com</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR training</td>
<td>Human rights training sessions held for senior managers and internal auditors (147 trained since 2010)</td>
<td>On track</td>
</tr>
<tr>
<td>CSR monthly newsletter sent to more than 600 internal stakeholders</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR eg-learning module shared with all CSR correspondents in countries and functions</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>Face-to-face CSR training program developed for CSR correspondents</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>Local implementation of materiality: • Local materiality toolkit finalized</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>Materiality findings implemented</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>Gap analysis of our human rights approach against the requirements of the UN Guiding Principles</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>Profile developed for continuous improvement in identifying, preventing and mitigating human rights risks</td>
<td></td>
<td>On track</td>
</tr>
<tr>
<td>Internal CSR collaborative platform with CSR blog developed: 150 country initiatives posted in 2015</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR quarterly newsletter distributed to 1,200 external stakeholders and</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR report, the program was well received</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR training</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>CSR training</td>
<td></td>
<td>Completed</td>
</tr>
<tr>
<td>2016 CSR Awards Challenge launched across functions and countries</td>
<td></td>
<td>Completed</td>
</tr>
</tbody>
</table>

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 to train 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.

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 Merial. It coordinates the implementation of our CSR strategy across all business activities.

CSR NETWORKS

- PLANET, 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
- ETHICS, with a special prize for the 3Rs replacement, reduction and refinement of the use of animals in research, development, testing and production;

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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.

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:

- PEOPLE, with a special Diversity prize;
- ETHICS, with a special prize for the 3Rs replacement, reduction and refinement of the use of animals in research, development, testing and production;
- 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.

SOME OF OUR AFFILIATES PRODUCED THEIR OWN CSR PUBLICATION IN 2015

- Brochure, Canada, Japan, Egypt
- Report, China, Brazil, Germany, Spain, Russia

MATERIALITY FINDINGS IMPLEMENTED

Priorities determined for continuous improvement in identifying, preventing and mitigating environmental, social and ethical risks.

We have published our Materiality Analysis factsheet 2013-2014.

CSR training

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**STAKEHOLDER ENGAGEMENT**

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**OUR CSR APPROACH**

**STAKEHOLDER ENGAGEMENT**

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**WHY ARE STAKEHOLDER RELATIONS IMPORTANT?**

Stakeholder engagement is based on an ongoing dialogue that embraces all 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.

**STAKEHOLDER ENGAGEMENT AT THE LOCAL LEVEL**

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 was established in 2012. Since 2012, Sanofi has established a forum for ongoing dialogue with our stakeholders in France. The Sanofi 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 medicines and our business units, Sanofi Pasteur, Merial and Genzyme.

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**HUMAN RIGHTS LENS**

**Right to health**

- Rights to benefit from scientific progress

**Ethics**

- Ethics in R&D

**People**

- People Development

**Environment**

- Environment

**CSR**

- Carbon footprint

**Waste**

- Waste management

**Business Ethics**

- Business ethics

**Right to information**

- Right to information

**Right to privacy**

- Right to privacy

**Right to work**

- Right to work

**Right to an environment that is not only favorable working conditions**

Targeted actions help Sanofi avoid causing adverse impacts on patients, employees, clinical trial participants, local communities or the general public. Our aim is to protect their interests wherever possible, within the limits of our resources and influence.
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 Scleroses, Oncology, Immunology and Consumer Healthcare), and explore strategic options (Animal Health and Genetics 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 endemic 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 Lixisn® (the bispecifical insulin glargine aspart association project). Second, we are also strengthening our market position in rheumatoid arthritis with April® 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. Withsatulimumab and dupilumab, developed in partnership with Regeneron, we have the cornerstone of an important new franchise in immunology. Takisulin will also 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 roadmap through 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®, PalesCourier® and Dphans®) and submitted three dossiers for regulatory review. Lixisn® (U.S.), satlumab (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 (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.

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**OUR CSR APPROACH**

**POLICIES & MANAGEMENT SYSTEMS**

**OUR FRAMEWORK**

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**

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 and internal audits to monitor compliance and drive continuous improvement. The table provides more details on the management systems that are important to 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 shareholder landscape and new stakeholder expectations, and the business model's shift towards biotechnology.

**RISK MANAGEMENT GOVERNANCE**

The Group Risk Committee assists the Executive Committee in identifying, assessing and monitoring the risks and opportunities that are part of the risk management network led by the Risk Management Team.

**OPERATING CYCLE OF OUR MANAGEMENT SYSTEMS**

- **IMPROVE**
  - Remediation, adjustments, corrections, etc.
- **DEFINE**
  - Policies, codes, charters, directives, guidelines, etc.
- **CONTROL**
  - Surveillance programs, quality controls, audits
- **DEPLOY**
  - Awareness and training programs

**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, testing, monitoring and reporting internal and external risks and opportunities. The 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 the 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 containing risks and to members of the Risk Committee to allow decision making.

The following 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.

**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.

**RISKS RELATING TO OUR BUSINESS**

- The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.

**RISKS RELATING TO THE GROUP STRUCTURE AND STRATEGY**

- We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.

**ENVIRONMENTAL ISSUES OF OUR INDUSTRIAL ACTIVITIES**

- Risks from the handling of hazardous materials could adversely affect our business, results of operations and financial condition.

**RISKS RELATING TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

- The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.

**OUR INDUSTRIAL ACTIVITIES**

- Risks from the handling of hazardous materials could adversely affect our business, results of operations and financial condition.

**OUR FRAMEWORK**

<table>
<thead>
<tr>
<th>MANAGEMENT SYSTEM</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUALITY</td>
<td>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.</td>
</tr>
<tr>
<td>RISK</td>
<td>Protect the health and safety of all employees; develop safe industrial processes; limit the environmental impact of the Group’s activities.</td>
</tr>
<tr>
<td>ETHICS &amp; BUSINESS INTEGRITY</td>
<td>Develop processes to infill ethical values and clear standards of compliant behavior.</td>
</tr>
<tr>
<td>PHARMACOVIGILANCE</td>
<td>Seek to ensure patient safety by constantly evaluating and monitoring risks potentially associated with the use of our products; seek to monitor the benefit profile of our medicines and vaccines over their entire life cycle.</td>
</tr>
<tr>
<td>INTERNAL CONTROL &amp; INTERNAL AUDIT</td>
<td>Provide reasonable assurance to senior management about the level of control over operations, including efficiency and compliance with all internal and external requirements.</td>
</tr>
<tr>
<td>RISK MANAGEMENT</td>
<td>Foster a culture of risk management and assess cross-company risks that could impact the Group’s business strategy and values.</td>
</tr>
</tbody>
</table>

**RISKS RELATING TO OUR BUSINESS**

- A substantial share of the revenue and income of the Group continues to depend on the performance of certain flagship products.

**RISKS RELATING TO THE GROUP STRUCTURE AND STRATEGY**

- We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.

**ENVIRONMENTAL ISSUES OF OUR INDUSTRIAL ACTIVITIES**

- Risks from the handling of hazardous materials could adversely affect our business, results of operations and financial condition.
OUR CSR APPROACH

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 et la Mouvement des Entreprises de France (AFEP-MEDEF).

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 shares the CEO obtains on the 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 shares the CEO obtains on the roadshow campaigns; and

CORPORATE GOVERNANCE

In 2014 Patrick Kron’s appointment continued our policy of renewing the Board and brought additional industrial know-how and international awareness. The same year, the appointment of Rannine Brasier enhanced 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.

The appointment of Diane Souza and Thomas Sudhof 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 Sudhof, 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.

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

CSR RECOGNITIONS

OTHER LEADING GLOBAL CSR INDICES
- FTSE 4 Good
- Stoxx Global ESG Leaders Indices
- DJSI - EEM
dom in 2015. Sanofi was ranked among the top 3 CSR performers in the pharma sector by the rating agencies Vigeo and MSCI.

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 indices 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.

GLOBAL REPORTING INITIATIVE (GRI)
Since 2014, our CSR report has complied with the G4 guidelines of the Global Reporting Initiative and met the criteria for the “Core” application level.

WEBSITE
- Document de référence 2015 - section 1.2
- 2015 Annual Report on Form 20-F - Item 6
- Directors' Remuneration Report
- Employees
- 2015 CSR Awards - Received: French CSR Awards - Gold
- CSR Performance Index
- 2015 Sanofi Communication on Progress & Assessment 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.

منذ 2000، سنوفاً هو جزء مهم من إطار الإدارات المتقدمة في تعبير عن الأداء الاستدامة في مجال الرعاية الصحية، حيث شاركت سنوفا بلقب “أحسن 3 شركات في الصناعة”， كما شاكلت سنوفا تصنيف LS (المؤسسة القارية) ضمن قائمة Best Global Companies من الـ FTSE 4 Good’s في الدورة الثانية في عام 2015، حيث شاركت سنوفا بالمركز الأول في قطاع الصناعة، كما شاركت سنوفا في تقييم كلاسيك للدرجة ذهبية للتصنيف الاستدامة في عام 2015، كما شاركت سنوفا في تصنيف LS (المؤسسة القارية) ضمن قائمة Best Global Companies من الـ FTSE 4 Good’s في الدورة الثانية في عام 2015، حيث شاركت سنوفا بالمركز الأول في قطاع الصناعة، كما شاركت سنوفا في تصنيف كلاسيك للدرجة ذهبية للتصنيف الاستدامة في عام 2015، كما شاركت سنوفا في تصنيف LS (المؤسسة القارية) ضمن قائمة Best Global Companies من الـ FTSE 4 Good’s في الدورة الثانية في عام 2015، حيث شاركت سنوفا بالمركز الأول في قطاع الصناعة، كما شاركت سنوفا في تصنيف كلاسيك للدرجة ذهبية للتصنيف الاستدامة في عام 2015، كما شاركت سنوفا في تصنيف LS (المؤسسة القاري...
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 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.

Our Progress

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OUR PRESENCE AND IMPACT IN TERMS OF ACCESS TO HEALTHCARE</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Continue to include eligible beneficiaries in our Access to Healthcare programs</strong></td>
<td>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.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>Strengthen our presence in emerging markets by responding to local health needs through innovative programs</strong></td>
<td>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 comorbid 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.</td>
<td>On track</td>
</tr>
</tbody>
</table>

FIGHTING SPECIFIC DISEASES IN OUR AREAS OF EXPERTISE

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eliminate lymphatic filariasis by 2020 through collaboration with the Bill &amp; Melinda Gates Foundation and Eisai within the scope of the London Declaration on Neglected Tropical Diseases</strong></td>
<td>As per the terms of the collaboration: - Sanofi donated 120 million tablets of diethylcarbamazine (DEC) to the WHO in 2012 and 2013. - Eisai took over the production and provision of DEC tablets for the years to come.</td>
<td>Completed</td>
</tr>
<tr>
<td><strong>Eliminate sleeping sickness by 2020</strong></td>
<td>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 Initiative (DNDi) to develop new treatments, recruitment has been finalized for the Phase II/III trials of fexinidazole compound.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>Support the WHO’s target to reduce dengue mortality by 50% and morbidity by 25% by 2020</strong></td>
<td>After 20 years of R&amp;D, Sanofi Pasteur launched the first vaccine against dengue. Dengvaxia® was approved in Mexico, the Philippines and Brazil in 2015. See p.25.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>Support the Global Polio Eradication Initiative to eradicate polio by end 2018</strong></td>
<td>Through the price mechanism developed together with the Bill &amp; Melinda Gates Foundation, we provide significant quantities of inactivated polio vaccine (IPV) to Gavi countries for delivery in routine immunization. See p.27.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>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</strong></td>
<td>We extended our collaboration with Medicine for Malaria Venture (MMV) to jointly develop once single administration, fixed-dose combination therapy. We continue offering treatments of pricing designed to be affordable and raise awareness about prevention, diagnosis and appropriate treatment methods. See p.25.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>By 2030, contribute to reducing premature mortality from non-communicable diseases by 1/3 through prevention and treatment; promote mental health and well-being</strong></td>
<td>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.25.</td>
<td>On track</td>
</tr>
</tbody>
</table>
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, we aim 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, quality care and patient support.

**OUR INTEGRATED APPROACH CREATES VALUE FOR BOTH OUR STAKEHOLDERS AND SANOFI**

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 in 2015, 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 disease management program, for optimal benefit/risk ratio. Responsible roll-out in patient-centered solution.

**OUR CSR PERFORMANCE**

<table>
<thead>
<tr>
<th>VALUE FOR STAKEHOLDERS</th>
<th>VALUE FOR SANOFI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INNOVATION</strong></td>
<td></td>
</tr>
<tr>
<td>• Fulfill unmet medical needs</td>
<td>• Develop innovative culture and portfolio</td>
</tr>
<tr>
<td>• Focused products offering to meet local conditions</td>
<td>• Control R&amp;D costs and complexity</td>
</tr>
<tr>
<td>• Develop local R&amp;D capabilities</td>
<td>• Foster collaboration to foster innovation</td>
</tr>
<tr>
<td><strong>AVAILABILITY</strong></td>
<td></td>
</tr>
<tr>
<td>• Increase number of patients treated</td>
<td>• Increase number of patients treated</td>
</tr>
<tr>
<td>• Production and distribution centers in developing/emerging countries</td>
<td>• Enhance full production capacity</td>
</tr>
<tr>
<td>• Local manufacturing and supply chain to the highest quality standards</td>
<td>• Facilitate access to new markets</td>
</tr>
<tr>
<td><strong>AFFORDABILITY</strong></td>
<td></td>
</tr>
<tr>
<td>• Increase number of patients treated</td>
<td>• Increase number of patients treated</td>
</tr>
<tr>
<td>• Differentiated pricing where appropriate</td>
<td>• Develop relations with authorities and other players</td>
</tr>
<tr>
<td>• Offer includes generics</td>
<td>• Improve license to operate</td>
</tr>
<tr>
<td>• Decrease financial burden on healthcare systems</td>
<td></td>
</tr>
<tr>
<td>• Contribution toward universal health coverage</td>
<td></td>
</tr>
<tr>
<td><strong>QUALITY CARE AND PATIENT SUPPORT</strong></td>
<td></td>
</tr>
<tr>
<td>• Raise awareness about disease</td>
<td>• Collaborate with health authorities, physicians and patient associations</td>
</tr>
<tr>
<td>• Training of healthcare professional</td>
<td>• Improve usage of medicines for optimal benefit/risk ratio</td>
</tr>
<tr>
<td>• Improve health literacy and patient empowerment</td>
<td>• Foster innovation roll-out in patient-centered solution</td>
</tr>
<tr>
<td>• Improve disease management</td>
<td></td>
</tr>
</tbody>
</table>

**SUPPORTING LONG-TERM EFFORTS TO IMPROVE GLOBAL HEALTH**

**Facts and figures**

- Number of disease deaths\(^1\) in the WHO top 20 list for which we have products or R&D (excluding our generic portfolio)
- \(^1\)Data reflect data from the WHO Global Health Estimates (GHE) 2014, deaths by age, sex and cause.
- \(^2\) As defined by the WHO.

**Supporting long-term efforts to improve global health**

**Facts and figures**

- Number of neglected Tropical Diseases\(^1\) (NTDs) for which we have products or R&D
- \(^1\)Data reflect data from 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 50 

**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
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 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; 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.

**Facts and figures**

**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 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 authorization. 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.

**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 of 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...
partnership began in 2004 under the lead-ership 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 biotechnology 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 3.4 million 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 Artemisinin Amodiaquine Winthrop® (AAW) 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.

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 sustainable changing behavior. 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.

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 actively for young people worldwide. We have contributed U.S.$5.75 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 Institute 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 govern-ments. 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, RUBELLA (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, mostly among African children. In 2015 alone, we provided more than 50 million treatments of AAW Winthrop®. To date, around 400 million treatments have been delivered.

Within the scope of “Schoolchildren Against Malaria”, in Nigeria 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.

With “Schoolchildren Against Malaria”.

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 your yellow fever vac-cine 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 vaccine training program by co-funding a similar program in Nigeria and.

Sanofi Pasteur has worked with global partners to facilitate the affordability and opti-mal use of inactivated polio vaccines (IPV).

Through the price mechanism developed together with the Bill & Melinda Gates Foun-dation, we provide significant quantities of IPV to Gavi countries for delivery in routine immunization. In November 2015, we announced the shipment of Shanchol®, a new injectable, inactivated polio vaccine manufactured by our affiliate Shantha Bio-technics in Hyderabad, India. The first vac-cine 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 vac-cine 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 Infections Disease Research Institute (IDRI), a United States-based non-profit institute with a focus on developing new products to combat the world’s most devastating infectious diseases. This project is also supported by a 10-year 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 leverages the resources and expertise of this external R&D innovation center and obtains access to IDRI’s adversaries and vaccine antigens.

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 542 million people with diabetes by 2040. Sanofi strives to help people manage the complex challenge of diabetes by delivering innovative, integrated and personalized solutions. By involv-ing in collaboration, Sanofi pioneers sustain-able solutions designed to provide compre-hensive 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. Sanofi funds the T1D³s registry study, the largest world-wide observational study assessing Type 1 diabetes management and the population characteristics of nearly 6,000 young people aged 8 to 25 with Type 1 diabetes. This study aims to better understand the characteristics faced by these young people. Sanofi has collaborat-ed with more than 100 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. T1D³s provides a unique opportunity to lay the groundwork for imple-menting recommendations to enhance care and patient outcomes by focusing on multi-faceted 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 76,000 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 Endocrinological Scientific Center in Russia launched the largest-ever epidemiological study of Type 2 diabetes prevalence among Russian adults. On the basis of such 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 2013 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 Heathly, 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 aims 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 for targeting different segments of the population. Sanofi is involved in “M-Diabetes,” 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 “M-illmannad” campaign reached more than 10,000 people in 30 areas around the world, compared to the pilot year, with an observed impact on eating habits. The “M-illmannad” 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 of Salisbury 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 improve 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 140,000 children have Type 1 diabetes. Sanofi launched the “Kids and Diabetes in Schools” (KIDS) program in India in 2013 and China in 2014 in collaboration with the International Diabetes Federation, the International Society for Pediatric and Adolescent Diabetes and local entities. KIDS is designed 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 to create a diabetes-friendly school. The initial results of the second campaign were presented during the World Diabetes Congress in December 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 60% of them in low- and middle-income countries. About three fourths of people with epilepsy in these countries do not get the treatment they need. 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.

In Madagascar, Sanofi has joined with the Ministry of Public Health and WASH 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 people with violent behavior are planned as part of this 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.
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 mor-
tality, the Foundation put in place a unique initiative, “Midwives for Life,” aimed at combat-
ing 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, includ-
ing six pilot projects in Asia (Myanmar, Cam-
bodia, Laos, Vietnam, Malaysia and Thailand),
and five in Africa (Senegal/Ivory Coast, Tansania,
and the Democratic Republic of Congo, South
Africa).

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” pro-
t program has been developed by the Founda-
tion since 2016 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 capac-
ity of local teams deployed in collaboration
with the St Jude’s Children’s Research Hospital,
the International Society of Pediatric Oncol-
ogy, the Union for International Cancer Con-
trol, the French-African Pediatric Oncology
Group (GPAOP), Childhood Cancer Interna-
tional 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 soci-
ety 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 multi-
plied by four.

GENZYME: TREATING PATIENTS WITH RARE DISEASES

More than 650 patients are currently receiv-
ing free therapy through Genzyme Human-
itarian Programs and more than 1,700 patients
in 70 countries have received free therapy
since these programs were introduced. Today
Genzyme Humanitarian Programs are meet-
ing the needs of eligible patients on six con-
tinents and include the International Char-
table 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 imple-
ment the Ghahteur 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, representa-
tives from Project HOPE, Sanofi Genzyme, the
Egyptian medical community and physicians
from the Medical Expert Committee of the
Ghahteur Initiative gathered in Dubai to cel-
brate 15 years of successful, shared com-
mmitment 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 pro-
gram has helped build the capacity of the
Egyptian health system to properly diagnose,
treat and manage Gaucher disease patients,
and has contributed to worldwide under-
standing of the disease.

ANIMAL HEALTH AND THE “ONE HEALTH” CONCEPT

Animal health and human health are closely
tied together. The “One Health” concept rec-
ognizes that the health of humans is con-
ected to the health of animals and the
environment.

Sanofi’s animal health division, is leading the “Zoonoses® Anticipation and Prepara-
edness Initiative” (ZAPI) program, which started in March 2015. ZAPI is the first
“One Health” project supported by the Euro-
pean Union as part of the Innovative Med-
icine Initiative public-private partnership.

ZAPI’s five-year project involving 20 entit-
ies from six countries, including three industrial
enterprises. The project team shape to design
new R&D and manufacturing processes with
the aim of producing vaccines and neutral-
izing agents against zoonotic diseases in
less than six months, in the event of an emer-
gency. 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 Syn-
drome Coronavirus (MERS-CoV). The new
R&D and manufacturing processes are designed
to should be applicable to pre-
venting an outbreak for both animal and human
health needs to address infectious diseases.
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.

Our Progress

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
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</thead>
<tbody>
<tr>
<td>Ensure that employees at all levels and in all positions understand and embrace the fundamentals of quality.</td>
<td>The quality fundamentals e-learning program was launched company-wide, and more than 82,000 people had been trained by the end of 2015.</td>
<td>On track</td>
</tr>
<tr>
<td>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.</td>
<td>A new inspection database has been implemented progressively by all entities; the CAPA module has been deployed in 89 manufacturing sites (77%).</td>
<td>On track</td>
</tr>
<tr>
<td>Continuously improve the oversight of pharmacovigilance data sources.</td>
<td>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.</td>
<td>On track</td>
</tr>
<tr>
<td>Ensure that all employees are aware of counterfeit risks so they can report any suspicious products.</td>
<td>More than 50 sites participated in the 2015 Anti-Counterfeit Day. E-learning modules (general and specific) were designed and launched.</td>
<td>On track</td>
</tr>
<tr>
<td>Improve sampling, analysis and data collection for counterfeit Sanofi products.</td>
<td>More than 30,000 entries have been recorded since 2008 by the Central Anti-Counterfeit Laboratory to analyze potential counterfeit products.</td>
<td>On track</td>
</tr>
</tbody>
</table>
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.

**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.

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**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.

**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 made to look identical to an authorized product. Counterfeiting can apply to both branded and generic products and can have severe health consequences. Counterfeit medicines can look identical to the genuine product, but can contain incorrect ingredients or with fake packaging. Counterfeiting can apply to both branded and generic products and can have severe health consequences.

**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).

**Sanofi’s Global Pharmacovigilance & Epidemiology (GPE) Department Process**

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.

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This process extends from the early detection of a potential safety signal to its submission to 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 increasing its ability to leverage data from our drug development programs, including real-world evidence from patients and healthcare professionals.

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 healthcare professionals.

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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.

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 these 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 is interconnected with the relevant Sanofi functions (e.g., Medical Affairs,4 Medical Affairs, Affairs, Medical Affairs, 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.

In addition, 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-related activities, and to ensure the integrity of the data we use and submit to the authorities.

Improving our internal quality performance: Internal quality audits, measurement quality reviews, management of complaints, recalls

In 2015, we continued to enhance our management of our 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 to 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 considering both the specific site characteristics and recent compliance performance. Following audits, corrective and preventive actions (CAPAs) are determined, documented, and communicated to the nature and severity of the audit findings. CAPAs are recorded in a specific quality management tool (CAPA Module, see “Our Progress, p.3”). In addition, we use a process for tracking and managing complaints.

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

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 and 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/performance of audits is defined for each entity, and an audit plan is established. The compliance risk score is specific to each type of entity, with manufacturing sites, marketing and distribution, 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 for a variety of reasons. Sanofi has an established recall process in place, covering all types of products and all phases of recall. This process decision-making process involving all relevant internal entities, transparent interaction with concerned authorities and rapid communication with patients, pharmacists, wholesalers and healthcare professionals), depending on the nature of the recall. In 2015, our rate of batches recalled1 for quality reasons was less than 0.34%, 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 ensues to fulfill full implementation. In 2015, Sanofi underwent 335 inspections worldwide, with no resulting regulatory action. Systematic trends and key success factors were discussed with the inspection team. A follow-up inspection is planned for the majority of the visits, with the first follow-up implementation starting in 2016.

The “Human Error Prevention” project

A Global Quality Strategic Project was conducted in 2015 of all manufacturing sites around the world to investigate the topic of human error. 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 captured in a detailed action plan, and a broad action plan was designed and implemented in 2016.
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.

Facts and figures

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 is 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 (CACL). 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.

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:
- 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.
- 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.

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 16% of respondents in Asia and 15% in the U.S. linked counterfeiting with pharmaceuticals. Consumers in Asia seem to be aware of the problem, yet 79% 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 risks associated with counterfeit medicines.

SANOFI’S ANTI-COUNTERFEIT LABORATORY

At the Sanofi Central Anti-Counterfeit Laboratory (CACL) in Tours, France, a dedicated team of specialists use 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 2005, the CACL 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.

Our Progress

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

The Sanofi Group recognizes the importance of defining, respecting, and continually reviewing and improving consistent and transparent ethical 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 procedures.

- 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 continuously assesses and appraises 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 to human and animal health and when the 3Rs principles (replacement, reduction, and refinement) are applied. Animals remain an integral part of our comprehensive research and strategy that includes non-animal methods (such as computational models and in vitro testing) and the use of real and simulating animal use as a part of many regulatory requirements. For example, testing vaccines before batch release requires mandatorily 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 in our research. Our approach is designed to use animals only when a non-animal method is not suitable for the required research (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, their use is carefully planned and monitored to ensure their welfare and minimize their suffering. Procedures are performed in accordance with regulations and involve minimal pain or distress.

**ETHICS COMMITTEE OVERSEES ANIMAL CARE AND USE**

Sanofi’s ethics committees oversee animal care and use in all five therapeutic areas. While regulatory and scientific merit is established, the ethics committees confirm that the results will contribute to the protection and improvement of human or animal health.

All research and testing protocols must be validated by the ethics committees, and their ratification is required for Sanofi to use animals for research, testing or production of medicinal products. 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 bistocitalitif 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 long-term commitment to the 3Rs, the policy applies to all animals used by Sanofi for research, testing or production of medicinal products, vaccines, vaccines, medical devices, veterinary products, nutraceuticals and active 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.

**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.

**YOU WANT TO KNOW?**

- **Reducing the number of animals necessary to ensure reliable, quality scientific results.**
- **Refining techniques to promote animal welfare and minimize pain and distress.**

**DID YOU KNOW?**

- **99% OF THE ANIMALS USED ARE RODENTS, RABBIT, AND POULTRY.**
- **20% OF THE ANIMALS ARE USED FOR RESEARCH.**
- **40% OF THE ANIMALS ARE USED BY OUR ANIMAL HEALTH DIVISION.**

**OUR CSR PERFORMANCE**

- **Planetary:**
  - Enhancements to our Ethics in Research program
  - Participation in the Global Alliance for Animal Health in Action (GAAH)
  - Development of a policy on animal protection

- **People:**
  - 39 horses have been rehomed thanks to this collaboration, and participants’ feedback has been very positive.

**MORE ONLINE**

- **Animal Protection factsheet**
- **BEINGS2015 website**
- **Animal Protection website**

**ANIMAL PROTECTION**

Through our R&D activities, Sanofi is committed to develop alternative test systems (such as in vitro testing) that are not only time consuming, labor intensive and heavily observer- and environment-dependent, but also may create stress for the animals. Moreover, results from behavioral and translational models are often inconclusive due to high variability, lack of reproducibility and limited validity for the investigated behavioral phenotypes.

To address these difficulties, we adopted a commercial solution known as the “OptiMan” system uses a fully-automated behavioral testing system for rats that combines these 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.

**BEINGS2015 symposium**

In our house animal science and welfare lab, mice is an ideal system for the broader Sanofi R&D community. In 2015, external experts, veterinarians and representatives of Sanofi’s 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 ethical methods (such as biomaking techniques) across Sanofi’s different therapeutic areas.

**Replacing animals used for plasma production**

In line with our commitment to animal welfare and the responsible use of animals, Sanofi seeks to find replacements for opportunities for animals 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 biomedicine 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 exceptional riding. To date, 39 horses have been rehomed thanks to this collaboration, and participants’ feedback has been very positive.
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 select 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.

**HOW DO CLINICAL TRIALS WORK?**

### PRECLINICAL RESEARCH

<table>
<thead>
<tr>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
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<tbody>
<tr>
<td>LABORATORY TESTS</td>
<td>OBJECTIVES</td>
<td>OBJECTIVES</td>
</tr>
<tr>
<td>Anatomoclinical</td>
<td>Determine the side effects associated with increasing doses</td>
<td>Determine short-term side effects</td>
</tr>
<tr>
<td>TESTS</td>
<td></td>
<td>Monitor side effects</td>
</tr>
<tr>
<td>APPROVED PROTOCOLS</td>
<td>CRITERIA</td>
<td>CRITERIA</td>
</tr>
<tr>
<td>Gain early evidence of efficacy</td>
<td>Evaluate efficacy against placebo or other treatment at optimal dose</td>
<td>Confirm efficacy against other possible treatments</td>
</tr>
<tr>
<td>ANIMAL TESTING</td>
<td>SUBJECTS</td>
<td>SUBJECTS</td>
</tr>
<tr>
<td>Healthy volunteers (30-180)</td>
<td>Patients (hundreds)</td>
<td>Patients (thousands)</td>
</tr>
</tbody>
</table>

### CLINICAL RESEARCH

<table>
<thead>
<tr>
<th>PHASE 4</th>
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<tbody>
<tr>
<td>FOLLOW-UP</td>
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<tr>
<td>OBJECTIVES</td>
</tr>
<tr>
<td>Phase II</td>
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<td>OBJECTIVES</td>
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<td>Phase III</td>
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<td>OBJECTIVES</td>
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<td>Phase IV</td>
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<td>OBJECTIVES</td>
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<tr>
<td>Phase V</td>
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</tbody>
</table>

**PHARMACEUTICALS**

**CLINICAL TRIALS 2015, SUBJECTS ENROLLED**

- **25,064 subjects**

**BY PHASE**

- Phase I: 9%
- Phase II & II: 64%
- Phase III: 42%
- Phase IV: 15%
- Phase V: 5%

**BY REGION**

- North America: 36%
- Europe: 40%
- Asia Pacific: 24%
- Latin America: 19%
- Africa & Middle East: 15%
The individual informed consent process is delicate. It is not just about signing participants in clinical trials. The study participants must be informed about the purpose of the research so that they can understand the information and be 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, that all study participants (patients and healthy subjects) are 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 enrolment 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.

7. Respect for potential and enrolled subjects

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 also is a healthcare provider, it is important that a patient not be confused or mislead by this fact, as a treating physician, but also as an investigator. Explaining the experimental nature of the proposed study and help ensure 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 case payment for free during the study but not under the local health system).
6. Study participants must be presented with the choice to withdraw from 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.
7. 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.
8. Measures in the case of an adverse event.
9. Participants' post-study access to the medicine or vaccine being tested, or alternative treatment.
10. Study interruption and withdrawal of consent.
11. Access to information before, during, and after the study.
12. 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, reasonable, 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 or 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 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 information

Compassionate access to Sanofi investigational products (2015)

ETHICS IN CLINICAL RESEARCH: OVERSIGHT OF CLINICAL TRIAL PRACTICES

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: ETS projects involves periodic operational checks within each functional department to make sure that clinical data are generated, collected, handled, analyzed and reported in line with requirements. The investigational site is monitored by a representative of Sanofi and representatives of the European regulatory authority. The site-specific constraints are met and all clinical data are submitted. If the site-specific constraints are met and all clinical data are submitted, the investigator is notified of any deviations.

• Quality assurance: In the event of serious deviations, the investigator is notified of any deviations. If the investigator is notified of any deviations.

Limiting the risk of misconduct

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 falsification, 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.

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, clinical trials sponsored by Sanofi (including Sanofi Pasteur) • 26 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/severe 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.
In 2015, Sanofi (including Sanofi Pasteur) conducted 218 audits for our clinical trials 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.

**Facts and figures**

**2015 CLINICAL TRIAL AUDITS**

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**CLINICAL TRIALS AUDITS*, 2015 BY TYPE**

- Investigator site audits: 142
- Other: 76
- Project: 2
- Other: 1

**CLINICAL TRIALS INVESTIGATOR SITE AUDITS*, 2015, BY REGION**

- Asia Pacific: 34%
- North America: 28%
- Europe: 19%
- Latin America: 14%
- Others: 10%

**INSPECTIONS BY REGULATORY HEALTH AUTHORITIES*, 2015, BY REGION**

- Americas: 48%
- Europe: 29%
- Asia Pacific: 15%
- Others: 8%

**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).

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**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 trials refer to trials to support dosing, 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 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 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 clinical trial 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.

**Facts and figures**

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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 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 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 clinical trial 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.
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.

**BUSINESS ETHICS**

**Our Progress**

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deploy a system (4M) for the review and approval of promotional and non-promotional materials</td>
<td>The project was launched in 2014 and deployment of the tool began in 2014.</td>
<td>On track</td>
</tr>
<tr>
<td></td>
<td>We started exploring the integration of 4M with other existing tools (such as digital materials).</td>
<td>In development</td>
</tr>
<tr>
<td>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</td>
<td>See Page 58 of the report.</td>
<td>Completed</td>
</tr>
<tr>
<td>Implement new transparency requirements in our relationships with healthcare professionals</td>
<td>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.</td>
<td>Completed</td>
</tr>
<tr>
<td>Deploy our ethical sourcing of promotional items on a worldwide basis</td>
<td>The solution was deployed in 26 countries across Europe, the US, Latin America (Argentina, Brazil, Chile, Colombia, Ecuador and Peru), and Asia (China, Hong Kong, Singapore and South Korea).</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td>The solution will be deployed in the remaining countries across Africa, the Middle East and Asia Pacific.</td>
<td>On track</td>
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</tbody>
</table>
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.

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.

SANOFI AG AND SANOFI-AVISÉE DIABETES EURL have implemented in-house policies governing our relations with healthcare professionals, including policies to prevent violations of internal rules. 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.

HEALTHCARE PROFESSIONALS
Relationships between 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, consulting 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 a 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
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 65,000 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 role-playing, the certification process assesses whether representatives possess the appropriate competences 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 the probationary period to ensure the company's expectations, and our active representatives must repeat the certification process on an annual basis.

Facts and figures

Sanofi in the regions

(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 (EC).
(2) The AMESA region encompasses Africa, the Middle East, Eurasia and South Asia.
(3) Arab States, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.
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. 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 or “Medical-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 whose 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 websites management

**SUPPLIERS AND PARTNERS**

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 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 MediDirect initiative was launched to address such risks, which are higher when distributors lack visibility and control over the manufacturers of promotional items. Today, the initiative is run through InnerWorkings and Scode, 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 MediDirect project was introduced in more than 40 countries, covering all our procurement regions worldwide.

**Suppliers’ Day organized in Asia**

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’ networks to meet Sanofi’s strategic and operational objectives while helping to ensure our ethics standards are upheld.

## Facts and figures

### ASSIGNED SUPPLIERS IN 2015, BY SEGMENT

<table>
<thead>
<tr>
<th>Segment</th>
<th>Number of Suppliers</th>
</tr>
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<tbody>
<tr>
<td>North America</td>
<td>190 suppliers</td>
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<tr>
<td>Europe</td>
<td>190 suppliers</td>
</tr>
<tr>
<td>Asia-Pacific</td>
<td>190 suppliers</td>
</tr>
<tr>
<td>Latin America</td>
<td>190 suppliers</td>
</tr>
<tr>
<td>Other regions</td>
<td>190 suppliers</td>
</tr>
</tbody>
</table>

**ASSIGNED SUPPLIERS IN 2015, BY PROCUREMENT ACTIVITY**

- Marketing and sales: communication agencies, events and media, market research, promotional items
- Common spend: food and travel, energy and waste, IT, real estate and site services, consulting, R&D and insurance
- Scientific and clinical: clinical laboratory equipment, research materials and subcontracting
- Manufacturing capital expenditure (CAPEX) and maintenance: buildings, manufacturing equipment, spare parts and industrial maintenance
- Cost of goods sold (COGS) and distribution: raw materials, packaging and devices, subcontracting, license and supply chain

**Suppliers Evaluation in 2015**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Suppliers Assessed</th>
<th>Number of Suppliers That Meet Our CSR Requirements</th>
<th>Number of Buyers Trained in the Responsible Procurement Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>45</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>2012</td>
<td>185</td>
<td>129</td>
<td>0</td>
</tr>
<tr>
<td>2013</td>
<td>188</td>
<td>103</td>
<td>0</td>
</tr>
<tr>
<td>2014</td>
<td>128</td>
<td>64</td>
<td>0</td>
</tr>
<tr>
<td>2015</td>
<td>190</td>
<td>115</td>
<td>120</td>
</tr>
</tbody>
</table>
Our Ethics & Business Integrity

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 150 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, provide risk assessment, prevention and investigation. The Head of the Ethics & Business Integrity Department and Global Compliance Office, who has direct access to the Group’s CEO, meets periodically with the Audit Committee and/or the Board of Directors and/or the Chief-Anti Fraud Officer in charge of supporting internal investigations. The Ethics & Business Integrity Department also runs a secured compliance helpline available 24/7 to all Sanofi employees.

Our commitment to preventing corruption is shaped by 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 wrongdoing, 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

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 integrity throughout the Group and beyond.

Policies to guide and support employees

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

- Anti-bribery;
- Gifts and remittance 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;
- Responsibility 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.

Mandatory employee training

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 on “principle-based decision making” with these 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.

E-learning on ethics and business integrity services and resources 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 to and personal information, communication, confidentiality and information security, understanding lobbying, donations and other contributions to organizations, and interactions with external stakeholders.

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.

Manditory training topics

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<tr>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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<tr>
<td>Fighting bribery and corruption</td>
<td>Prevention of conflicts of interest</td>
<td>Information security &amp; confidential propriety information</td>
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<tr>
<td>Anti-fraud</td>
<td>Financial fraud prevention</td>
<td>Ethical decision making and integrity</td>
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<tr>
<td>• Focus in the workplace</td>
<td>• E-mail: think before you click</td>
<td>• Interpersonal relations</td>
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<td>• Global financial fraud prevention</td>
<td>• Global financial fraud prevention</td>
<td>• Mediation</td>
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<tr>
<td>Communications</td>
<td>Ethical business and integrity</td>
<td>• Communication skills</td>
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<tr>
<td>• E-mail: think before you click</td>
<td>Ethical decision making and integrity</td>
<td>• Delegations and negotiations</td>
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<td>• Interpersonal relations</td>
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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.
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.”

Our Progress

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attract and retain talents</td>
<td>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.</td>
<td>On track</td>
</tr>
<tr>
<td>Develop employees’ capabilities at every level of the Sanofi Group</td>
<td>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.</td>
<td>In development</td>
</tr>
<tr>
<td>Assess and reward performance</td>
<td>52.2% (1) of employees were engaged in our global performance and development planning process.</td>
<td>On track</td>
</tr>
<tr>
<td>Build and diversity Career</td>
<td>We scaled up our “People Development Principles” to encourage a diversified career and maximize our employee’s potential and performance.</td>
<td>On track</td>
</tr>
<tr>
<td>Value and support diversity</td>
<td>“Good Morning Sanofi” videos made by employees: 11 released in 2015 and 16 more planned in 2016.</td>
<td>On track</td>
</tr>
</tbody>
</table>

(1) This percentage corresponds to 60,018 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.
Ensuring that every individual across the Group has a chance to develop is the key to building and sustaining the growth of our organization.

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

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.

A single HR system solution

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 define 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.

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

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 us 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 onboard 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)
Facts and figures

WHO ARE SANOFI’S FOLLOWERS

LinkedIn Performance

DID YOU KNOW?

Measuring LinkedIn Performance

LinkedIn Impacted 15% of Sanofi group new hires in 2015

Sanofi ranked at the top

Sanofi's learning centers and academies help employees develop their expertise and discover new ways of working. In 2015, we founded the first Sanofi Academies covering six areas: Legal, Finance, Human Resources, Information Systems, Procurement and R&D. 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, sales, and key skills and capabilities.

• 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, Market Access, and IT functions. By late 2015, the MAx Academy had conducted 48 training sessions for more than 850 employees.

DEVELOP AND GROW EMPLOYEES’ CAPABILITIES

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 expertise and develop their expertise for a positive impact on our performance and their own. Employees are strongly encouraged to take charge of defining their career path, where appropriate.

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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 education programs, such as leading 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 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, expected to deliver the design and functionality of a robust, flexible and scalable system in line with our business needs going forward. In early 2015, 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 equipping them to seize new opportunities. 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 the Corporate Open Online Course European initiative from around the world, earning visas along the way and encountering digital experts who provide in-depth information about selected concepts and practices.

**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, learning what is happening around the world.

**Assess and reward performance**

**Goals**

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**
  - **Begin-to-Near**
  - **Set expectations**
  - **Performance review**

- **Development**
  - **2** Individually developed

- **3** Work-end performance review

Ongoing dialogue makes the difference to developing your career!
How is performance assessed?
The annual performance and rewards review process provides a key opportunity for managers to talk to their managers, agree on performance and development goals, and determine how they have been accomplished. The performance review process gives the employee's contribution measured through individual and team achievements against pre-set objectives.

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 have been 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 market positioning. Compensation budgets are linked to business performance and market competition. 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.

Antonio Tatarnini, 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.

David Leve, 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? 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. 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? Could you share an example of feedback you once received?

Think Strategically
Think in plan broadly and long term to inspire excellence in execution

Act for Change
Influence change and take action and initiate new and innovative ways of working

Strive for Results
Drive ongoing improvement of performance quality, added value

Lead Teams
Build, manage, motivate and empower teams and workgroup

Develop People
Take responsibility for developing own self and others in anticipation of future business needs

Cooperate Transversally
Collaborate effectively with peers, stakeholders and partners across the organization to perform and achieve project’s goals

Make Decisions
Make data-driven decisions based on the information available

Commit to Customers
Understand, meet and exceed internal and external customer’s needs and expectations

Facts and figures

79.4% of executive vacancies of Top 400 were filled by internal candidates in 2015

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, acquire and mobilize key talents as a shared resource across the Group, and ultimately foster and drive our performance culture.
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 solutions to the workplace,” she says. Since September 2015, Niven was appointed General Manager of Sanofi Canada. She describes her new role as a success story that inspires her, saying: “Why wouldn’t I make it?” I feel extremely valued when I drive impact and bring solutions to the workplace, but I said to myself: “I’m going to drive there, but I said to myself: ‘Why wouldn’t I make it?’ I feel extremely valued when I drive impact and bring solutions to the workplace.”

**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 customers 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. “I 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 of France’s Festival de la Communication Santé. We received the Jury’s Coup de Cœur prize as well as an award for “Good Morning Sanofi” in the Capable Communication, Employee Brand & Information category.

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

**Cherry, Finance Director Vaccines (China)**

Cherry Lu 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.

**Yannick, Deputy Director Global Performance & Systems Sanofi Pasteur (Ivory Coast)**

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.

**Virginia, Chief of Staff**

Virginia’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.
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.
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

PRODUCTION IMPACTS
MORE in our Download Center
See our Planet factsheet:
- Protection of the Atmosphere
  - Circular Economy
  - Packaging
  - Biodiversity and Biosecurity
  - Green Chemistry
- Soil and Groundwater Protection

RELATED CONTENT in this report
- Page 79, Carbon footprint
- Page 85, Waste management
- Page 85, Water management

RAW MATERIALS IMPACTS
MORE in our Download Center
See our Planet factsheet:
- Biodiversity and Biosecurity
  - Circular Economy
  - Green Chemistry
  - Implementation of REACH Regulation

RELATED CONTENT in this report
- Page 85, Water management

Water consumption
- 14.8% reduction in Sanofi’s overall water withdrawal since 2010
- “B” score obtained on the 2015 CDP Water questionnaire

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

Promoting maritime transport
- 24% decrease in CO₂ emissions from 2010 to 2015 by using maritime transport
- 88% of our international shipments are by sea

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 85, 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).

Usage impacts
MORE in our Download Center
See our Planet factsheet:
- Disposal of Unused Medicines and User Recommendations

RELATED CONTENT in this report
- Page 85, 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.

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

“Aware that environmental issues are increasingly important, we are currently assigning 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.”
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.

Our Progress

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010-2020: Achieve a 20% reduction in the combined scope 1 and scope 2 CO2 emissions for industrial and R&amp;D sites, and sales force vehicles</td>
<td>In 2015, we achieved a 15.8% reduction in our scope 1 and scope 2 CO2 emissions compared to 2010.</td>
<td>On track</td>
</tr>
<tr>
<td>• We signed a new agreement with Suez Environnement.</td>
<td></td>
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<tr>
<td>• A waste-to-energy plant and a refrigeration unit were built at our Sisteron (France) site.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• We installed cogeneration units at our Cuggio (Italy) and Cologne (Germany) sites as well as a refrigeration unit at our Scoppito (Italy) site.</td>
<td></td>
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</tr>
<tr>
<td>• A total of 15 sites obtained ISO 50001 certification and 16 sites underwent energy audits.</td>
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<tr>
<td>• We implemented a carbon footprint approach for our Mestan® manufacturing process in Italy.</td>
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<tr>
<td>• We made efforts to improve our buildings’ environmental efficiency.</td>
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<tr>
<td>• We reduced CO2 emissions due to the transport of medicines, resulting in a 24% reduction since 2010 for pharmaceutical manufacturing sites.</td>
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<tr>
<td>• We encouraged employees to use car-pooling, electric cars and public transportation.</td>
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<tr>
<td>• We took steps to encourage the use of low carbon emitting cars by our medical sales force.</td>
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<tr>
<td>• We equipped more telepresence and video-teleconference rooms.</td>
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</table>

On track

2013: Publish scope 3 emissions

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.

Completed

RELATED CONTENT in this report

Page 24, Climate Change and Health Initiative, Patient section
# 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.  

As a global pharmaceutical company, we feel that we have a responsibility to reduce our carbon footprint and to contribute to decreasing a significant portion of the health sector’s footprint. Since 2013, to improve the energy efficiency of our facilities at our sites, specific partnerships were set up by our Global Industrial Affairs department in close collaboration with the energy sector leaders: Suez Environnement (France), Engie, etc.). 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 15.9% 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%).

### IMPROVING ENERGY EFFICIENCY AT OUR SITES

**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/Citylife 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 centered 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 waste 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.

### RELATED CONTENT in this report

- Page 43: Waste management
- Page 45: Water management
Cogenation and trigeneration units in Italy and Germany

In 2015, thanks to the Sanofi-Genzyme partnership and following initiatives carried out in Italy—at Anagni in 2014 and Birtisal in 2013—we invested about €10 million to set up two new cogenation units (combining heat and power) at our Cologne (Germany) and Origgio (Italy) sites. Also in Italy, we are building a trigeneration unit at the 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 16% 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 Sistoron site

Within the scope of the Sanofi-Genzyme partnership, we have begun installation of a central refrigeration unit at our Sistoron (France) site using the most advanced techniques. This 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 cogenation 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: Compiegne (France), Cairo (Egypt), Zanata (Morocco), Le Trait (France), Bucharest (Romania), Prague (Czech Republic), Gael (Belgium) and Csarnokvég (Hungary). Such certification attests to the efficiency of our sites’ energy management systems.

ON TARGET TO PROVIDE ROBUST SCOPE 3 CO2 EMISSIONS DATA

We are on target to provide a 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.

REDUCING OUR CARBON FOOTPRINT: THE MALAŁOCK 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

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 (Hauts Qualités Environnementales), located at the Campus Sanofi Val de Bèvère (CSVB), Lyon Carteret, Toulouse and La Boètie sites.

In 2015, we inaugurated a new administrative site at the Campus Sanofi Val de Bèvère 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). 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” and High Environmental Quality with a rating of “exceptional.”

LIMITING CO2 EMISSIONS DUE TO THE TRANSPORT OF MEDICINES

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” fact sheet (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 44,177 tCO2e for the Group’s overall perimeter. For the strict perimeter of pharmaceutical manufacturing sites, CO2 emissions accounted for 57,999 tCO2e and 87 kg 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 passing maritime shipping for all intercontinental product flows. In 2015, the quantity of medicines transported by barge represented 86% of our international shipments, reducing these CO2 emissions.

Facts and figures

CO2 Emissions – Scope 3 fact sheet

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 techniques, as well as rainwater recovery.

FUNCTIONAL GROUPS

IN THE UNESCO

BIOCLIMATIC RATING OF "VERY GOOD"
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 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.

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 Bèvère 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 ideas 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 drive for the work-home commute.

Our medical sales vehicles fleet
In 2015 the progressive renewal of the Group’s medical sales fleet vehicles (estimated) was carried out with a focus on improving the fuel efficiency of our fleet and bringing it in line with the limit set at 120 g CO₂/km. So far, around 97.2% of our total vehicle fleet is compliant with this limit, including two wheel electric vehicles. To promote carpooling, a mobile application called “Smart Autostop” makes it easy for employees to locate nearby passengers and drive for the work-home commute.

Facts and figures

CO2 EMISSIONS (IN t CO2e)

<table>
<thead>
<tr>
<th>Year</th>
<th>Scope 1 and 2</th>
<th>Scope 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>145,788</td>
<td>1,713</td>
<td>147,501</td>
</tr>
<tr>
<td>2014</td>
<td>149,626</td>
<td>2,070</td>
<td>151,696</td>
</tr>
<tr>
<td>2015</td>
<td>149,046</td>
<td>2,069</td>
<td>149,115</td>
</tr>
</tbody>
</table>

SCOPE 3 CO2 EMISSIONS

<table>
<thead>
<tr>
<th>Year</th>
<th>Employee Commuting</th>
<th>Business Travel</th>
<th>Transportation and Distribution</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>444,777 tCO₂e</td>
<td>187 tCO₂e</td>
<td>2,075 tCO₂e</td>
<td>478,998 tCO₂e</td>
</tr>
<tr>
<td>2014</td>
<td>454,227 tCO₂e</td>
<td>187 tCO₂e</td>
<td>2,053 tCO₂e</td>
<td>464,199 tCO₂e</td>
</tr>
<tr>
<td>2015</td>
<td>464,199 tCO₂e</td>
<td>187 tCO₂e</td>
<td>2,053 tCO₂e</td>
<td>464,199 tCO₂e</td>
</tr>
</tbody>
</table>

Sanofi has reduced its total CO₂ emissions from business travel and employee commuting are part of our scope 3 CO₂ emissions.
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.

## Our Progress

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>2015 PROGRESS AND ACTIONS</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REDUCING OUR WATER CONSUMPTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010-2020: Achieve a 25% reduction in water consumption</td>
<td>In 2015, we achieved a 14.8% reduction in our water consumption compared to our 2010 baseline year.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>ASSESSING THE ENVIRONMENTAL IMPACT OF EFFLUENTS FROM OUR MANUFACTURING SITES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By 2015: Implement an effluent assessment plan at 100% of chemistry sites that manufacture 30 selected active pharmaceutical ingredients (APIs)</td>
<td>We completed the review of the effluents of 100% of our chemical manufacturing sites that manufacture the 30 selected APIs.</td>
<td>Completed</td>
</tr>
<tr>
<td>By 2015: Define environmental target values for the 30 selected APIs</td>
<td>Target environmental values have been assigned to 100% of APIs found in effluents from our chemical manufacturing sites to date.</td>
<td>Completed</td>
</tr>
<tr>
<td>Implement an effluent assessment plan of dosage form manufacturing facilities</td>
<td>We began implementing an effluent assessment program for a first series of 5 facilities.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>MEASURING THE POTENTIAL ENVIRONMENTAL IMPACT OF OUR MEDICINES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conduct voluntary environmental hazard and risk assessments for APIs in drugs already on the market</td>
<td>We completed voluntary assessments for 42 APIs in marketed drugs.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>CONTRIBUTING TO RESEARCH TO LEARN MORE ABOUT PHARMACEUTICALS IN THE ENVIRONMENT (PIE)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop and share our knowledge about pharmaceuticals in the environment</td>
<td>We co-funded a research project of 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.</td>
<td>On track</td>
</tr>
<tr>
<td><strong>ENCOURAGING THE PROPER USE OF MEDICINES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support targeted programs to take back unused and expired medicines</td>
<td>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 Merial Canada site.</td>
<td>On track</td>
</tr>
<tr>
<td>Develop programs to promote the proper use of medicines</td>
<td>We launched a platform for healthcare professionals and patients about the responsible use of antibiotics.</td>
<td>On track</td>
</tr>
</tbody>
</table>

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

**WATER MANAGEMENT**

**STRATEGIC APPROACH**

**REDUCING OUR WATER CONSUMPTION**
Sanofi uses water for many of its industrial processes—in cooling systems during manufacturing, for lavation and vaccination, 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 organize systematic assessments of 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 micromgrams 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. Nevertheless, further 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).

**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 micropolitobalts."

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

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**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.**
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 of two of its R&D buildings. This improvement is anticipated to lead to a 55% reduction in annual water usage for the R&D center while it generates 20% 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 risk. Since 2014, the Group has fine-tuned its methods of determining locations where activities may be impacted by water-related risks. Our approach relies firstly on absolute water usage at the site level, and secondly of absolute local water stress risk and regional relative water usage levels. In 2015, we completed an analysis with input from an outside consultant, and we defined these 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.

At Sanofi’s R&D center in Frankfurt, Germany, switches to a closed-loop water cooling system, the number of annual water withdrawals decreased by 55%, saving 20% in operational costs. This improvement is anticipated to lead to a 55% reduction in annual water usage for the R&D center while it generates 20% operational cost savings. Sanofi invests in technologies to improve water efficiency by implementing closed-loop systems and reducing water consumption at its facilities.
Facts and figures

**GROUP WATER WITHDRAWAL (MILLION M³)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Surface Water</th>
<th>City Water</th>
<th>Well Water</th>
<th>City &amp; Well Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>16.9</td>
<td>16.9</td>
<td>9.3</td>
<td>32.1</td>
</tr>
<tr>
<td>2014</td>
<td>16.5</td>
<td>14.3</td>
<td>9.6</td>
<td>30.4</td>
</tr>
<tr>
<td>2015</td>
<td>18.0</td>
<td>15.0</td>
<td>18.5</td>
<td>51.5</td>
</tr>
</tbody>
</table>

**SANOFI TOTAL WATER CONSUMPTION (MILLION M³)**

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21.0</td>
<td>16.0</td>
<td>15.0</td>
</tr>
</tbody>
</table>

**WATER CONSUMPTION BY BUSINESS IN 2015 (75 SITES)**

<table>
<thead>
<tr>
<th>Business</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopharmaceuticals</td>
<td>18.2%</td>
<td>18.4%</td>
<td>18.2%</td>
</tr>
<tr>
<td>Biotech</td>
<td>12.2%</td>
<td>14.8%</td>
<td>18.5%</td>
</tr>
<tr>
<td>Biopharma</td>
<td>18.9%</td>
<td>17.2%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Genentech</td>
<td>15.2%</td>
<td>15.0%</td>
<td>15.0%</td>
</tr>
<tr>
<td>Merck</td>
<td>8.5%</td>
<td>7.3%</td>
<td>8.2%</td>
</tr>
<tr>
<td>Novartis</td>
<td>4.7%</td>
<td>3.5%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Pfizer</td>
<td>3.2%</td>
<td>2.8%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Roche</td>
<td>1.5%</td>
<td>1.4%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Sanofi</td>
<td>1.3%</td>
<td>1.2%</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

**CHEMICAL OXYGEN DEMAND**

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.1%</td>
<td>10.6%</td>
<td>9.8%</td>
</tr>
</tbody>
</table>

**EFFLUENTS IN WATER DISCHARGED (15 SITES)**

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21.0</td>
<td>16.0</td>
<td>15.0</td>
</tr>
</tbody>
</table>

**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 from a multidrug-resistant bacterial infection. From 30 to 50% of antibiotic prescriptions in France are inappropriate, 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 antibiot-responsable.fr](http://www antibiot-responsable.fr)

Take-back programs for unused medicines

We support targeted take-back programs that collect unused drugs from patients and informal 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 Merital Canada site, leader in antipsychotic 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. Merital donates $10 to a local 4-H Club (a national Canadian club to educate youth in agriculture, 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 1999.

**Download Center**

- Disposal of Unused Medicines and User Recommendations (French)
- In French only
- [medikit@pssail.eu](mailto:medikit@pssail.eu)

**4-H Club (a national Canadian club)**

Eprinex® products with respect to a dedicated pollution and waste management program. This program is designed to encourage farmers to return empty and clean jugs of Ivomec® and Eprinex® products with respect to a dedicated protocol. Merital donates $10 to a local 4-H Club (a national Canadian club to educate youth in agriculture, 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 1999.

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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.

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.

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 processes and data to 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 contract to ensure that the contractor has the necessary qualifications, competence and compliance for the type of waste to be handled.

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 contract to ensure that the contractor has the necessary qualifications, competence and compliance for the type of waste to be handled.

To promote the use of recycled solvents whenever possible, 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.

In North America, Sanofi has streamlined waste management through the harmonization of best practices in North America. Sanofi has developed tools and 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 contract to ensure that the contractor has the necessary qualifications, competence and compliance for the type of waste to be handled.

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, recollection 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 period 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 steam after material is recycled, and decreasing the amount of waste disposed in landfills.
**Facts and figures**

**OUR RESULTS IN 2015**

**SANOFI WASTE MANAGEMENT**

<table>
<thead>
<tr>
<th>TOTAL HAZARDOUS WASTE</th>
<th>TOTAL NON-HAZARDOUS WASTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TONS</td>
<td>TONS</td>
</tr>
<tr>
<td>154,149</td>
<td>150,809</td>
</tr>
<tr>
<td>153,719</td>
<td>152,819</td>
</tr>
</tbody>
</table>

**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.

**MAKING THE BEST USE OF BLISTER PACKAGING MATERIALS**

To reduce waste at the source, we seek to optimize the utilization of blister packs made of PVC, aluminum, and 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 reusing barriers 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.

**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 re-used 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 Aix-en-Provence (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 Mureaux (France) facility, toner is provided by a neighboring factory and used as a solvent. 1,000 tons per year of toner is returned to the provider to be regenerated and reused.
- In mid-2014, Sanofi’s Frankfurt (Germany) site began to reuse polyvinyl chloride trays 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 Aix-en-Provence (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 needs to define and set in place a corresponding environmental impact for its production.

**“Sanofi will reach environmental excellence if it manages to work its business case according to the principles of the circular economy; that 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.”**

Julie Vol, Managing Director, World Watch Institute Europe

“...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...”

Julie Vol, Managing Director, World Watch Institute Europe
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**

<table>
<thead>
<tr>
<th>Description</th>
<th>G4-SO1</th>
<th>G4-SO2</th>
<th>Number</th>
<th>261</th>
<th>303</th>
<th>283*</th>
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</thead>
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<tr>
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<td>G4-SO01</td>
<td>G4-SO02</td>
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<td>190,013,414</td>
<td>325,588,954*</td>
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<td>Estimated number of beneficiaries of above programs, which included:</td>
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<td></td>
<td>Number</td>
<td>25,000</td>
<td>27,000</td>
<td>29,000*</td>
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<tr>
<td>- Number of healthcare professionals trained</td>
<td>G4-SO01</td>
<td>G4-SO02</td>
<td>Number</td>
<td>163,505</td>
<td>273,283</td>
<td>569,751*</td>
</tr>
<tr>
<td>- Number of individuals targeted by awareness campaigns</td>
<td>G4-SO01</td>
<td>G4-SO02</td>
<td>Number</td>
<td>79,148,558</td>
<td>101,101,301</td>
<td>268,791,753*</td>
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<tr>
<td>- Number of patients receiving diagnosis, vaccination or treatment</td>
<td>G4-SO01</td>
<td>G4-SO02</td>
<td>Number</td>
<td>97,462,490</td>
<td>99,539,300</td>
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**Innovation**

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<th>G4-SO2</th>
<th>Number</th>
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<th>236</th>
<th>249*</th>
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</thead>
<tbody>
<tr>
<td>Number of new molecular entities (NME) and vaccine candidates in clinical development</td>
<td>Number</td>
<td>49</td>
<td>43</td>
<td>46</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>Number</td>
<td>12</td>
<td>14</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approximate percentage of projects coming from collaborations and partnerships</td>
<td>%</td>
<td>50</td>
<td>50</td>
<td>50</td>
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**Product quality and safety**

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<th>Description</th>
<th>G4-SO1</th>
<th>G4-SO2</th>
<th>Number</th>
<th>9,000</th>
<th>12,700</th>
<th>15,000</th>
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<tbody>
<tr>
<td>Number of internal quality audits</td>
<td>Number</td>
<td>30,000</td>
<td>&gt;30,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate of batches recalled for quality reasons</td>
<td>%</td>
<td>0.1%</td>
<td>0.34%</td>
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<td></td>
<td></td>
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**Fight against counterfeit drugs**

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<tr>
<th>Description</th>
<th>G4-SO1</th>
<th>G4-SO2</th>
<th>Number</th>
<th>17,000</th>
<th>20,000</th>
<th>15,000</th>
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</thead>
<tbody>
<tr>
<td>Number of employees Sanofi has trained about counterfeit drugs</td>
<td>Number</td>
<td>9,000</td>
<td>12,700</td>
<td>15,000</td>
<td></td>
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<tr>
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<td>12,700</td>
<td>15,000</td>
<td></td>
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</tr>
<tr>
<td>- Public health agents, customs officials and police officers from around the world</td>
<td>Number</td>
<td>9,000</td>
<td>7,300</td>
<td>9,317</td>
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**Research and Development**

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<td></td>
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<td>7,300</td>
<td>9,317</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

[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/Alejato 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

### ETHICS

<table>
<thead>
<tr>
<th>Definition</th>
<th>GRI 4</th>
<th>Reference GRI 2 (French law)</th>
<th>Unit</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
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</thead>
<tbody>
<tr>
<td>Human rights</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employees trained to human rights since 2010</td>
<td>3.C, 3.E</td>
<td>Number</td>
<td>188</td>
<td>128</td>
<td>190*</td>
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<tr>
<td>Supplier-related risks</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of suppliers assessed on their CSR performance</td>
<td>3.C, 3.E</td>
<td>Number</td>
<td>103</td>
<td>64</td>
<td>115*</td>
<td></td>
</tr>
<tr>
<td>Number of assessed suppliers that met our CSR requirements</td>
<td>3.C, 3.E</td>
<td>Number</td>
<td>103</td>
<td>64</td>
<td>115*</td>
<td></td>
</tr>
<tr>
<td>% of assessed suppliers that met our CSR requirements</td>
<td>3.C, 3.E</td>
<td>%</td>
<td>55</td>
<td>50</td>
<td>61*</td>
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<tr>
<td>Number of buyers trained to the Responsible Procurement Platform</td>
<td>3.C, 3.E</td>
<td>Number</td>
<td>106</td>
<td>120</td>
<td>153*</td>
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<td>Corruption</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total number of people trained through e-learning courses (4)</td>
<td>3.D</td>
<td>Number</td>
<td>97,000</td>
<td>96,663</td>
<td>[6]</td>
<td>96,663</td>
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<tr>
<td>Clinical trials</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of clinical trials</td>
<td>G4-PR1/G4PR2</td>
<td>Number</td>
<td>271</td>
<td>277</td>
<td>197</td>
<td></td>
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<tr>
<td>by Pharmaceuticals</td>
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<td>200</td>
<td>171</td>
<td>160*</td>
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<td></td>
</tr>
<tr>
<td>by Vaccines [8]</td>
<td>Number</td>
<td>71</td>
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<td>47</td>
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<tr>
<td>Number of subjects enrolled</td>
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<td>[9]</td>
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<tr>
<td>with Pharmaceuticals</td>
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<td>26,906</td>
<td>[9]</td>
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<tr>
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<td>35,721</td>
<td>13,599</td>
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### PEOPLE

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<tr>
<th>Definition</th>
<th>GRI 4</th>
<th>Reference GRI 2 (French law)</th>
<th>Unit</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workforce</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employees under contract [10]</td>
<td>G4-10</td>
<td>G4A1</td>
<td>1.A</td>
<td>Number</td>
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<td>113,496</td>
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<tr>
<td>Employees under contract</td>
<td>Include all employees who have a contract with Sanofi, including interns and apprentices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part time</td>
<td>G4-10/G4A1</td>
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<td>Number</td>
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<td>4,522</td>
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<td>Workforce by employment type</td>
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<td></td>
<td></td>
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<td>%</td>
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<td>89.1</td>
<td>89.2</td>
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<tr>
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<td>G4-10/G4A1</td>
<td>1.B</td>
<td>%</td>
<td>10.0</td>
<td>10.9</td>
<td>10.8</td>
</tr>
<tr>
<td>% of employees under fixed-term contracts</td>
<td>G4-EC9</td>
<td>3.D</td>
<td>Number</td>
<td>106</td>
<td>120</td>
<td>153*</td>
</tr>
<tr>
<td>Total number of departures G4-10/G4A1</td>
<td>3.B</td>
<td>Number</td>
<td>14,191</td>
<td>14,769</td>
<td>14,070*</td>
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<tr>
<td>Retirement G4-10/G4A1</td>
<td>3.B</td>
<td>%</td>
<td>29.9</td>
<td>30.1</td>
<td>29.5</td>
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<tr>
<td>End of term contracts G4-10/G4A1</td>
<td>3.B</td>
<td>%</td>
<td>16.0</td>
<td>16.5</td>
<td>16.8</td>
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<tr>
<td>Total number of hours of training, Germany G4-10/G4A1</td>
<td>3.B</td>
<td>Number</td>
<td>N/A</td>
<td>321,327</td>
<td>314,094*</td>
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<tr>
<td>Total number of hours of training, France G4-10/G4A1</td>
<td>3.B</td>
<td>Number</td>
<td>N/A</td>
<td>591,931</td>
<td>423,130</td>
<td>554,758*</td>
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<tr>
<td>Average hours of training per year per trained employee, France G4-4A4</td>
<td>3.B</td>
<td>Hours</td>
<td>26.3</td>
<td>21.2</td>
<td>24.8</td>
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<td>Europe G4-10/G4A1</td>
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<td>Number</td>
<td>48.1</td>
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<td>Including France G4-10/G4A1</td>
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<td>Number</td>
<td>24.6</td>
<td>25.7</td>
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<td>North America G4-10/G4A1</td>
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<td>Number</td>
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<td>16.4</td>
<td>16.7</td>
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<td>Other countries G4-10/G4A1</td>
<td>1.A</td>
<td>Number</td>
<td>35.2</td>
<td>36.8</td>
<td>36.3</td>
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<td>Workforce by function</td>
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<td>Sales force G4-10/G4A1</td>
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<td>29.9</td>
<td>30.1</td>
<td>29.5</td>
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<tr>
<td>Marketing and support functions G4-10/G4A1</td>
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<td>16.0</td>
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<td>16.8</td>
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OUR CSR PERFORMANCE

Total reportable injury frequency rate (TRI-FR) worldwide

| G4-LA6 | 1.D | Number | 2.9 | 3.1 | 2.8* |

Motor vehicle accidents (MVA)

| G4-LA6 | 1.D | Number | 4,901 | 4,194 | 4,095 |

Total number of medical sales representatives vehicles

| G4-LA6 | 1.D | Number | 24,285 | 24,456 | 26,767 |

Motor vehicle accidents (MVA)

| 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 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.

[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. This table includes every injured employee, including those involved in accidents occurring during the home-workplace commute, and excludes accidents occurring during the workplace commute and accidents occurring when employees are on paid medical leave.

[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.


[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 reference document for the 2015 CSR report.

[18] The definition of the term “manager” corresponds to every person who has one or more direct reports.
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<tr>
<td>Solvents used</td>
<td>G4-EN1</td>
<td>2.C</td>
<td>Ltr</td>
<td>169,234</td>
<td>178,483</td>
<td>190,016</td>
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<tr>
<td>- including 5% regenersted</td>
<td>G4-EN2</td>
<td>2.C</td>
<td></td>
<td>80</td>
<td>85.45</td>
<td>85.32</td>
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<td><strong>Energy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total energy consumption [19]</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>17,653,077</td>
<td>16,998,198</td>
<td>17,342,779</td>
</tr>
<tr>
<td>Total gas/liquefied petroleum gas</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>8,439,273</td>
<td>8,016,725</td>
<td>7,807,641</td>
</tr>
<tr>
<td>Electricity</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>6,906,563</td>
<td>6,746,148</td>
<td>6,840,753</td>
</tr>
<tr>
<td>Liquid hydrocarbon fuel</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>656,531</td>
<td>284,299</td>
<td>288,097</td>
</tr>
<tr>
<td>Coal</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>158,018</td>
<td>44,476</td>
<td>15,720</td>
</tr>
<tr>
<td>- Other (plastics, thermal fluids, etc.)</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>1,566,656</td>
<td>1,317,069</td>
<td>1,395,911</td>
</tr>
<tr>
<td><strong>Total fuel consumption from medical sales fleets vehicles</strong></td>
<td>G4-EN3</td>
<td>2.C</td>
<td>GJ</td>
<td>2,200,978</td>
<td>2,353,489</td>
<td>2,173,294</td>
</tr>
<tr>
<td>- Total number of medical sales representatives vehicles including motorcycles</td>
<td>G4-EN3</td>
<td>C</td>
<td></td>
<td>25,309</td>
<td>24,977</td>
<td>18,584</td>
</tr>
<tr>
<td>- Distance travelled</td>
<td>G4-EN3</td>
<td>2.C</td>
<td>Km</td>
<td>764,356,479</td>
<td>714,754,747</td>
<td>794,528,026</td>
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<tr>
<td>- Normalized consumption</td>
<td>G4-EN3</td>
<td>2.C</td>
<td></td>
<td>8.1</td>
<td>8.2</td>
<td>7.7</td>
</tr>
<tr>
<td><strong>Water</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total water consumption</td>
<td>G4-EN8</td>
<td>2.C</td>
<td>m³</td>
<td>48,070,488</td>
<td>46,400,118</td>
<td>46,475,532</td>
</tr>
<tr>
<td>Surface water</td>
<td>G4-EN8</td>
<td>2.C</td>
<td>m³</td>
<td>16,003,949</td>
<td>16,271,792</td>
<td>16,003,942</td>
</tr>
<tr>
<td>Well water</td>
<td>G4-EN8</td>
<td>2.C</td>
<td>m³</td>
<td>21,049,842</td>
<td>21,241,291</td>
<td>24,085,427</td>
</tr>
<tr>
<td>City water</td>
<td>G4-EN8</td>
<td>2.C</td>
<td>m³</td>
<td>8,891,201</td>
<td>8,989,002</td>
<td>9,322,729</td>
</tr>
<tr>
<td>Percentage reduction (baseline year: 2010)</td>
<td>G4-EN8</td>
<td>2.C</td>
<td></td>
<td>-17.4</td>
<td>-20.1</td>
<td>-14.8</td>
</tr>
<tr>
<td>Percentage of water consumed by sites located in water scarcity and water stress areas [21]</td>
<td>G4-EN9</td>
<td>2.C</td>
<td></td>
<td>56</td>
<td>54.4</td>
<td>52.1</td>
</tr>
</tbody>
</table>

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

[20] Renewable fuels are only renewables for biofuels, hydrogen, and other renewable fuel purchased and burnt on site.

[21] Only vehicular travel was considered in the water stress assessment.

#### Biodiversity

<table>
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<th>GRI 4</th>
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<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plants and animals appearing on the CITES lists</td>
<td>G4-EN14</td>
<td>2.D</td>
<td>%</td>
<td>2.6</td>
<td>2.6</td>
<td>2.6</td>
</tr>
<tr>
<td>Based on available information to date, no vegetal or animal listed in the CITES lists (Appendices I and II) are used in our production</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

#### CO2 emissions

- **Forest fuel (direct CO2)** medical sales cars not included
- **Production of electricity and steam (indirect CO2)**
- **Total scope 1 and 2**
- **Estimated CO2 emissions from medical sales fleets vehicles**

**Percentage of the Group vehicles compliant with the 120g CO2/km maximum defined by Sanofi**

**Transporting medicines (23)**

**CO2 emissions related to the transport and distribution of medicines**

**CO2 emitted by pallet transported**

**Scope 3 CO2 emissions (estimate)**

**1 Purchased goods and services (25)**

**2 Capital goods**

**3 Fuel and energy related activities**

**4 Upstream transportation and distribution**

**5 Trade generated by operators**

**6 Business travel**

**7 Employee commuting**

**8 Upstream leased assets**

**9 Downstream transportation and distribution (24)**

**10 Processing of sold products**

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## OUR CSR PERFORMANCE

### Definitions

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<th>2014</th>
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</thead>
<tbody>
<tr>
<td>- 11 Use of solid products [27]</td>
<td>G4-EN4</td>
<td>G4-EN27</td>
<td>tCO₂e</td>
<td>6,300</td>
<td>99,164</td>
<td>585,944</td>
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<tr>
<td>- 12 End of life treatment of solid products</td>
<td>G4-EN4</td>
<td>G4-EN27</td>
<td>tCO₂e</td>
<td>103,000</td>
<td>123,524</td>
<td>71,275</td>
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<tr>
<td>- 13 Downstream leased assets</td>
<td>G4-EN4</td>
<td>G4-EN27</td>
<td>tCO₂e</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>- 14 Franchises</td>
<td>G4-EN4</td>
<td>G4-EN27</td>
<td>tCO₂e</td>
<td>8,800</td>
<td>9,284</td>
<td>NA</td>
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<tr>
<td>- 15 Investments</td>
<td>G4-EN4</td>
<td>G4-EN27</td>
<td>tCO₂e</td>
<td>NA</td>
<td>NA</td>
<td>6,000,000</td>
</tr>
</tbody>
</table>

### Emissions to air

| - VOC emissions [28]                          | G4-EN1| 2.8 | Tons | 2,801      | 3,338*     | NA         |
| - NOx emissions                               | G4-EN1| 2.8 | Tons | 343        | 303        | 308*       |
| - SOx emissions                               | G4-EN1| 2.8 | Tons | 219        | 264        | 284*       |

### Water waste discharge

| - Chemical oxygen demand (COD)                | G4-EN2| 2.8 | 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 90 chemicals that was defined based on environmental hazard criteria | G4-EN26 | % | 75 | 76 | 102% |
| Percentage of APIs for which a target value has been defined | G4-EN26 | % | 23 | 44 | 100% |

### Waste

#### Total hazardous waste

| G4-EN32 | 2.8 | Tons | 103,100 | 135,909 | 213,989 |

#### Recycled

| G4-EN3 | 2.8 | Tons | 34,437 | 32,291 | 35,525 |

#### Incinerated (with thermal recovery)

| G4-EN3 | 2.8 | Tons | 49,768 | 40,316 | 41,425 |

#### Incinerated (without thermal recovery)

| G4-EN3 | 2.8 | Tons | 57,420 | 70,023 | 105,908 |

#### Sent to authorized landfill

| G4-EN3 | 2.8 | Tons | 2,485 | 3,020 | 3,561 |

### Total non-hazardous waste

| G4-EN3 | 2.8 | Tons | 106,364 | 142,089 | 144,463* |

#### Recycled

| G4-EN3 | 2.8 | Tons | 69,970 | 103,820 | 120,892 |

#### Incinerated (with thermal recovery)

| G4-EN3 | 2.8 | Tons | 17,997 | 16,255 | 19,239 |

#### Incinerated (without thermal recovery)

| G4-EN3 | 2.8 | Tons | 1,200 | 1,908 | 2,254 |

### Expenditure/investment

| G4-EN3 | 2.8 | Euros | 78,003,000 | 119,000,000 | 120,000,000* |

### Definitions of regions of quality inspections and audits

- **Africa**: Algeria, Angola, Benin, Botswana, Burundi, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d’Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Morocco, Mozambique, Namibia, Niger, Nigeria, Reunion, Rwanda, Senegal, South Africa, Swaziland, Tanzania, Togo, Tunisia, Uganda, United Republic of (Tanzania), Zambia, Zimbabwe
- **Asia Pacific**: Australia, Bangladesh, Cambodia, China, Hong Kong, India, Indonesia, Japan, Korea (South), Malaysia, New Zealand, Pakistan, Philippines, Singapore, Taiwan, Thailand, and Vietnam
- **Latin America**: Argentina, Brazil, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, Falkland Islands, French Guiana, Grenada, Guyana, Haiti, Honduras, Jamaica, Montserrat, Mexico, Montserrat, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Barthélemy, Saint Kitts and Nevis, Saint Lucia, Saint Martin, Saint Vincent and the Grenadines, Saint George and the South Sandwich Islands, Suriname, Tristan da Cunha and the Falkland Islands, Uruguay, Venezuela, and Bermuda
- **Europe**: Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Faroe Islands, Finland, France, Georgia, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Isle of Man, Italy, Jersey, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Scotland, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sweden and the Netherlands, Sweden, Switzerland, Turkey, Ukraine, United Kingdom
- **North America**: Canada, Puerto Rico and USA

**Note:** Definitions of regions of quality inspections and audits are based on International Maritime Organization (IMO) format. Definitions of regions of procurement are based on the United Nations Economic Commission for Europe (UNECE) format.
**OUR CSR PERFORMANCE**

**GRI INDEX REPORTING 2015**

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

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## OUR CSR PERFORMANCE

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**MATERIAL ASPECT: SUPPLIERS ASSESSMENT FOR IMPACTS ON SOCIETY**

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In order to ensure the uniformity and reliability of data across the Group, the following measures have been implemented:

- The Group uses a standard reporting format across all its sites.
- Data is collected on a uniform basis and is verified through internal controls.
- Reporting guidelines are published annually to ensure consistency.
- A management system based on ISO 9001 and ISO 14001 is in place.
- Data is updated and reviewed on a regular basis.

In 2015, the Group decided to publish all data on safety, health, and environmental performance. This decision was made to ensure transparency and to facilitate comparisons across different sites and countries. The Group also implemented a new management system based on ISO 14001 to improve its environmental performance.

Sanofi has decided to consolidate all 2015 Sanofi data contained in the Factsheet available in our download center. This consolidated data includes all sites and activities within the Group, as well as any additional data that was not included in the previous Factsheet. The data includes information on safety, health, and environmental performance for the entire Group.

For non-mobile personnel, accidents occurring at work are included in this indicator. However, they are included in the occupational injury frequency rate but not the “absent” rate. Thus, it may be necessary to adjust the data to reflect the actual severity of injuries, as these rates are calculated on the basis of headcount, in-accident, hours worked, and days worked. The total occupational injury frequency rate is defined as the number of accidents per million hours worked.
The 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 analyses, including post-marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates, the ability of 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.
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.