CORPORATE SOCIAL RESPONSIBILITY

Chapter 4 of the 2018 Document de référence*

SANOFI

Empowering Life

(*) *This is a free translation into English of the "Chapitre 4, Responsabilité sociale, environnementale et sociétale" of our 2018 Document de référence issued in French. It is provided solely for the convenience of English-speaking readers.*

4

Corporate Social Responsibility

4.1. SOCIAL, SOCIETAL AND ENVIRONMENTAL COMMITMENTS IN SUPPORT OF SUSTAINABLE DEVELOPMENT 2

4.1.1. Access to healthcare for the underserved 2
4.1.2. Human capital 6
4.1.3. Environment 17

4.2. STATEMENT OF EXTRA-FINANCIAL PERFORMANCE AND VIGILANCE PLAN 23

4.2.1. Overview 23
4.2.2. Methodology for selecting major risks and issues 23
4.2.3. Presentation of risks and issues 24
4.2.4. Policies, action plans and performance indicators 25
4.2.5. Other vigilance plan issues 43

4.3. METHODOLOGICAL NOTE ON DATA REPORTING 44

4.3.1. Scope of consolidation 44
4.3.2. Changes in scope 44
4.3.3. Reporting methods 44
4.3.4. Additional information and methodological limitations 45
4.3.5. Social indicators 45
4.3.6. Safety indicators 46
4.3.7. Environmental indicators 46
4.3.8. Other indicators 47
4.3.9. Consolidation and internal controls 47

4.4. INDEPENDENT THIRD PARTY'S REPORT 48

4.5. CORPORATE SOCIAL RESPONSIBILITY CROSS-REFERENCE TABLE 52

This chapter sets out the material issues facing Sanofi in terms of corporate social responsibility (CSR).

Section 4.1. deals with our voluntary social, societal and environmental commitments in support of sustainable development. Section 4.2. deals with the issues identified using a risk analysis conducted in compliance with:

- Articles L. 225-102-1 and R. 225-104 to R. 225-105-2 of the French Commercial Code, which introduced a requirement to publish a statement of extra-financial performance (SEFP) in order to transpose into French law European Directive 2014/95/EU on the publication of non-financial information; and
- Law no. 2017-399 of March 27, 2017 on the duty of vigilance of parent companies and companies acting as principals.

Tables cross-referencing the contents of this chapter to those legal disclosure requirements are provided in an appendix, "Corporate social responsibility cross-reference tables".

Our extra-financial reporting principles are based on the guidelines of the Global Reporting Initiative (GRI) standards, under the "Core" option first attained in 2015. Sanofi is also a signatory of the United Nations Global Compact. A methodological note on how we report our data is provided in Section 4.3.

The present chapter forms an integral part of the French-language *Rapport de Gestion* (Management Report). It has been verified by an independent third party, whose report is presented in Section 4.4.

4.1. Social, societal and environmental commitments in support of sustainable development

Today we are confronted by societal challenges like a growing and ageing population, income disparities and climate change. At the same time, digitization and technological progress present tremendous opportunities. Given these profound upheavals, companies are not only required to perform well financially, but must also explain what they are doing to respond to those challenges and demonstrate that they are making a positive contribution to society.

Sanofi's primary contribution is to serve patients' needs throughout their health journeys, whether they be a rare disease sufferer or one of the millions of men and women living with a chronic illness. It also includes providing vaccine protection to whole populations as well as pain relief treatments. In this respect we contribute to Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages", in particular SDG 3.3 on communicable diseases through our vaccine portfolio and SDG 3.4 on non-communicable diseases through our treatments for diabetes, cardiovascular diseases and rare diseases.

The fulfilment of our mission, which is to understand and meet the healthcare needs of patients across the world, is largely based on the passion and professionalism of our people. Building an inclusive work environment is essential to uniting staff in a truly collaborative spirit in a diversified global environment.

Finally, as a major global healthcare player, we recognize the close link between climate change and health problems. The causes and effects of climate change impact on populations whether through weather events, changes in air and water quality, or the growing scarcity of certain resources, including agricultural resources.

All this underpins our existing and planned initiatives to help make growth more inclusive, sustainable and useful in terms of reducing inequalities in access to healthcare for the underserved (4.1.1.); human capital (4.1.2.); and the environment (4.1.3.).

In addition to SDG 3, these initiatives also contribute to the SDGs on the environment (SDG 6, 12, 13 and 15, see Section 4.1.3.1. "Planet Mobilization roadmap"); SDG 5, Gender Balance (see Section 4.1.2.2., "Diversity and inclusion"); and SDG 8, Decent Work and Economic Growth (see Section 4.2.4.7., "Employee health and safety").

4.1.1. Access to healthcare for the underserved

4.1.1.1. Context and approach

Access to healthcare is a priority for Sanofi. We are helping to improve access in various ways, from R&D to the fight against counterfeiting. We also operate a responsible pricing policy for our medicines to ensure that they are affordable for all (see Section 4.2.4.1, "Pricing Policy"), and we design and conduct initiatives to assist vulnerable populations.

These initiatives focus on the most important healthcare needs in fields within our expertise, and target the most underserved populations, mainly in low-to-intermediate income countries. We act in collaboration with public- or private-sector partners or non-governmental organizations, aiming to achieve sustainable and measurable outcomes.

There are a number of obstacles to be cleared before access to healthcare can be improved. Our initiatives to tackle these obstacles fall into three categories:

- developing new treatments and solutions through R&D and innovation;
- making products, treatments and associated services more affordable; and
- strengthening local healthcare capabilities.

Sanofi's strategy of improving access to healthcare for the underserved is as much about ending global epidemics of infectious diseases and avoiding their resurgence, as it is about meeting the growing needs of patients suffering from non-communicable diseases.

In low-to-intermediate income countries, up to 70% of the cost of medicines is met by patients themselves, so it is important to make access to healthcare fairer by applying differentiated pricing based on the country and socio-economic segment. For countries and pathologies identified in the "Access to Medicine" index as priorities, nearly 30% of our products are subject to a fair pricing regime.

Making products, treatments and associated services more affordable is just one aspect of improving access to healthcare. It also requires innovation that can address unmet medical needs, develop new solutions so that patients can get better access, and ensure that products and treatments reach patients by optimizing production, the supply chain, and access to the market. Improving access to healthcare also requires the capacity of healthcare systems and awareness campaigns to be stepped up. Sanofi is therefore developing programs which will apply various levers to help the underserved in low-to-intermediate income countries. These programs are described below.

4.1.1.2. Infectious diseases

SDG 3.3: Between now and 2030, to end the Aids epidemic, tuberculosis, malaria and neglected tropical diseases, and combat hepatitis, water-borne diseases and other communicable diseases.

	Sleeping sickness and other neglected tropical diseases	Malaria and tuberculosis	Polio
Global context	More than one billion people are at risk of contracting neglected tropical diseases which cost the developing world billions of dollars every year (source: WHO). Sleeping sickness threatens millions of people in 36 sub-Saharan African countries. Sanofi has been collaborating with the WHO since 2001 in a bid to eradicate sleeping sickness by 2020. Since the start of Sanofi's collaboration with the WHO, the number of cases of sleeping sickness has dropped from 26,950 in 2001 to 1,447 in 2017.	In 2017, 219 million cases of malaria and 435,000 deaths were recorded. In Africa a child dies of malaria every two minutes (source: WHO). In 2017, between 1.2 and 1.4 million deaths were due to tuberculosis (source: WHO).	Polio mainly affects children under the age of 5. One infection in 200 causes irreversible paralysis (source: WHO). Under the Global Polio Eradication Initiative (GPEI: http://polioeradication.org/) set up in 1988, in which Sanofi Pasteur is an active participant, 11 billion dollars have been invested, enabling 2.5 billion children to be vaccinated, thereby preventing more than 10 million cases of paralysis. The number of cases has fallen by more than 99%. The number of endemic countries has decreased from 125 in 1988 (estimated 350,000 cases) to 3 in 2017 (22 cases). The remaining 1% are a major challenge. Eradicating the disease would lead to savings of 40 to 50 billion dollars over the next 20 years.
	Source: WHO at https://www.who.int/home.		
Ambition	To help eradicate sleeping sickness by 2020.		To help eradicate polio.
R&D and innovation	**Sleeping sickness:** Sanofi is collaborating with the Drugs for Neglected Diseases *initiative* (DND*i*) to develop the first single-dose oral drug for the treatment of all stages of sleeping sickness. Fexinidazole could be a decisive advance in eradicating sleeping sickness in that it would simplify treatment, avoid systematic hospitalization and spare patients the ordeal of lumbar puncture tests. Sanofi is responsible for the development and industrial production of the drug, but also for its regulatory filing. A committee of experts from the European Medicines Agency (EMA)	**Malaria:** in collaboration with the Medicines for Malaria Venture (MMV), Sanofi is working to develop a OZ439/ferroquine association that could be a substitute for artemisinin-based treatments, which are meeting growing resistance. This project is currently going through phase II clinical trials. **Tuberculosis:** Sanofi is part of the "TB Drug Accelerator" program which aims to accelerate research and development of new molecules against tuberculosis.	

	Sleeping sickness and other neglected tropical diseases	Malaria and tuberculosis	Polio
	recommended the approval of fexinidazole in November 2018, clearing the way to its distribution in Africa in 2019: https://www.dndi.org/2019/media-centre/press-releases/fexinidazole-sleeping-sickness-approved-democratic-republic-congo/ **Other**: Sanofi is also collaborating with the DND*i* on the development of specific treatments for leishmaniosis, Chagas disease and Buruli ulcer.		
Affordability models	**Sleeping sickness:** since 2001 Sanofi has supported this initiative to the tune of nearly 80 million dollars, or 5 million dollars a year. More than 210,000 people have been treated since then.	**Malaria:** ASAQ Winthrop®, a drug developed with the DND*i* which we haven't patented, is distributed at preferential prices in compliance with the relevant local regulations. ASAQ Winthrop® has been used to treat over 450 million cases of malaria since it was launched in 2007, including more than 200 million babies and children under five thanks to our special pediatric formulation.	**Polio:** Sanofi Pasteur has partnered the GPEI for nearly 30 years and supplies UNICEF with polio vaccines at preferential prices via GAVI, the Vaccine Alliance, which aims to vaccinate the populations of 73 of the poorest countries on the planet. During this period, we have supplied over six billion doses of oral polio vaccine (OPV) to UNICEF. Over the 2014-2018 period, we also provided 80% by volume of the injectable polio vaccine (IPV) distributed by UNICEF in those countries.
Strengthening local capabilities	**Sleeping sickness and leishmaniosis:** the collaboration between Sanofi and the WHO involves sponsoring programs to combat and treat those diseases. These interventions include awareness and screening campaigns among populations in endemic regions; the training of medical personnel, logistical and equipment support; and treatment resistance surveillance. Since 2001, some 40 million people have been screened for sleeping sickness under this scheme.	**Malaria:** Since 2001, in partnership with national anti-malaria programs in various African countries, we have developed training and awareness tools specifically for children, such as Moski Kit, a set of edutainment tools, the most recent of which is Moski Toon. In collaboration with anti-malaria programs, education ministries and NGOs, we have developed the "Schoolkids against malaria" program and deployed it in 17 countries to promote the adoption of preventive behaviors in sub-Saharan African schools. Sanofi is also a member of the second phase of RAI, the Global Fund's Regional Artemisinin-resistance Initiative, which aims to eradicate malaria in the Mekong region.	

4.1.1.3. Non-communicable diseases

Globally, cardiovascular diseases, chronic respiratory diseases and diabetes are responsible for 43% of premature deaths before the age of 70.

Sanofi is a founder member of Access Accelerated (AA – https://accessaccelerated.org/), an international coalition of major pharmaceutical companies working to reduce the burden of non-communicable diseases on low-income countries.

Sanofi's commitment within the AA is focused on four flagship programs:

- My Child Matters (childhood cancers), an initiative of the Sanofi Espoir Foundation.
- KiDS (kids and diabetes in school) (diabetes).
- FAST – Fight Against STigma (mental health).
- Access and Affordability Initiative (several diseases) in Ghana and the Philippines.

SDG 3.4: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.

	Diabetes and cardiovascular diseases	Oncology	Mental health
Global context	Every year diabetes and cardiovascular diseases together kill nearly 20 million people worldwide, which represents nearly half of deaths due to non-communicable diseases (source: WHO).	Worldwide, nearly 300,000 cases of cancer are diagnosed in children under 15. Nearly 80% of them live in countries with limited resources where cure rates are only 40%, or even 10% – 20% in some sub-Saharan African countries, against 80% in developed countries (source: International Childhood Cancer Day).	Globally, mental or neurological disorders will affect one in four people at some time in their lives. Around 450 million are currently suffering from these pathologies, which makes mental disorders one of the main causes of morbidity and disability worldwide (source: WHO).
	Source: WHO at https://www.who.int/home.		
Ambition	To help reduce the burden on low-income countries of non-communicable diseases like childhood cancer, diabetes and mental health disorders.		
Affordability models	**Action on multiple diseases:** Sanofi and three other pharmaceutical companies have launched the Access and Affordability Initiative in Ghana and the Philippines in collaboration with the Bill and Melinda Gates Foundation (BMGF), Johns Hopkins University and local governments. In the pilot phase, drugs for the treatment of a number of non-communicable diseases, such as cardiovascular diseases, type 2 diabetes, high blood pressure and pre-eclampsia, have been distributed at preferential prices. Developing a pilot program in Kenya based on an innovative digital service model which provides full scope treatments for diabetes and high blood pressure by: ♦ supplying quality care and treatments at affordable prices for low-to-intermediate income populations for non-communicable diseases; ♦ sharing data in near real time thanks to connections between patients, healthcare professionals and payers; ♦ helping patients improve their treatment adherence; and ♦ working with payers to secure the long-term sustainability of the model and its rollout across the country and in other countries (source: http://partnerships.ifpma.org/partnership/ngao-ya-afya-shield-for-health).		
Strengthening local capabilities	**Diabetes:** The KiDS project was born of a partnership between the International Diabetes Federation (IDF) and the International Society for Pediatric and Adolescent Diabetes (ISPAD). It is a schools-based educational program designed to improve the treatment and integration of children with type 1 diabetes, and to increase awareness of the benefits of a balanced diet and physical activity in preventing the development of type 2 diabetes. The educational material comprises an information and awareness pack for teachers and school staff, and school children aged 6-14 and their parents, and is currently available in 15 languages. The project is up and running in 8 countries (India, Brazil, the United Arab Emirates, Pakistan, Egypt, Poland, Japan and Hungary). In 2017, in the United Arab Emirates, KiDS project documents were incorporated into the National	**Oncology:** Since 2006, the Sanofi Espoir Foundation's My Child Matters program has been working to provide children with the same conditions for accessing healthcare whatever country they live in. The program is helping improve access to healthcare and strengthen local capabilities by training healthcare professionals. It also produces and distributes information about childhood cancers in order to promote early detection. Since the launch of My Child Matters, 58 projects in 42 countries have led to the training of 20,000 healthcare professionals and the treatment of more than 75,000 children.	**Mental health:** In 2008, Sanofi and the World Association of Social Psychiatry (WASP) joined forces to develop the Fight Against STigma (FAST) program to combat the social stigmatization of mentally ill people and promote access to care in developing countries. Under the program, Sanofi is collaborating with the Myanmar Medical Association to remedy poor mental healthcare provision in Myanmar by supplying digital tools to healthcare professionals. The FAST program also aims to incorporate mental healthcare into primary medicine by training community health personnel and primary care physicians in mental healthcare.

	Diabetes and cardiovascular diseases	Oncology	Mental health
	Health Manual used in all schools. In 2018, the results of the pilots in Brazil and India were published in the Pediatric Diabetes journal. The KiDS project in Poland won the healthcare collaboration prize (prevention and awareness category) awarded by the European Federation of Pharmaceutical Industries and Associations (EFPIA).		

4.1.2. Human capital

Sanofi had 104,226 employees under contract at the end of 2018, compared with 106,566 in 2017. A table showing a split of our employees by activity and geographical area is provided in "Item 6.D – Employees" on page 187 of our Annual Report on Form 20F.

The main changes in 2018 arose from our acquisitions of Bioverativ (512 people) and Ablynx (493 people); the divestment of Zentiva, our European Generics business, to Advent International (2,616 people); and the transfer of our infectious diseases research unit to Evotec (98 people).

External staff represented a total of 7,088 full time equivalents in 2018 (7,426 in 2017), comprising 5,211 temporary staff (5,401 in 2017) and 1,877 third party sales forces staff (2,025 in 2017).

A more detailed analysis of our workforce (trends, male/female split, contract term, etc.) is provided in Section 4.1.2.6., "Workforce".

4.1.2.1. Strategy, progress and performance indicators

♦ **Context**

The pharmaceuticals market is changing at an ever faster pace. The challenges facing the healthcare sector are also becoming ever more substantial. Chronic illnesses are becoming more prevalent, self-medication is on the rise, and the ageing population has very specific needs. This is coupled with growing demand in emerging economies, while developed countries are focusing more sharply on measures that have a positive impact on patient health. Digitization is resetting the relationship between the key players (the pharmaceutical industry, healthcare systems, physicians and patients), forcing the industry to develop new skills adapted to changes in the healthcare ecosystem.

Our mission at Sanofi is to understand and meet the healthcare needs of patients around the globe. In delivering on this mission, we place great reliance on the passion and professionalism of our employees.

Our Human Resources teams are therefore faced with a growing number of challenges, but also many opportunities. Several generations work together, sharing the same space but with varying needs and working practices. To unite them in a truly collaborative spirit, we need to create an appropriate working environment. Talent management challenges vary widely from region to region. Workforce has become global and diversified : people take career decisions on a world scale, looking at job opportunities outside their home countries. Companies are embracing diversity of cultures, lifestyles and experiences, so they can build teams that mirror the diversity of their customers.

♦ **Our ambition: Empowering People**

2018 marked a step change in employee engagement at Sanofi, with the phased rollout of our "Empowering People" ambition as our new Human Resources value proposition and employer brand.

"Empowering People" reflects the values that unite us as we pursue our shared goals and that we seek to communicate as an employer, successfully delivering on our mission of "Empowering Life".

"Empowering People" is structured so as to meet our objectives while addressing the specific needs of our regions, business units and support functions. It is built on three pillars:

♦ Dare to care;

♦ Co-operate with passion;

♦ Inspire your journey.

Dare to care reflects the attention we pay to people, and our desire to always do better. We invest in innovative R&D partnerships (see Item 4.B.1 – "Strategy" of our Annual Report on Form 20F), take decisions that express our engagement (such as the Boehringer Ingelheim/Merial swap), and work on transformational projects to meet the healthcare needs of the greatest number. We are present in more than 100 countries and provide healthcare solutions in more than 170, from prevention to self-medication and helping people manage chronic diseases.

Co-operate with passion: we work together on one of the biggest healthcare portfolios on the planet. Respect and inclusivity are essential to building an innovative and effective

commercial environment. We bring together people from different generations and cultures and with a diversity of life experiences so that we can respond better to human healthcare needs.

Inspire your journey illustrates our desire to develop and value our people throughout the world, while recognizing the diversity of people's lifestyles, backgrounds and aspirations. We commit to helping our people grow personally and professionally, with a wide range of training opportunities and an environment conducive to career progression.

To support this ambition, we have developed a Human Capital strategy to engage and develop our people, and to transform our organization to make it fitter to meet the challenges of a changing external environment.

- **Organization**

We have reorganized our Human Resources function, creating a "One HR" global model using standardized processes across the whole of Sanofi. Shared tools and systems are deployed throughout the organization, including:

- the Workday tool, which provides a single unified Human Resources framework;
- a worldwide job grading system;
- an up-to-date global mobility policy;
- a leadership and management training curriculum; and
- a single unified Learning Management System (LMS).

♦ **Strategy, action plan and performance indicators**

Our Human Capital roadmap focuses on the following key topics:

Human Capital strategy	Action plan	Performance indicators 2018	Performance indicators 2017
Maximize our organizational effectiveness and progress the Sanofi culture			
Make sure we have what it takes to be a competitive, streamlined and agile organization with a clear roadmap, and build employee engagement.	Our People Survey provides reference based indicators against which we can measure our future development. The survey data helps us identify and rank opportunities to improve employee engagement and our corporate performance. Survey results are communicated to all our employees.	People Survey 2018 statistics: ♦ Response rate: 83% ♦ Engagement index: 73% (measures the extent to which employees are engaged with their everyday work).	First survey conducted in 2017. People Survey statistics: ♦ Response rate: 73% ♦ Engagement index: 69% (measures the extent to which employees are engaged with their everyday work).
Develop our growth potential			
Ensure that our employees have the competencies needed for their jobs.	♦ We have embarked on a strategic human capital planning process to determine the capabilities needed for the future, assess our competencies, and develop appropriate learning solutions at every level of our organization. ♦ We use iLearn, a centralized training management system. ♦ We have set up a talent recruitment unit, using specialist head-hunters who focus on finding quality candidates to fill vacancies fast. All job vacancies are advertised internally and accessible to all employees.	Total number of new hires in 2018: 14,639. See Section 4.1.2.6.2., "New hires and departures".	Total number of new hires in 2017: 13,927. See Section 4.1.2.6.2., "New hires and departures".
		Number of interns and apprentices hired: – Interns: 2,594 – Apprentices: 907	Number of interns and apprentices hired: – Interns: 3,111 – Apprentices: 1,054
		Number of iLearn training modules: see Section 4.1.2.3., "Training and career development".	Number of iLearn training modules: see Section 4.1.2.3., "Training and career development".
Develop Sanofi leaders			
Sanofi leaders run their operations and build their team's skills, to deliver success aligned on our core values of teamwork, respect, courage and integrity.	♦ We continue to expand the international reach of our leadership development programs, to accelerate the transformation of our culture and ensure that we have a coherent leadership team with clearly defined objectives. ♦ High-quality global programs have been developed for first-line managers and managers of managers, helping them acquire the leadership qualities they need to meet the challenges of tomorrow and presenting them with a shared set of tools and principles to help them deliver sustainable results. ♦ Sanofi offers a range of high-impact leadership development programs and cross-disciplinary training opportunities. We ensure that our programs and solutions are implemented consistently across regions, and take account of gender balance at all levels of the management hierarchy.	Over 5,000 employees took part in training programs: ♦ Overall satisfaction rating: 4.3/ 5 Participation in leadership development programs: ♦ 22% of Sanofi Executives ♦ 30% of Sanofi Senior Leaders Programs for managers: ♦ 555 managers of managers took part in training on the fundamentals of leadership.	Over 4,000 employees took part in training programs: ♦ Overall satisfaction rating: 4.5/ 5 Participation in leadership development programs: ♦ 33% of Sanofi Executives ♦ 49% of Sanofi Senior Leaders Programs for managers: ♦ 610 managers of managers took part in training on the fundamentals of leadership.

Human Capital strategy	Action plan	Performance indicators 2018	2017
	♦ The promotion of gender balance lies at the core of Sanofi's strategy, and bringing more female talent on board is one of the individual variable remuneration objectives for Executive Committee members. This policy is embedded in the hiring process, with an obligation to integrate women into the recruitment process for executive roles. ♦ In 2018, we rolled out "Elevate", a new program intended to prepare women to assume Senior Leader roles within Sanofi. ♦ Our ambition is to achieve gender balance in Sanofi Senior Leaders by 2025.	♦ 2,292 first-line managers took part in training on the fundamentals of management. At the end of 2018, 35.4% of our 2,044 Senior Leaders were women. Proportion of women at LE1 and LE2 grades[(a)]: 29.3%	♦ 2,367 first-line managers took part in training on the fundamentals of management. Proportion of women at LE1 and LE2 grades: 27.5%

(a) See methodological note 4.3.5.5., "Definition of grades".

♦ **Ambition contributing to sustainable development goals**

Topic Human Capital	Ambition	Progress 2018	2017	Contribution to SDGs
Gender parity	Achieve gender balance in Sanofi Senior Leaders by 2025.	35.4%	N/A	**SDG 5: Gender equality** **SDG 5.5:** Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life.

4.1.2.2. Diversity and inclusion

Inclusion and diversity are at the heart of how we operate at Sanofi, and are embedded in our core values: courage, respect, teamwork, integrity. We respect the diversity of backgrounds and life experiences among the people who work for us. We are convinced that if we are to make the best use of the wealth that diversity brings us, we must encourage integration and create a workplace that can optimize those differences. This will help make life better for our employees, our patients and our customers.

Engagement	Action plans and performance indicators
Encourage inclusion and engagement	
Inclusive Work Environment	Inclusive Work Environment Program: Launch of the "Flex Work Guidelines" global policies: ♦ Flex at Work (flexible hours, home-working, etc.) ♦ Flex From Work (leave for family events, maternity/paternity leave, leave for carers, etc.) Regional rollout for these policies in 2019, with webinars to help Human Resources teams adapt them to local conditions. Launch of inclusive nudges for the year-end performance cycle (see below). Introduction of quarterly Diversity and Inclusion forums to develop tools and help our country-level networks implement good diversity practices.

Engagement	Action plans and performance indicators
Advance diversity and encourage a multi-cultural environment	
Gender balance	In 2018, our Chief Executive Officer announced our global ambition to achieve gender balance in Sanofi Senior Leaders by 2025 (see Section 4.1.2.6.1., "Year-on-year change").
	Launch of "I'm In", a viral video campaign promoting Sanofi's gender balance ambition ♦ 39 Senior Leaders posted videos. ♦ 12,000 views on the Gender Balance intranet. ♦ 1,570 support messages logged on the intranet (any employee can use this tool to register support for the cause).
	4 video portraits of female role models from the Sanofi Leaders team were broadcast internally and externally. This series of videos, which will continue through 2019, shows female leaders as they really are: what motivates them, and the rich variety of cultural perspectives they bring to our business.
	29.3% of executive posts held by women in 2018.
	40.7% of manager posts held by women in 2018.
	43 women followed the worldwide "Elevate HiPo" high-potential development program.
Employees with disabilities	Objective: Hire and retain people with disabilities. Sanofi has a total of 1,862 employees registered as having a disability in the following countries: United States (47), Germany (450), China (5), France (1,257) and Brazil (103).
Engage millennials	A digital reverse mentoring program was launched in mid-December 2018. A total of 60 millennials were selected for training as mentors, and 23 of them have been paired with executives based in the United States and France for Wave 1. Each wave lasts about six months, and each millennial/executive pairing exchanges views on digital issues connected with Sanofi's digital strategy. The main objectives are to improve digital maturity, encourage inter-generational dialogue, and engage our Senior Leaders in our digital transformation.
Eliminate bias from our behavior, processes and systems	Embed inclusive nudges to challenge bias in our HR processes. Nudges can be embedded in applications to encourage managers to adopt inclusive practices at key managerial decision-making points (introspective questions, know-your-bias, etc.).
	Raise awareness among staff recruiters of issues relating to inclusivity in recruitment: 1. Diversity training for European recruitment teams, followed by a test: 80 participants 2. Distribution of a survey on recruitment practices and diversity 3. Diversity training for North American recruitment teams
	Rollout of the Challenge Your Bias workshop: more than 3,200 participants since 2016, including over 800 Senior Leaders. "Discrimination-Free Hiring" e-learning module available to all recruiters via the iLearn platform since mid-2018.
Enhance our profile and reputation	
Set up global alliances to promote gender balance	In 2018, Sanofi sponsored the Women's Forum in Toronto, Singapore and Paris; 127 of our employees attended, representing Sanofi and acting as gender balance ambassadors.

Inclusion and diversity in France

– Equality of opportunity

In France, we stepped up our support for deprived urban areas through the many initiatives already in place on our sites, delivering on the commitments made on the four key areas in the "PaQte" program (Awareness, Training, Hiring, Purchasing) by taking measures in favor of young people from those neighborhoods.

Our employees have also committed time to sponsorship initiatives focused on equal opportunity: 32 employees worked with the "*Nos Quartiers ont des Talents*" non-profit organization, which aims to make it easier for people from deprived neighborhoods to enter the workforce; 16 with the Institut Télémaque, which supports talented and motivated young students from underprivileged backgrounds; and 30 with *"Sport dans la Ville*", which helps troubled young people find their place in society and begin their careers.

As well as these external initiatives, we are also continuing to implement our Inclusive Work Environment policy.

– People with disabilities

We continue to deliver on our commitments under the 2017-2020 Disability Agreement, which focuses on five key areas:

- priority support for employees with disabilities with a view to them retaining their jobs;
- depending on the job profile, the continued hiring of employees with disabilities, regardless of the nature of their disability;
- better communication and information, via awareness campaigns;
- ongoing actions to provide better accessibility to workspaces and information; and
- maintaining ties with the sheltered employment sector.

A network of 30 on-site disability contacts provides local support.

Achievements during 2018 included:

- European Disability Employment Week: we held awareness-raising events (workshops, round tables, personal testimonies) across 18 of our sites. The host sites were supplied with support materials (including brochures and videos) to accompany these events;
- the Disability Projects Appeal, which supports charitable initiatives by staff in support of people with disabilities, made awards to 11 projects in the Accessibility, Leisure and Sport categories;
- specialist recruitment firms were granted approved vendor status; and
- we continued to roll out the Tadeo software solution for employees with hearing difficulties.

In France, Sanofi employs 1,257 people with a disability (compared with 1,255 in 2017), including temporary staff.

4.1.2.3. Training and career development

Training and career development strategy

Developing our people is a key aspect of our Human Capital strategy. One of our key priorities is to identify and develop the most talented people, and secure their loyalty to the company. The transformation of training within Sanofi was designed in sync with our strategic roadmap.

Sanofi HR teams have initiated a strategic workforce planning process to anticipate and identify the talents and competencies required, and to analyze critical needs and find the resources to meet those needs. This process gives employees more visibility about our current and future needs, and is useful in devising development plans that ensure skillsets keep pace with the changing competitive environment.

We are migrating our training efforts to focus on delivering better solutions and constantly improving the skillsets of our people, aligning our training programs on our strategic workforce planning. The overall aim of this transformation of training within Sanofi is to foster a learning culture that supports our key objective: enabling our people to learn any time, anywhere, by accessing high-quality content through a shared digital platform. This will also support our aim of becoming an employer of choice for all generations.

This approach began in 2015 with our global leadership development program. We now have a catalogue of more than 200 digital training modules covering a range of personal development skills, available to all our people worldwide.

In 2018, we established a clear governance framework that will enable us to make the right investment decisions and optimize the training experience.

We now intend to take this transformational learning process forward, further improving the quality of our training. By accelerating innovation, we aim to provide state-of-the-art solutions and the best possible learning experience in support of what we do.

Towards a learner-focused solution

Training and professional development are important to all personnel grades and at every stage in each individual's career path. Our "One LMS" project, launched in 2016, took a big step forward with the October 2017 rollout of the iLearn system, which aims to deliver on a set of strategic objectives:

- ensuring easy access to training for all our people;
- providing a single data source and analytical tool;
- improving the visibility of training solutions across the whole company; and
- understanding better how our investment in training is used and accessed, and what impact it has.

Our iLearn platform consolidates all our training packages in a single unified system. It was designed to enable Sanofi employees to access training any time and anywhere, so that they can supplement their hands-on experience and address the changing needs of our business.

Some of our training solutions have not yet migrated to iLearn, but full migration is scheduled to be completed in 2020. This is why not all of our data are comparable with the previous year.

	iLearn[a]	Learning Gateway[b]	Isotrain[c]	Syfadis[d]	Peps[e]	Foederis[f]	
	2018	2018	2018	2018	2018	2018	2017
Number of training modules	2,629	709	4,214	113	109,921	991	943
Number of employees trained	113,605	4,851	6,482	3,275	6,925	18,604	19,495
Total number of training hours	678,451	74,410	255,790	24,857	214,669	498,486	514,455

(a) iLearn delivers all compulsory and support function training programs:
- *Compliance: Ethics and Business Integrity, Pharmacovigilance.*
- *Quality.*
- *Workplace First-Aiders.*
- *Business, Management and Leadership Development.*

Subcontractors are included in the iLearn figures.

(b) Learning Gateway provides our North American employees with compulsory and technical training, alongside personal and professional development programs.

(c) Isotrain delivers training to Sanofi Pasteur employees in France, North America and Global R&D.

(d) Syfadis is a 100% online platform.

(e) Peps is a training system for our German employees.

(f) Foederis is a dedicated platform for employees located in France, and covers training in various areas (business, regulatory and cross-disciplinary).

4.1.2.4. Social dialogue

Labor relations within Sanofi are based on respect and dialogue. In this spirit, management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented. Social dialogue is structured differently from country to country, as local circumstances call for a differentiated approach. Information, consultation and negotiation processes may take place at national, regional or company level and may be organized on an interprofessional or sectoral basis, or both. Social dialogue may be informal or institutionalized, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and participate in decisions aimed at improving the way we work. These efforts reflect one of the principles of our Social Charter: that improvements in working conditions and the need to adapt to our environment go hand in hand.

Since 2015, Sanofi has applied a worldwide policy on freedom of association that applies to all employees; see the Vigilance Plan, Section 4.2.4.10, “Human rights”.

In Europe, Sanofi’s European Works Council (EWC), which includes 40 members and 40 alternates, represents employees who work in European Union countries. In 2018, the EWC met in May, June and November, to be informed about matters including financial results and performance; news about the company; the Vigilance Plan; the European General Data Protection Regulation; and the divestment of our European Generics business.

In addition, interim meetings with EWC officers provide an opportunity for regular or one-off briefings based on developments affecting Sanofi.

4.1.2.4.1. Social dialogue in France

The France Group Committee, made up of trade union representatives (25 members and 25 alternates), met in April, May and September 2018. During those meetings, the Committee was informed about matters including the strategic orientations of Sanofi; the R&D pipeline; the employment situation; the Vigilance Plan; the proposed sale of our infectious diseases research and early-stage development unit to Evotec; and the proposed divestment of our Generics business.

In 2018, Sanofi hired 923 people on permanent contracts in France (versus 995 in 2017), of whom 40% were aged below 30 and 6% were aged 50 and over.

Overview of collective agreements in France:

Six agreements were signed in 2018, including agreements relating to gender parity; jobs and skills planning; the length of time for which employees covered by the Pharmaceutical Industries collective agreement whose employment contracts are suspended due to non work-related illness can maintain their length of service record; and support measures for trade union representatives and delegates whose terms of office end or are reduced in 2018 or 2019. In addition, 13 amendments to existing agreements were signed with trade unions representing Sanofi employees in France, covering issues such as employee savings plans and healthcare and death/disability cover. In 2018, 100% of our employees in France were covered by collective agreements.

♦ Sanofi Aventis Groupe:

The main feature of 2018 was the negotiation of an agreement on the establishment of the Economic and Social Committee, a new employee representative body required under legislation introduced by President Macron. An agreement was signed on June 19, 2018, alongside a pre-electoral protocol paving the way for staff elections in October. The new body has been in place since November 2018.

Negotiations on a collective contractual termination agreement across the support functions began in December 2018.

♦ Sanofi Chimie:

At an extraordinary meeting of the Works Council to discuss strategic orientations for the 2018-2020 period, management announced its decision not to continue the Universal Corticosteroid Intermediate (UCI) development project, and to focus future production on soya as a growth medium. The aim is to secure the company’s position as an established player in the corticosteroids market in a fast-moving, highly competitive environment.

Employees at the Saint-Aubin-lès-Elbeuf site affected by this decision found an internal solution, or were offered end-of-career leave plans as allowed for in the agreement on benefits to offset difficult working conditions.

Negotiations that began at the end of 2017 led in early 2018 to the signature of an agreement on benefits to offset difficult working conditions within Sanofi Chimie.

Negotiations on the composition of the Central Economic and Social Committee led to the signature of an agreement with the CFE-CGC, CFDT and FO trade unions.

Negotiations on the establishment of the Central Economic and Social Committee and the Economic and Social Committees of individual Sanofi Chimie sites led to the signature of an agreement with the CFE-CGC and CFDT.

- Sanofi Winthrop Industrie (SWI):

Key features of 2018 included further new hires as stipulated in the majority agreement on support measures involving internal mobility and voluntary departures, and completion of the new hires announced in connection with the compulsory annual negotiations.

In parallel, SWI also initiated industrial optimization measures at its production and distribution facilities, in order to attain its performance objectives and protect its competitiveness.

- Sanofi Aventis R&D (SARD):

From March to June 2018, the SARD Central Works Council was informed and consulted about the sale of the Infectious Diseases Unit at the Marcy l'Étoile site to Evotec. The sale took effect on July 1, 2018, and led to the automatic transfer of the employment contracts of 98 employees under Article L.1224-1 of the French Labor Code. A collective agreement on transfer support measures was signed on June 22, 2018 by three of the four representative unions.

In September 2018, the SARD Central Works Council was informed and consulted about the company's economic and financial situation, and strategic orientations. In November 2018, it was informed and consulted about social welfare policy.

Negotiations about the establishment of an Economic and Social Committee began in September 2018 and ended with the signature of an agreement with the CFDT, CFTC and CFE-CGC trade unions on December 14, 2018. Staff elections are scheduled for March 2019.

- Sanofi Pasteur:

The flexibility agreements signed in 2017 were implemented on January 1, 2018. All workforce productivity objectives were attained. Business was stable during 2018, and headcount reflected this. There were no further projects requiring headcount reductions during the year, and the proportion of employees on non-permanent contracts fell.

- Sanofi Aventis France (SAF):

A key feature of 2018 was the completion of the information/consultation process relating to the transfer of SAF's Generics operations to a newly-created entity, Zentiva France. The legal transfers took effect in July, and Zentiva France was sold in October.

A second information/consultation process, which began in 2017, related to the integration of employees of the legal entity Genzyme SAS into SAF which took effect in January 2018.

4.1.2.4.2. Social dialogue in Germany

Employees are represented through the Works Council or the Employee Representatives Committee. Both bodies are affiliated to the German chemistry sector, and delegates are elected by the employees for a four-year term.

All discussions with these bodies are conducted with a view to striking a balance between the respective interests of the employees and the company.

During 2018, negotiations were conducted with these bodies on a range of issues:

- reorganization proposals for the Global Business Units, negotiated with both the local and central Works Councils;
- the divestment of the European Generics business, which was successfully completed;
- ongoing enhancements to our new systems (such as the Workday recruitment module and the One LMS learning management system), with the Central Works Council agreeing to the rollout of new functionalities;
- consultation with the Berlin Works Council on the introduction of part-time working for sales forces; and
- implementation of an agreement on the reintegration of employees on long-term sick leave, especially in Industrial Affairs.

As in previous years, Sanofi also participated in major initiatives in Germany to promote diversity and gender balance. We also conducted in-depth analysis of employee demographics, to help us anticipate future demographic challenges.

4.1.2.5. Employee health and well-being

"Take Care & Bwel!", Sanofi's employee wellness program initiated in 2012, aims to promote healthy lifestyles and prevent or delay the onset of chronic disease by focusing on four pillars: regular physical activity ("Move Often"), a balanced diet ("Eat Well"), sleep and stress management ("Feel Good"), and disease prevention ("Stay Healthy"). The program uses interventions developed with the help of in-house and external experts, and relies on dedicated resources and employee engagement.

By the end of 2018, the program had been rolled out in 59 countries (versus 47 in 2017) and at 136 sites (versus 125 in 2017) worldwide. Our goal is to continue expanding the program by supporting sites as they implement good practices. Other commitments made in 2017 included developing novel initiatives to help our employees make lifestyle changes. These initiatives incorporate ground-breaking mobile apps developed in collaboration with the European Institute of Innovation and Technology for Health. Implementing these measures at industrial, administrative and R&D sites in France, China, the United Kingdom and Spain has led to significant changes in sedentary and sleep behaviors.

4.1.2.6. Workforce

4.1.2.6.1. Year-on-year change

As of December 31, 2018, Sanofi had a total of 104,226 employees under contract, down 2.2% year-on-year.

Distribution of employees under contract by region

Employees under contract as of December 31	Worldwide		Europe		United States		Emerging Markets		Other Countries	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Employees under contract	104,226	106,566	46,256	48,358	13,434	13,810	38,672	38,401	5,864	5,997
%	100.0%	100.0%	44.4%	45.4%	12.9%	13.0%	37.1%	36.0%	5.6%	5.6%

Distribution of employees under contract by activity

Employees under contract as of December 31	Worldwide		Pharmaceuticals		Vaccines		Consumer Healthcare		Other[a]	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Employees under contract	104,226	106,566	67,364	69,946	14,918	15,217	10,300	9,834	11,644	11,569
%	100.0%	100.0%	64.6%	65.6%	14.3%	14.3%	9.9%	9.2%	11.2%	10.9%

(a) From 2017 the "Other" line includes employees of our global support functions (Medical Affairs, External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.), who were previously allocated between our Pharmaceuticals and Vaccines operating activities.

For the distribution of our workforce by function (production, R&D, sales forces, and marketing and support functions) see Note D.24., "Personnel costs", to our consolidated financial statements, included at Item 18 of our annual Report on Form 20F.

Workforce in main countries where Sanofi operates

Employees under contract as of December 31	Worldwide		France		United States		Germany		China		India		Brazil	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Employees under contract	104,226	106,566	25,215	25,427	13,434	13,810	9,355	9,322	9,159	8,714	5,285	5,181	3,772	3,795
% of total employees under contract	100.0%	100.0%	24.2%	23.9%	12.9%	13.0%	9.0%	8.7%	8.8%	8.2%	5.1%	4.9%	3.6%	3.6%

Distribution of employees under contract by type of contract, work time and gender

Employees under contract as of December 31	Worldwide		Europe		United States		Emerging Markets		Other Countries	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Distribution of employees under contract by gender										
Employees under contract	104,226	106,566	46,256	48,358	13,434	13,810	38,672	38,401	5,864	5,997
% women	46.2%	46.2%	48.2%	48.5%	50.3%	50.0%	42.9%	42.6%	42.0%	40.9%
% men	53.8%	53.8%	51.8%	51.5%	49.7%	50.0%	57.1%	57.4%	58.0%	59.1%
Distribution by type of contract, work time and gender										
Permanent contracts	88.0%	88.2%	94.0%	92.8%	99.7%	99.8%	75.7%	77.1%	95.7%	95.7%
% women	45.6%	45.6%	48.1%	48.4%	50.3%	50.0%	40.7%	40.4%	41.4%	40.2%
Temporary contracts	12.0%	11.8%	6.0%	7.2%	0.3%	0.2%	24.3%	22.9%	4.3%	4.3%
% women	50.0%	50.1%	50.3%	49.9%	51.4%	53.1%	49.7%	50.0%	56.3%	57.0%
Part-time employees	3,802	4,070	3,673	3,911	77	71	2	31	50	57
Full time equivalents	2,923	3,078	2,834	2,968	52	47	2	22	35	42
% women	87.9%	84.8%	88.0%	84.9%	85.7%	91.5%	50.0%	61.3%	87.6%	86.0%

Worldwide distribution of employees by managerial status

Employees under contract as of December 31	Worldwide		Non-manager		Manager[(a)]		Senior Leader[(a)]		Executive post[(a)]		Executive Committee	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
% women	46.2%	46.2%	47.4%	46.9%	40.7%	42.2%	35.4%	N/A	29.3%	27.5%	18.8%	14.3%
% men	53.8%	53.8%	52.6%	53.1%	59.3%	57.8%	64.6%	N/A	70.7%	72.5%	81.2%	85.7%

(a) See methodological note 4.3.5.5., "Definition of grades".

Distribution of employees under contract by age bracket

Distribution of employees under contract by age bracket	Worldwide	
	2018	2017
Under 21 years	0.2%	0.3%
21 to 25 years	4.9%	5.0%
26 to 30 years	12.0%	12.3%
31 to 40 years	31.0%	31.4%
41 to 50 years	29.6%	29.8%
51 to 60 years	20.1%	19.2%
Over 60 years	2.2%	2.0%

4.1.2.6.2. New hires and departures

New hires and departures by region[a] December 31	Worldwide		Europe		United States		Emerging Markets		Other Countries	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Employees under contract	**104,226**	**106,566**	**46,256**	**48,358**	**13,434**	**13,810**	**38,672**	**38,401**	**5,864**	**5,997**
Permanent staff[b]	88.0%	88.2%	94.0%	92.8%	99.7%	99.8%	75.7%	77.1%	95.7%	95.7%
Total number of new hires	14,639	13,927	4,769	4,572	2,005	1,319	7,276	7,034	589	1,002
of which permanent contracts	7,717	8,657	2,165	2,603	1,976	1,308	3,140	3,847	436	899
of which permanent contracts %	*52.7%*	*62.2%*	*45.4%*	*56.9%*	*98.6%*	*99.2%*	*43.2%*	*54.7%*	*74.0%*	*89.7%*
Total number of departures	17,173	14,507	7,030	3,404	2,304	2,695	7,061	7,913	778	495
of which permanent contracts	11,432	10,052	4,524	1,632	2,286	2,691	3,943	5,343	679	386
of which permanent contracts %	*66.6%*	*69.3%*	*64.4%*	*47.9%*	*99.2%*	*99.9%*	*55.8%*	*67.5%*	*87.3%*	*78.0%*
Resignation rate – permanent contracts[C]	5.1%	4.5%	1.9%	1.5%	8.3%	7.7%	8.3%	7.4%	5.6%	4.8%
Turnover – permanent contracts[d]	10.4%	10.0%	7.7%	4.7%	15.9%	14.6%	12.1%	15.5%	10.1%	11.2%

(a) Data on movements (new hires and departures) cover more than 99% of the reporting scope but exclude companies for which data on new hires and departures are not collected because they are not included in the Workday system. In addition, the data do not include in-house transfers.

(b) Employees on permanent contracts.

(c) Resignation rate on permanent contracts $= \frac{\text{Voluntary departures of permanent staff}}{\text{Total permanent staff at year-end}}$ *The resignation rate is not wholly comparable between 2018 and 2017, which explains the slight year-on-year increase in the rate. Refer to the methodological note in Section 4.3.4.*

(d) Turnover of employees on permanent contracts $= \frac{\text{(New hires of permanent staff + departures of permanent staff)/2}}{\text{Total permanent staff at year-end}}$

Sanofi hired 14,639 new employees in 2018, 52.7% of them on permanent contracts.

The main reasons for new hires were as follows:

- the integration of the employees of Ablynx, a biotechnology company based in Belgium engaged in the discovery and development of Nanobodies®;
- the integration of the employees of Bioverativ, a biotechnology company based mainly in the United States specializing in therapies for people with hemophilia and other rare blood disorders; and
- the integration of the employees of Protein Sciences in the United States.

Departures during the year (17,173 in total) related mainly to:

- Serio, an early retirement program specific to the United States, which began in 2017 and continued through 2018;
- the divestment of Zentiva, our European Generics business, to Advent International, which was completed on September 30, 2018 and led to the transfer of all 2,616 employees to the new owner. 85% of the transferred staff were based in four eastern European countries (Czech Republic, Slovakia, Romania and Poland). In addition to commercial subsidiaries, Zentiva operated two large production facilities (in the Czech Republic and Romania), which together represented 50% of the total workforce of Zentiva;
- in the United Kingdom, the sale of the Holmes Chapel industrial facility to Recipharm, the divestment of the Chapeltown logistics facility, and the reorganization of the Diabetes & Cardiovascular Global Business Unit;
- in Japan, the rollout of a voluntary redundancy program related to a slowdown in our Primary Care activities; and
- in France, the sale of the Infectious Diseases Unit at the Marcy l'Étoile site to Evotec.

Departures were due to resignations (40.0%), layoffs (45.2%), expiration of fixed-term contracts (11.9%), and retirement (2.9%):

Based on employees under contract as of December 31	Worldwide	
	2018	2017
Total number of departures	17,173	14,507
Resignations:	40.0%	39.2%
of which voluntary departures: fixed-term contract employees	32.4%	26.2%
of which voluntary departures: permanent contract employees	67.6%	73.8%
Layoffs	45.2%	45.2%
Expiration of fixed-term contracts	11.9%	12.7%
Retirement	2.9%	2.9%

Of the total number of resignations, 32.4% were voluntary departures of employees on fixed-term contracts (74.7% of which were in China, where new employment contracts are generally renewable fixed-term contracts) and 67.6% were voluntary departures by employees on permanent contracts, representing a 5.1% resignation rate for permanent contract employees. Turnover of permanent contract employees is 10.4%.

4.1.3. Environment

4.1.3.1. The Planet Mobilization roadmap

We have embarked upon an ambitious policy to limit the direct and indirect impacts of our operations on the environment through every stage of the life cycle of our products. We have identified five key environmental issues associated with our operations: greenhouse gas emissions and climate change; water; pharmaceutical products in the environment; waste; and biodiversity.

Back in 2010, we made ambitious commitments for our industrial and R&D sites: to reduce scope 1 and 2 CO2 emissions by 20% and water withdrawals by 25% (on a constant structure basis) by 2020.

Our existing initiatives are ongoing, but have been given fresh impetus through our Planet Mobilization program. Reflecting our broader environmental strategy, Planet Mobilization sets even more ambitious objectives for reducing environmental impacts across the entire value chain by 2025. Planet Mobilization is a company-wide project that calls upon all our people to support the objectives and engage with our external partners.

The table below summarizes the objectives:

Environmental issue	Planet Mobilization commitments 2015 – 2025	2018 progress versus:		Contribution to SDGs
		2017	2015 (baseline year)	
Carbon footprint (CO_2 emissions)	Industrial, R&D and tertiary sites for Scopes 1 & 2 (including medical rep fleet) 50% reduction in greenhouse gas emissions (CO_2 equivalent) by 2025 (relative to 2015)	-5%	-9%	**SDG 13:** Take urgent action to combat climate change and its impacts
	Achieve carbon neutrality in 2050 for emissions caused by our operations	Ongoing		
Water (withdrawal)	Industrial, R&D and tertiary sites 10% reduction in water consumption by 2020 (relative to 2015)	-8%	-14%	**SDG 6:** Ensure availability and sustainable management of water and sanitation for all
	Management plan at all sites (priority to those in water stress zones)	Ongoing		
Pharmaceutical products in the environment	Industrial and R&D sites Life cycle management plan	All chemicals facilities evaluated, pharmaceuticals sites ongoing		**SDG 12:** Ensure sustainable consumption and production patterns **ODD 12.4:** By 2020, achieve environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.
Waste	Industrial, R&D and tertiary sites Recycle/Reuse/Recover (3R) rate > 90% in 2025 (>80% in 2020)	2018: 73%		**ODD 12.5:** By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse
	Landfill disposal rate <1% in 2025 (<3% in 2020)	2018: 8%		
Biodiversity	Biodiversity awareness plan on all sites	Sanofi World Environment Day		**SDG 15:** Protect and restore terrestrial ecosystems, and halt biodiversity loss
	Risk evaluation and management plan at priority sites	1 pilot site under way		

4.1.3.2. Climate change and carbon footprint

Our strategy to address climate change focuses mainly on energy consumption, using low-carbon energy sources, and greenhouse gas emissions.

Sanofi's new ambition, aligned on "Trajectory 2°C", is to become carbon-neutral by 2050 in terms of emissions from industrial, R&D and administrative sites, and from medical rep vehicle fleets (Scope 1 & 2). Our intermediate goal is to reduce our CO_2 emissions by 50% by 2025 (from a 2015 baseline) for the same scope. Further proof of our commitment came in March 2018 when we signed up to the Science Based Target Initiative. We are also working to supplement our roadmap by setting priority objectives for reducing Scope 3 emissions. In addition, we are taking the lead role in a working group set up by the Pharma Environmental Group, a consortium of around 20 pharmaceutical industry players, to establish Carbon Scope 3 accounting methods for the pharmaceutical industry at a global level.

In 2018, we investigated the improvements needed to ensure compliance with TCFD (Task Force on Climate-related Financial Disclosures) requirements.

Our performance is also being evaluated via the Carbon Disclosure Project (CDP) using their Climate Change questionnaire. At the start of 2019 we obtained an A- rating, unchanged from the previous year, making us one of the highest-ranked pharmaceutical companies.

4.1.3.2.1. Energy

4.1.3.2.1.1. Improve energy efficiency and encourage the use of renewables

To address the challenges of diminishing fossil fuel resources and climate change, we have adopted a strategy based on the three objectives presented below:

4.1.3.2.1.1.1. Consume less

An energy conservation program has been implemented at all our sites, with a specific focus on the air treatment systems that ensure high-quality environments in manufacturing and R&D buildings. These systems are some of our biggest users of energy, accounting for up to 70% of energy consumption at some of our pharmaceutical and vaccine manufacturing sites. Since 2013, an energy performance management tool has been in place at all our industrial sites to identify potential reductions in energy consumption. At the start of 2016, we held our first-ever energy performance workshop at our Injectables site in Maisons-Alfort (France). A total of 13 joint workshops have now been held. They have become a powerful lever for developing robust energy-saving plans for our sites, and for effective knowledge-sharing about workshop methodology and energy efficiency.

Our energy efficiency approach extends to all our activities including our medical rep vehicle fleets, decisions on how we transport our products, and the architectural and functional design of new buildings.

4.1.3.2.1.1.2. Consume smarter

We use tools at our industrial sites that enable us to factor in the total cost of equipment ownership, especially for those items where energy costs represent the highest proportion of total cost of ownership (motors and lighting). In 2012, we signed a master service agreement with Engie to install high efficiency cogeneration units and/or heat production units at our European sites. In 2013, the term of the agreement was extended to 2017 and its scope was expanded to include sites in China, Latin America and North America. Cogeneration units went live in 2016 at four sites in Italy (Origgio, Anagni, Brindisi and Scoppito) and in Germany (Cologne). "Blue-Print", an energy cost reduction program developed through an enhanced partnership with energy supplier Engie, was launched in 2018, initially at five major sites.

4.1.3.2.1.1.3. Consume differently (use renewables)

As part of our strategy to reduce greenhouse gas emissions, whenever we call for tenders on energy-buying contracts we consider using renewable energies, based on risk/opportunity analyses (risk of supply outages versus economic opportunities) and financial criteria.

4.1.3.2.1.2. Energy consumption

Energy consumption (MWh)	2018	2017
Natural gas	2,164,781	2,208,829
Electricity[(a)]	1,574,225	1,609,254
Renewables[(b)] (electricity and biofuels)	41,872	41,673
Other energy sources (bought-in steam, waste-to-energy)	460,893	426,527
Total	4,241,771	4,286,283

(a) Includes the country-level energy mix but excludes renewable electricity from Sanofi in-house projects.
(b) Includes renewable electricity from Sanofi in-house projects.

We reduced our energy consumption by 1% relative to 2017.

At the end of 2018, we launched a global low-carbon electricity policy through our procurement department. This policy falls within our Planet Mobilization program, and seeks to promote renewable energy through corporate power purchase agreements (PPAs) to create solar and wind power sources.

4.1.3.2.2. Greenhouse gas emissions

4.1.3.2.2.1. Emissions linked to energy consumption: Scope 1 & 2

The Planet Mobilization project sets more ambitious targets for reducing Scope 1 & 2 emissions, including our industrial, R&D and tertiary sites but also our medical rep vehicle fleet: we are targeting a 50% reduction by 2025 from the 2015 baseline, with an interim target of a 25% reduction by the end of 2020.

Greenhouse gases (tonnes of CO_2 e)[(a)]		2018	2017
Scope 1	Direct emissions	578,579	611,405
	Medical rep vehicle fleet emissions	*98,334*	*125,930*
Scope 2	Indirect emissions	376,098	391,293
Total		**954,677**	**1,002,698**

(a) CO_2 e = CO_2 equivalent

Direct and indirect CO_2 emissions were 5% lower in 2018 than in 2017. Specifically, CO_2 emissions from our medical rep vehicle fleet fell by 22%. This reduction was made possible by eco-driving action plans, and new rules on vehicle selection.

Compared to 2015 (the baseline year for the Planet Mobilization program), direct and indirect emissions linked to energy consumption (Scopes 1 & 2) are down 9%.

4.1.3.2.2.2. Indirect emissions: Scope 3

Scope 3 was calculated for the 15 categories listed in the Greenhouse Gas (GHG) protocol. Eleven of those categories are significant, and six of them accounted for over 90% of our Scope 3 greenhouse gas emissions in 2018. The 21% increase in Scope 3 emissions in 2018 relative to 2017 is mainly due to Category 1 (Purchased Goods and Services), and in particular outsourced manufacturing of pharmaceutical products.

Scope 3 (tonnes of CO_2e)[(a)]	2018 vs. 2017	% of 2018 emissions	2018	2017
Category 1: Purchased goods and services[(c)]	The 39% year-on-year increase in emissions reflects a 26% rise in the quantity of bought-in products (outsourced manufacturing of pharmaceutical products doubled, largely as a result of the integration of Boehringer Ingelheim). The metrics for this category are subject to considerable uncertainty, especially as regards modelling the impact of outsourced manufacturing. We are hoping to upgrade this model in 2019, and improve our knowledge of the environmental impact of our main suppliers.	44%	4,024,003	2,883,850
Category 2: Capital goods[(c)]	This relates to emissions generated to produce capital goods purchased by Sanofi, and fell in 2018.	7%	619,972	708,993
Category 3: Fuel and energy-related activities[(c)]	This category is related to Scope 1 and 2 energy consumption levels, and is on a downtrend due to action plans already in place (see Section 4.2.3.2.1, “Energy”).	4%	370,315	377,687
Category 4: Upstream transportation and distribution[(c)]		2.5%	225,382	172,395
Category 5: Waste generated in operations[(c)]	This category includes emissions arising from the treatment of solid or liquid waste generated, handled or controlled by or under the control of Sanofi.	4%	371,036	417,021
Category 6: Business travel[(c)]		1.5%	136,452	111,439
Category 7: Employee commuting[(c)]		2%	161,037	167,823
Category 9: Downstream transport and distribution[(b)(c)]	This category consists of transportation and storage not directly managed or operated by Sanofi, such as patients driving to pharmacies or cold storage of vaccines; the figures show a slight year-in-year reduction of 4%.	11%	983,559	1,021,046

Scope 3 (tonnes of CO_2e)[a]	2018 vs. 2017	% of 2018 emissions	2018	2017
Category 10: Processing of sold products[c]		1%	115,755	111,722
Category 11: Use of sold products[c]	The 42% increase in emissions in this category is directly dependent on the quantity of injectables and vaccines that need to be administered by medical personnel, which rose by nearly 30% in 2018.	21%	1,935,412	1,359,430
Category 12: End-of-life treatment of sold products[c]		2%	175,565	198,853
Total[d]		**100%**	**9,118,488**	**7,530,260**

(a) CO_2e = CO_2 equivalent.
(b) Qualitative improvement in metrics.
(c) Change in activity levels.
(d) GHG Protocol emission categories 8 and 13 (upstream and downstream leased assets) and 14 (franchises) are not material. We consider Category 15 (Investments) to be non-applicable, since emissions relating to products and services bought and sold in this way are already included in the other categories.

4.1.3.2.3. Adapting to the consequences of climate change[1]

Extreme weather events caused by climate change could present a risk both to our production facilities and to our supply chain, right up to delivery of our products to patients. To guard against these risks, our facilities are constructed to the highest standards, using state-of-the-art engineering techniques and taking maximum constraints into account in the design phase. In addition, during site visits, technical experts from our insurers issue recommendations for dealing with extreme weather conditions, such as putting in place emergency flood risk plans. Risks related to natural disasters are taken into consideration in our crisis management plan, across all levels of our production sites and supply chains.

Climate change has direct impacts on health as a result of weather events, heat waves or severe cold snaps, food shortages, difficulties accessing clean drinking water, and the increased atmospheric pollution it causes. It also has indirect effects, for example by intensifying and spreading vector-borne diseases or exacerbating the allergenic potential of pollens.

As a global healthcare leader, we tackle issues raised by climate disruption and its health impacts through initiatives involving various internal stakeholders including our Global Business Units and Global Support functions, alongside country-level teams:

- continuing R&D activities in a number of diseases sensitive to climate swings such as sleeping sickness and malaria;
- exploiting the potential of our product portfolio and collaborating actively with a range of organizations and institutions to distribute medicines to patients affected by diseases sensitive to climate swings such as malaria, sleeping sickness and leishmaniosis;
- providing aid to communities suffering humanitarian crises due to extreme weather events, especially through initiatives led by the Sanofi Espoir Foundation; and
- raising awareness among our stakeholders such as our employees, healthcare professionals and patients.

4.1.3.2.4. Raising awareness about climate-related health challenges

We are committed to working on the issue of climate disruption and raising awareness among stakeholders about its impact on health. In 2015 we set up an advisory board of climate and health experts tasked with identifying the challenges related to climate change and health, and ensuring that we have a coherent strategy. As a sign of our commitment, Sanofi was an official partner of the 21st Conference of the Parties (COP 21) at the United Nations Framework Convention on Climate Change that took place in Paris during November and December 2015. To coincide with COP 21, our CEO joined 38 other French business leaders in signing a call for action to curb climate change. This commitment was reiterated in December 2017 with the publication of the French Business Climate Pledge, at the international One Planet Summit hosted by France. The pledge reaffirmed the desire to reduce the effects of climate change by limiting the rise in temperatures to 2°C by 2100. We publicly share our achievements in limiting our environmental footprint on a regular basis, and our strategy for anticipating the health impact of climate change in areas such as pollution-related allergies and vector-borne diseases like dengue and malaria.

We are also working on several programs for climate-sensitive diseases, including:

- fine-tuning an oral treatment for sleeping sickness;
- developing a novel cell-culture yellow fever vaccine specifically for Latin America; and
- research into new malaria treatments to counter potential resistance.

4.1.3.3. Water management

4.1.3.3.1. Water resource management plan

Water is a key component in our industrial operations. We need it to keep our factories running, and it is an integral part of the manufacturing process for medicines. We are committed to managing this resource responsibly, and pay particularly close attention to sites identified as sensitive in terms of water use.

(1) This paragraph contains the information required under the application decree of Article 173 of French law no 2015-992 on energy transition for green growth.

Utility services (such as process and cooling systems) are by far the biggest users of water at Sanofi. Water is primarily used as a vector for calorific transfer (cooling and heating) in the manufacturing processes for our products, from chemical synthesis to vaccine manufacture.

Water is also used directly in chemical and pharmaceutical production, whether as an ingredient at the synthesis or formulation stage or to clean equipment and networks between production cycles. In such cases, a range of water treatment processes are in place at each site to guarantee a very high degree of purity prior to use.

Further investigations have been carried out based on our own local data and a comprehensive independent review. This has enabled us to fine-tune our list of sites potentially at risk from water scarcity and those where additional investigation is needed at local level to confirm the situation.

Following a more in-depth analysis of local conditions, the list of sites was updated in 2017. Only four sites are still considered to be priority at-risk sites: Brindisi (Italy), Vertolaye (France), Karachi (Pakistan) and Jakarta (Indonesia). A further 13 sites are on the watch list.

Our internal HSE standards require all of our sites to create and follow a water management plan. In addition, our internal rules require any sites at potential risk from hydric stress to establish and comply with a plan for reducing water consumption that is tailored to the site's local context and industrial characteristics. This reduction plan must set appropriate goals for reducing water consumption and ensure they are monitored, in association with any specific investments.

Each site that is located in a hydric stress zone or uses more than 1 million m3 of water a year must prepare a specific study that documents and classifies the actual level of risk exposure. Based on the findings of the study, actions plans must then be drawn up to reduce the probability of adverse events and mitigate the likely effects.

Since 2014, we have been revising and fine-tuning our approach at potentially water-sensitive sites, taking into account the volume of water withdrawn by the site and the local hydric stress situation.

A new hydric stress study, looking at the current situation and future projections, was initiated at the end of 2018, with results expected in early 2019.

Together, these sites consume 6.9 million m3 of water, or 19% of Sanofi's total water consumption.

4.1.3.3.2. Water consumption

Water used during manufacturing (for fermentation in particular) and heat exchange (cooling for processes, with no contact with manufacturing) is essentially withdrawn directly by Sanofi from underground or surface bodies of water. We have specific operating procedures for effectively managing our use of water, and for reducing our consumption through moderation and recycling.

Water consumption (m^3)	2018	2017
Withdrawal of surface water (lakes, rivers, etc.) (millions of m^3 per year)	9.1	9.0
Withdrawal of groundwater (millions of m^3 per year)	20.3	23.5
Withdrawal of water from public supply (millions of m^3 per year)	7.7	7.7
Total (millions of m^3 per year)	**37.1**	**40.2**

Water consumption fell by 7.7% in 2018 relative to 2017. This was mainly due to various local energy efficiency programs, which reduced the amount of water used for cooling. For example, the chemical production site at Brindisi in Italy, one of our biggest consumers of water, managed to cut withdrawal by 24% in 2018.

Measured against the environmental commitments in our Planet Mobilization program, we withdrew nearly 14% less water in 2018 than in 2015, the baseline year.

4.1.3.4. Managing pharmaceutical products in the environment

The management of pharmaceutical products in the environment throughout their life cycle is one of our Planet Mobilization commitments, adding to commitments previously made in 2010. We apply a global approach, focusing on three key areas:

- deepening our understanding of the environmental impact of our products, by analyzing their potentially hazardous properties and evaluating the risk to the environment of their use by patients. We are looking beyond regulatory assessments – which apply mainly to new medicines – to proactively assess the impact of all of the products we sell, starting with our strategic products. Our efforts in this field are being supported by research partnerships with various stakeholders, including universities and other manufacturers. To date, we have proactively assessed 55 of our products;
- encouraging appropriate use of medicines, especially antibiotics. This involves awareness campaigns directed at healthcare professionals and/or patients. Using medicines properly not only improves patient health, it also helps the environment: correct diagnosis, prescription and dispensing, followed by good therapeutic observation and proper disposal of unused medicines, all reduce the impact of waste medicines on the environment; and
- helping to implement collection programs for unused or date-expired medicines. To this end, we have developed a list of tips for patients on "What to do with your unused medicines".

For a description of how we manage emissions and discharges from our production and R&D operations, see section 4.2.4.8., "Environmental releases".

4.1.3.5. Waste management

The key to our waste management policy is to reduce waste generation at source, followed by a systematic examination of recycling possibilities before waste is disposed of in any other manner. We have set further objectives out to 2025 as part of Planet Mobilization: to reach a reuse/recycle/recovery (3R) rate of over 90%, and to reduce the rate of landfill disposal to 1%.

4.1.3.5.1. Waste management principles and programs

Inspired by the circular economy, each site manages its waste according to the following principles:

- reduce waste at source;
- reuse, recycle or recover on-site or with selected contractors;
- incinerate, with energy recovery wherever possible; and
- send waste to landfills as a last resort, provided that the landfill is properly regulated and monitored. Landfills used for hazardous waste are required to be audited annually, and those used for non-hazardous waste every three years.

Our waste management standards include procedures to categorize and identify waste generated by each process, and then to collect, sort, store, transport and treat each type of waste appropriately. In addition, we keep records of all waste management documents to ensure traceability up to final treatment.

Prior to engaging a new waste contractor, the contractor's qualifications, competence and compliance with regulations are thoroughly verified for each class of waste.

Integrated country-wide waste management approaches have been implemented in those countries where we have our biggest industrial footprint or where the potential synergies are greatest (for example France, Canada and the United States).

4.1.3.5.2. Waste generated

Hazardous waste (tonnes)	2018	2017
Hazardous waste recycled or incinerated with thermal recovery	85,361	86,899
Hazardous waste incinerated without thermal recovery or sent to authorized landfills	40,049	55,746
Total	**125,410**	**142,645**

The 12% reduction in hazardous waste volumes in 2018 relative to 2017 is due partly to changes in activity patterns, but also to the first full-year effects of the new onsite biological waste treatment plant at our Elbeuf site (France) and to a 29% reduction at our Vertolaye plant (France) due to onsite waste treatment using activated carbon.

Sending hazardous waste to landfill is used only as a last resort when local incineration plants are unavailable, or for dry soils.

Non-hazardous waste (tonnes)	2018	2017
Recycled non-hazardous waste	91,642	90,062
Non-hazardous waste incinerated with thermal recovery	18,846	28,320
Non-hazardous waste incinerated without thermal recovery	12,929	17,103
Non-hazardous waste sent to authorized landfills	19,008	20,532
Total	**142,425**	**156,017**

We generated 9% less non-hazardous waste in 2018 than in 2017. This was mainly due to reduced activity levels at our fermentation facility.

Overall, total waste generated by Sanofi was 10% lower than in 2017.

Building waste is not included in the data reported above, although we make every effort to maximize post-treatment recovery of such waste.

4.1.3.5.3. Initiatives to reduce food waste

Many of our industrial, R&D and tertiary premises in France have already taken measures to cut food waste in three key areas:

- Reducing waste at source. This is promoted by enforcing precise contractual specifications on portion size and conducting regular surveys, especially in advance of periods when canteen footfall is expected to be low.
- Responsible food management. This includes matching quantities to needs and using just-in-time techniques for some outlets; charging users for bread so that users do not automatically take bread without eating it; reducing the range of options available towards the end of mealtimes; and charging users by weight for items such as salad and prepared fruit.
- Managing leftovers and waste. This is helped by recovering leftover vegetables for reuse the next day; introducing sort bins to facilitate recycling of waste; and setting up food donation agreements with charities to help the needy.

We also conduct regular awareness campaigns at our French sites. These include weighing leftovers (especially bread) and informing canteen users of the results, using sort bins as a hook for campaigns about the benefits of sorting waste, and sharing information about good practice in preventing food waste.

4.2. Statement of extra-financial performance and vigilance plan

4.2.1. Overview

4.2.1.1. Statement of extra-financial performance (SEFP)

The statement of extra-financial performance required under Articles 225-102-1 and R. 225-104 to R. 225-105-2) of the French Commercial Code must present:

- the business model for the group of companies for which the reporting entity prepares consolidated financial statements;
- to the extent necessary to an understanding of the reporting entity's situation, of trends in its business, of its economic and financial results and of the impacts of its operations: information about how the reporting entity takes account of the social and environmental consequences of its operations, and about the effects of those operations on human rights and the fight against corruption and tax evasion;
- and for each of the categories mentioned above:

  (1) a description of the principal risks associated with the operations of the reporting entity or group, including where relevant and proportionate the risks created by its business relationships, products or services;

  (2) a description of the policies applied by the entity or group, including any reasonable due diligence implemented to prevent, identify and mitigate the risks mentioned in item (1);

  (3) the results of those policies, including key performance indicators.

A cross-reference table showing all the information required in the SEFP, including the presentation of the business model, is provided in an appendix, "Corporate social responsibility cross-reference tables".

4.2.1.2. Duty of vigilance (DV)

Law no. 2017-399 of March 27, 2017 on the duty of vigilance of parent companies and companies acting as principals (the "Duty of Vigilance Law") introduced into the French Commercial Code a duty of vigilance for parent companies of groups that employ at least 5,000 people in France or 10,000 people worldwide.

This duty of vigilance requires such companies to establish, implement effectively and disclose "reasonable vigilance measures capable of identifying risks and preventing serious violations of human rights and fundamental freedoms and serious harm to the health and safety of people and to the environment". Such measures must apply to subsidiaries, subcontractors and suppliers with which the reporting entity has an established commercial relationship.

The measures must be formally documented in a Vigilance Plan, which must be publicly disclosed and included in the entity's annual report, along with a report on the effective implementation of those measures. Vigilance measures include risk mapping; procedures for evaluating the value chain; mitigation and prevention measures; alert reporting mechanisms; and systems for monitoring the effective implementation of those measures.

A cross-reference table showing all the information required by the duty of vigilance is provided in an appendix, "Corporate social responsibility cross-reference tables".

4.2.2. Methodology for selecting major risks and issues

Sanofi believes that the risk identification principles applied for SEFP purposes and those applied for duty of vigilance purposes do not wholly overlap. Consequently, we conducted two risk identification exercises in parallel, using the same basic methodological framework but applying criteria specific to each of the two pieces of legislation. Risk identification for SEFP purposes sought to take account of the impacts on Sanofi and its stakeholders, while for the duty of vigilance the emphasis was on the impacts on people and the environment.

This means that although the risk mapping exercises are complementary and to a large extent overlap, there are some risks that are specific to just one of the two pieces of legislation. All these risks, and the related policies and action plans, are presented in Section 4.2.3., "Presentation of risks and issues" and Section 4.2.4., "Policies, action plans and performance indicators".

4.2.2.1. Statement of extra-financial performance (SEFP)

The principal SEFP risks were identified by our Corporate Social Responsibility (CSR) department, in collaboration with our Risk Management department, on the basis of Sanofi's list of global risks. The list of principal risks was then validated by the Sanofi Risk Committee.

To determine which risks have a CSR dimension due to their importance to external stakeholders, we used responses to questionnaires alongside checklists of issues regarded as material by extra-financial ratings agencies and socially responsible investors. We drew up four distinct matrices, one for each extra-financial risk category defined by law: social and societal, anti-corruption, human rights, and the environment. For each risk, we applied the Sanofi risk management methodology to assess the seriousness of the impact for Sanofi, the probability of occurrence, and the seriousness of the impact for stakeholders. The risks with the highest ratings were identified as Sanofi's principal risks for SEFP purposes, and are presented in the table shown in Section 4.2.3. below.

Issues relating to health and safety at work were not identified for SEFP purposes, but are described in this report in connection with the Duty of Vigilance Law (see Section 4.2.4.7., "Employee health and safety"). Human capital was not identified as an issue for SEFP purposes, but is presented in this report (see Section 4.1.2. above) given its importance for Sanofi's strategy.

4.2.2.2. Duty of vigilance (DV)

As early as 2016, we set up a working group to identify and analyze internal actions associated with our approach to vigilance on human rights, health and safety, and the environment. The results showed that some issues were already being addressed, but that in some cases further action was needed to strengthen our existing policies. We drafted an action plan in late 2017, and began rolling it out in 2018.

Our methodology involved three steps:

- identify major issues inherent to the sector in which we operate;
- classify and evaluate, at business unit and support function level, the criticality of the risks associated with each major issue;
- evaluate the level of control over those risks, and prepare action plans to manage them.

In identifying major risks to people or the environment, we applied a sector-based approach to identify which of our stakeholders are potentially affected and our major vigilance issues. For this, we drew largely upon feedback on our existing policies and internal processes, and in particular:

- our "Human Rights in our Activities" guide;
- our policy, reinforced in 2017, of identifying the highest-risk categories of purchases and hence of suppliers; this involves allocating each category a score in terms of inherent risk (to human rights, health and safety, and the environment), and then weighting that score to reflect country risk.

Based on this analysis, backed up by external data (sourced from industry initiatives, international research studies and a peer benchmarking exercise), we were able to identify major vigilance issues relating to the protection of patients, our employees, the environment, and local communities. These vigilance issues are related to Sanofi's activities, whether we carry out those activities ourselves or through our direct commercial relationships.

For each of the issues identified, we assessed our existing risk management actions against criteria such as the existence and implementation of a policy (from definition of the commitments underpinning the policy, through to controls over its application) or of a company-wide action plan. Based on this assessment of the level of control, we were able to rank the residual risk and establish adequate action plans.

The vigilance plan covers the operations of Sanofi and of entities fully consolidated by Sanofi for financial reporting purposes, as well as the operations of our Tier 1 suppliers and subcontractors.

4.2.3. Presentation of risks and issues

The table below shows the risks and issues selected for Sanofi's statement of extra-financial performance (SEFP) and duty of vigilance (DV).

Category	Field or activity	Regulation	Description
Social and societal	**Pricing policy**	SEFP	Risk that our pricing policy will not align on the expectations of certain stakeholders and/or the market, undermining our social commitment to patients and the healthcare system.
	Product quality(*)	SEFP	Risk that we will fail to comply with good clinical, laboratory, manufacturing, distribution and pharmacovigilance practices and other regulatory requirements relating to product quality through the entire life cycle of our healthcare products.
	Product safety for patients and consumers(*)	SEFP & DV	Risk of product safety breaches, from first administration in clinical trials on humans through to the end of the product's life cycle.
	Medical ethics and bioethics(*)	SEFP	Risk that we will breach the ethical standards and principles that are essential to conducting our scientific and medical activities responsibly.
	Biopiracy(*)	DV	Risk that we will fail to respect state sovereignty or the intellectual property rights of indigenous peoples when obtaining patents and commercializing endemic resources identified as a result of bio-prospecting traditional practices and know-how.
	Personal data protection(*)	DV	Risk that the integrity, confidentiality or accessibility of personal data will be compromised.
	Employee health and safety(*)	DV	Risk that we may fail to provide a safe work environment and cause harm to our employees, suppliers or subcontractors, with immediate or future consequences for their health.

Category	Field or activity	Regulation	Description
Environment	Environmental releases(*)	SEFP & DV	Risk that discharges and emissions from our industrial and R&D operations will pollute the environment or adversely impact human health, or will not be appropriately managed by our own staff or by our suppliers or subcontractors.
	Use of water resources	DV	Risk that we will withdraw too much water relative to the capacity of the ecosystem and the needs of other users, especially the most vulnerable.
Actions to support human rights	Human rights(*)	SEFP & DV	Risk that human rights will be breached as a result of our operations, or those of our suppliers or subcontractors.
Combatting corruption and tax evasion	Business ethics and integrity(*)	SEFP	Anti-corruption: risk of non-compliance with the laws and regulations applicable to our operations in jurisdictions where we do business, in particular those relating to combatting and preventing corruption and fraud; and also of non-compliance with pharmaceutical industry codes of conduct or our own values and ethical policies.
	Tax policy	SEFP	Risk of non-compliance with applicable tax laws and regulations, resulting in failure to pay the appropriate amounts of taxes and duties as they fall due, in countries where we operate.

* *Indicates risks that apply not only to our own operations, but also to those of our suppliers, subcontractors and partners. See Section 4.2.4.13, "Procurement and subcontracting", for measures taken to manage risks within our supply chain relating to employee health and safety, environmental releases and human rights.*

4.2.4. Policies, action plans and performance indicators

4.2.4.1. Pricing policy

Improving access to healthcare involves various strands, but pricing policy and the affordability of products, treatments and associated services are crucial. The other strands are developing new products, treatments or services through R&D and innovation, and reinforcing local healthcare capabilities. For a discussion of how these issues are addressed for underserved populations, see Section 4.1.2., "Access to healthcare for the underserved".

In a highly competitive environment where payers are subject to tight budgetary constraints, decisions by governments and health authorities, and cost reduction measures, have a growing influence on the pricing and reimbursement of our products. In response, Sanofi is committed to:

- addressing increased scrutiny of the value and price of medicines, whether by the general public or external stakeholders, by clearly explaining the value that underpins how a product is priced; and
- improving affordability and offer solutions to access issues by adopting differentiated approaches in developed countries and emerging markets.

4.2.4.1.1. Organization

The mission of our global Market Access and Pricing teams is to ensure optimal access to each drug we sell, at a price that reflects the value of the product and conditions in the target market. Our Pricing team has its own Innovation Unit, running projects to help overcome barriers to access through innovative pricing differentiation strategies for populations with different economic circumstances and innovative types of contract. This team works closely with our global and local sales teams, and where necessary collaborates with external stakeholders in developing solutions to address identified needs.

In 2017, Sanofi created a new Global Health organization as part of the reorganization of our Access to Medicines department. To deliver on its mission of improving access to healthcare, this new organization works with a wide range of partners including the WHO and other international bodies, private donors and charitable foundations, R&D partners, NGOs, and health ministries.

4.2.4.1.2. Policies, action plans and performance indicators

Given the growing concerns over rising healthcare costs, our approach to pricing reflects our continued efforts to support patient access while minimizing our contribution to healthcare cost inflation.

This is why we have laid down principles for prescription medicine pricing, especially in the United States. The United States is our largest market, representing 33.5% of our annual net sales, and is unusual among mature markets in that the authorities do not impose price controls.

Our pricing principles were first published in May 2017, and updated in May 2018 and February 2019. They are available at: www.sanofi.us/en/corporate-responsibility/access-to-healthcare.

4.2.4.1.2.1. Prescription medicine pricing

We are committed to making our treatments accessible and affordable for all patients, including the most vulnerable. Our pricing principles embody that commitment, while also enabling us to continue to expand scientific knowledge and develop innovative medicines and treatments.

Sanofi's prescription medicine pricing principles focus on three key areas:

- clear rationale for pricing on a worldwide scale when we launch a new medicine;
- limited price increases for our medicines in the United States; and
- transparency around our gross and net prices in the United States.

4.2.4.1.2.1.1. Clear rationale for pricing on a worldwide scale when we launch a new medicine

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers the following factors:

- a holistic assessment of value, including:
  1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care;
  2) economic value, or how the medicine reduces the need – and therefore costs – of other healthcare interventions; and
  3) social value, or how the medicine contributes to quality of life and productivity.
- similar treatment options available or anticipated at the time of launch in order to understand the landscape within the disease areas in which the medicine may be used;
- affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payers and healthcare systems; and
- unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials at the request of regulators or to reinforce understanding of the product (e.g. long-term studies), or develop patient support tools that improve care management and help decrease the total cost of care.

4.2.4.1.2.1.2. Limited price increases for our medicines in the United States

Should we take a list price increase on one of our medicines, our guiding principle is to limit the total annual increase to a level at or below the projected US National Health Expenditure (NHE) growth rate for that year, as estimated and published annually by the Centers for Medicare & Medicaid Services (CMS).

Should we take a price increase above the NHE growth rate for a given medicine that results in a list price increase greater than $15 for a full course of treatment per year, we will provide our rationale, highlighting clinical value, real world evidence, regulatory change, new data, or other circumstances that support our decision.

- Projected US NHE growth rate for 2017: 5.4%

During 2017, we increased the price of 29 of our 85 prescription medicines:

- 28 of those increases were below the projected NHE growth rate for 2017 of 5.4%;
- only one medicine had its price raised by more than the projected NHE growth rate. This was the quadrivalent influenza vaccine Flublok®. The rationale for the price rise was a recent evaluation of clinical efficacy data which demonstrated that Flublok® offered substantial advantages in preventing symptomatic influenza, giving 30% greater efficacy in persons aged 50 and over relative to standard dose quadrivalent influenza vaccine.

- Projected US NHE growth rate for 2018: 5.3%

During 2018, we increased the price of 35 of our 76 prescription medicines. All those price increases were in line with our pricing principles.

4.2.4.1.2.1.3. Transparency around our prices in the United States

Our policy reflects a desire both to help our stakeholders better understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines. The data we provide may help illustrate how pricing changes accrue to manufacturers versus others in the value chain, highlighting that manufacturers are just one player in the broader US healthcare environment.

While list prices (gross prices) often receive the most attention, they are not the prices typically paid by the insurers, employers or pharmacy benefit managers (PBMs) who purchase our medicines on behalf of patients. We negotiate significant discounts and rebates with these payers, to ensure greater access and affordability for patients. That negotiated price is the net price. Net prices more accurately reflect the prices we are paid as the manufacturer, and are the most accurate gauge to measure effective price increases.

However, the level of discounts and rebates varies, and is often not visible to patients. It is important to note that decisions on patient cost-sharing and the number of patients entitled to discounts are ultimately made by payers, not manufacturers. Simply put, the out-of-pocket payments made by patients depend on how the plan is structured and the extent to which the negotiated discounts are passed on to patients.

This is why we have committed to publish annually the overall increase or decrease in our gross (list) prices and net prices in the United States:

Year	Aggregate annual change in average list price[(a)]	Aggregate annual change in net price[(a)]
2016	+4.0%	-2.1%
2017	+1.6%	-8.4%
2018	+4.6%	-8.0%

(a) For the entire portfolio of Sanofi prescription medicines.

4.2.4.2. Product quality

4.2.4.2.1. Organization

Sanofi's dedicated Global Quality function is dovetailed with our Global Business Units and support functions, our country-level organizations and manufacturing platforms, and is consistent with our corporate values.

Global Quality is headed up by the Chief Quality Officer, who is directly accountable to Sanofi's Chief Executive Officer for developing and implementing our Quality policy. The Chief Quality Officer is also a member of Sanofi's Global Industrial Affairs Board, Risk Committee and Compliance Committee.

Global Quality implements our Quality policy across the entire life cycle (from discovery and development to manufacture, distribution and commercialization), for all the product families in the Sanofi portfolio: active pharmaceutical ingredients, prescription and over-the-counter medicines, vaccines, medical devices (including apps and hybrid products), nutritionals and cosmetics.

It ensures that harmonized quality standards are applied worldwide, so that we can comply with regulatory requirements and our own internal rules and deliver on our commitment to allow patients access to safe, effective products that meet public health needs.

At the operational level, quality managers are appointed at each site and each sales office. Their role is to manage and control the way in which the principles of the Sanofi quality management system are implemented, so that we can sure that our products meet quality and regulatory standards.

4.2.4.2.2. Policy and action plan

The fundamental principles of Sanofi's Global Quality policy are set out in a document signed jointly by our Chief Quality Officer and our Chief Executive Officer. This policy document is made available to all our employees in all countries. The latest version was revised and approved in September 2017, and is available in 27 languages.

The structure and key processes of our quality management system are described in the Sanofi Quality Manual, which must be applied by everyone at every level in our organization. The Sanofi Quality Manual includes the following processes:

- product life cycle processes: research, lab trials, medical and clinical trials, manufacturing and distribution;
- transverse processes: documentation management, improvements to products and processes, training and certification, management of third-party suppliers, information system management;
- organizational processes: quality system management, quality audit, quality risk management.

Our quality management system has built-in flexibility, so that it can incorporate specific quality standards to address rules specific to each field in which we operate. In line with our overall principles of risk management and continuous improvement, we constantly adapt our quality management system in anticipation of regulatory changes and to ensure an optimal response to Sanofi's strategic objectives for innovation, simplification and refocusing.

The Sanofi quality management system is wholly in line with the requirements described in guideline Q10, "Pharmaceutical Quality System", published by the International Council on Harmonization (ICH). It incorporates all good practice rules – Good Clinical Practice (GCP), Good Distribution Practice (GDP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Pharmacovigilance Practice (GPVP) – as well as other requirements relating to human health.

Our Quality Policy and Quality Manual are the cornerstones of our quality commitment, as regards both our regulatory compliance obligations and our obligations to patients. They serve as vectors to ensure that our quality management principles are fully deployed within Sanofi, and are central to our vision of Quality culture.

Practical measures taken to implement the Sanofi quality management system include:

- Our Global Business Units, sites, countries and Global Support Functions are subject to regular audits to check that they are complying with our quality management system. The audits are conducted by a dedicated Global Quality Audit team; a risk-based approach is used to determine the frequency and duration of audits, and the number of auditors involved. They also help prepare Sanofi business units and support functions for regulatory inspections, and to make sure that they are meeting all their regulatory requirements and commitments.
- Throughout the physical journey undertaken by Sanofi products, we maintain the same levels of quality, security and traceability.

  To do this, we use technology to protect our products against attempts at misappropriation, counterfeiting or falsification. These include tamper-proof packaging, authentication stickers to combat counterfeiting, and data matrix codes for traceability.

  And at every stage in the logistics chain, Sanofi ensures that products are stored, transported and delivered in appropriate conditions compatible with maintaining product quality.
- Quality risk management is integral to Sanofi's control and governance de system. This means we can take appropriate decisions and provide assurances to regulators about our ability to anticipate and prevent potential crises.

  Our approach addresses risk both reactively and proactively. In reactive mode, we deal rapidly and efficiently with any quality issue, deploying corrective actions and adequate preventive measures.

  In proactive mode, we monitor internal and external information sources to identify potential risks that have not yet materialized so that we can take preventive measures.
- Sanofi has identified the quality culture as an essential factor in our corporate performance and in delivering on our strategy.

  We promote quality as a core value through our Quality Academy, which offers training programs to help ensure that our people are always properly trained and qualified.

4.2.4.2.3. Performance indicators

- Internal audits

  Internal audits conducted by Global Quality teams: 210 in 2018 (206 in 2017).

- Regulatory inspections
  Inspections conducted by regulatory authorities: 279 in 2018, with no enforcement actions (such as a warning letter from the US Food and Drug Administration or a *lettre d'injonction* from French regulator ANSM), versus 302 inspections in 2017.
- Quality Academy
  A total of 80 quality training modules were developed or updated in 2018, 24 of which used digital techniques like virtual visits and videos. The Academy also made available 13 courses training employees for quality-related jobs.

4.2.4.3. Product safety for patients and consumers

Sanofi develops, manufactures and sells a vast portfolio of healthcare solutions around the globe, from prescription medicines and consumer health products to vaccines and medical devices. We are obliged to meet legal and regulatory requirements on the safety of products through their entire life cycle, from research to end use, and also to:

- protect patient health by monitoring the safety of our medicines and constantly assessing the benefit/risk profile of our products;
- supply physicians, healthcare professionals and patients with full and up-to-date safety information, including potential risks associated with a product;
- report to the regulatory authorities on a timely basis, in accordance with international and local regulatory requirements and our own Global Quality standards.

4.2.4.3.1. Organization

Sanofi's Global Pharmacovigilance (GPV) function is headed up by the Chief Safety Officer (CSO). The CSO reports to the Chief Medical Officer (CMO), responsible for medical affairs worldwide, who in turn reports directly to our Chief Executive Officer. These direct lines of communication ensure that information flows directly and rapidly to Sanofi's decision-making bodies, especially in the event of a potential or actual public health crisis.

GPV is Sanofi's center of excellence for assessing and monitoring the benefit/risk profile of our entire product portfolio at a global level. The Sanofi portfolio consists of a diverse range of therapeutic solutions, mainly comprising ethical prescription medicines, biological medicines to treat rare diseases and cancer, consumer healthcare medicines, vaccines, and medical devices. Sanofi also offers various ranges of generics products.

All pharmacovigilance activities relating to the use of the portfolio report to GPV. Staff from GPV are involved at all stages of the product life cycle, from pre-development to the end of the commercialization cycle.

To meet the expectations of the supervisory authorities, patients and healthcare professionals, GPV has specialist scientific and medical teams for each therapeutic range. These multi-disciplinary teams prepare the supporting evidence needed for monitoring the benefit/risk ratio and for identifying and assessing potential warning signals, and for implementing risk minimization measures. We use a pragmatic, evidence-based benefit/risk approach that protects patients and consumers by ensuring that our scientific communications are transparent, robust and credible.

GPV also has full-time access to teams of pharmaco-epidemiologists, reporting to Global Medical Affairs, who are responsible for establishing the methods and/or scientific rationale to be applied in evaluating the efficacy, risk, benefit and use of our medicines in real-life situations, over large patient populations or via specialist databases.

4.2.4.3.2. Policies and action plans

GPV proactively monitors national and international regulations and recommendations, and draws upon a worldwide network of local and regional managers trained in pharmacovigilance. GPV provides a range of services to this network including resource allocation and budgeting, monitoring of good practices, regulatory compliance, training, and access to the tools needed for them to fulfil their duties in accordance with quality standards.

Sanofi systematically aligns on the most exacting standards of Good Pharmacovigilance Practices. Those standards also apply to clinical trials and clinical programs that are not directly conducted by Sanofi, and to collaborative projects with NGOs.

We also have a worldwide documentation architecture in place, to ensure that all our pharmacovigilance activities comply with official regulations.

Looking beyond regulatory compliance, Sanofi is closely involved in many international initiatives including scientific consortia, international pharmaceutical industry associations, and professional networks working on predictive pharmacovigilance scenarios.

Pharmacovigilance is a constantly changing field, whether scientifically and medically or in terms of data processing. To ensure that we continue to apply best practice in the changing landscape, we have made significant strategic changes to our pharmacovigilance governance structure. We have identified the following strategic areas as having the highest priority:

- deploying an individual skillset development model so that our pharmacovigilance staff are up to speed with the latest regulatory and scientific practices, and qualified to meet future needs;
- an ambitious technological development plan to automate and apply artificial intelligence to pharmacovigilance data. We regard this as a pre-requisite for managing not only the growing volume of data but also the diversity of data sources, including social media and patient support programs;
- a structured approach to evaluating the benefit/risk profile, relying if necessary on population-based epidemiological statistics in conjunction with the pharmaco-epidemiology unit within Global Medical Affairs;
- optimizing the mechanisms used to detect and evaluate potential safety signals associated with the use of our products; and
- setting up a new outsourced platform dedicated to the monitoring of mature products or therapeutic classes. This model is being adopted so that we can focus our in-house resources on high-priority tolerance issues for the products we regard as the most critical in terms of patient needs and regulatory requirements.

4.2.4.3.3. Performance indicators

Safety signals assessed	2018[a] (excluding Zentiva)	2018[a] (including Zentiva)	2017
Total safety signals	255	339	362
of which PRAC/HA signals[b][c]	*110*	*178*	*167*

(a) Period: January-November 2018.
(b) PRAC = Pharmacovigilance Risk Assessment Committee of the European Medicines Agency; HA = Health Authorities.
(c) The difference between total safety signals and PRAC/HA signals represents signals derived from the Sanofi Pharmacovigilance database.

4.2.4.4. Medical ethics and bioethics

Our business requires us to conduct scientific and medical activities, so that we can develop new healthcare solutions and make them available to patients. This means we must impose high ethical standards upon ourselves to protect the patients enrolled in our clinical trials, safeguard the integrity of scientific research, and carry on medical activities in a responsible manner.

We must also ensure that our practices are consistent across the entire organization by establishing a common definition and framework for bioethics, promoting a responsible culture, and anticipating and monitoring emerging bioethical issues. Sanofi policies in this area, which require approval from our Bioethics Committee, are prepared with reference to current laws and regulations, societal trends, and industry guidelines, and those issued by leading bodies in the field such as the Council for International Organizations of Medical Sciences (CIOMS) and UNESCO (United Nations Educational, Scientific and Cultural Organization). We also have a duty to ensure that external stakeholders, healthcare professionals, patients and the scientific community are informed about our R&D and medical activities. More specifically, we must show transparency in clinical trial protocols and results, the sharing of clinical data, and publication of scientific papers.

4.2.4.4.1. Organization

Sanofi Bioethics Committee

Sanofi set up an internal Bioethics Committee in 2012 to ensure that we conduct our research and clinical trials in compliance with high ethical standards, and in the interests of constant improvement. The Committee is chaired by our Chief Medical Officer, who reports to our Chief Executive Officer.

In 2017, we performed a review of our bioethics governance. The aim was to take greater account of stakeholder expectations and improve transparency. The main outcome was the decision to form a new Advisory Bioethics Council (ABC), consisting mainly of independent members with acknowledged expertise in bioethics, to give advice on key bioethics issues so that Sanofi can improve its practices. Sanofi is committed to taking account of their recommendations, and to explaining the position adopted on issues that will be examined by our Board of Directors. The existing Bioethics Committee will continue to establish Sanofi's position on bioethics, and ensure that its policies are implemented operationally. Another decisive outcome of the review was a reaffirmation of Sanofi's determination to move towards greater transparency on clinical trials and on policies adopted by the Bioethics Committee.

The new ABC was set up in 2018 and has seven members, three women and four men. All are independent bioethics specialists, drawn from different generations. They have varied university backgrounds (medicine, law, philosophy), and work in Europe, Asia or North America. The ABC met for the first time in November 2018, and will continue to meet through 2019.

Animal ethics

An Animal Ethics Advisory Committee was set up at the end of 2017 under the direction of Sanofi's Chief Veterinary Officer (who is a permanent member of our Bioethics Committee) to address issues of public concern relating to the use and welfare of animals. The Committee meets quarterly to determine guidelines and positions adopted by Sanofi on animal use and welfare, and ensure they are compatible with international recommendations. For example, it has developed a common position on the use of non-human primates for research and quality control purposes.

The Chief Veterinary Officer is responsible for liaising with animal dealers, vets and site-level Ethics Committees.

4.2.4.4.2. Policies and action plan

4.2.4.4.2.1. Medical ethics and clinical trials

Clinical trials are a mandatory part of the approval process for any new drug. Their purpose is to collect data about the efficacy and safety of products in healthy subjects and patients. Sanofi organizes clinical trials all over the world, including in developing countries and emerging markets. Clinical trials may also be carried out post-marketing to develop new indications for a drug, or monitor its safety.

When implementing and monitoring clinical trials anywhere in the world, Sanofi applies international standards: the Declaration of Helsinki, the recommendations of the International Council for Harmonization (ICH), and in particular Good Clinical Practices (GCP). In addition to those international standards, Sanofi complies with all national and international rules and laws applicable to clinical trials including European Directives 2001/20/EC (on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, published in Official Journal L 121 of May 1, 2001, page 34, as amended in 2006 and 2009) and 2005/28/EC (laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products, published in Official Journal L 91 of April 9, 2005, pages 13-19); the CFR21 regulations issued by the US Food and Drug Administration (FDA); and the regulations issued by the Japanese Ministry of Health, Labor and Welfare (MHLW).

Sanofi ensures that all participants enrolled in clinical trials (or their legal representatives) give their free and informed consent. Consent must be given before any procedure or intervention required by the study protocol is carried out on a participant, and before any data are collected. All documents related to clinical trials, in particular the consent form, must comply with applicable legislation and must provide participants with exhaustive, easily understandable information. To simplify the consent form supplied to participants and reflect recent major changes in the ethical landscape (especially in terms of informed consent), our teams use an internal reference document that is subject to regular review.

Sanofi has for many years implemented an internal audit program covering clinical trials, associated systems and any subcontractors involved in the conduct of trials. The aim is to obtain assurance that the conduct of trials complies with our quality standards and the applicable regulations, and to continually improve our practices. Our audit program is designed to cover trials conducted in various countries and regions around the world.

Sanofi is also subject to health authority inspections to ensure that we are complying with ethical standards and legislation.

4.2.4.4.2.2. Medical ethics and transparency of medical and clinical data

We are committed to being transparent about our medical research and to providing healthcare professionals and patients with all useful information about our development projects and products so that they can make informed medical decisions. This applies not just to information provided in advance of clinical trials (as described in Section 4.2.4.4.2.1., “Medical ethics and clinical trials”), but also to the sharing of the data generated by those trials.

Sanofi abides by the principles on the responsible sharing of clinical trial data, adopted by PhRMA and EFPIA members in July 2013 (www.phrma.org/about/codes-and-guidelines). In addition to those core principles, a new policy on sharing and transparency of clinical data was adopted by our Bioethics Committee in 2017. Our commitments are described (and fully accessible) on our corporate website.

4.2.4.4.2.3. Animal welfare

As a global healthcare leader focused on patient needs, we are morally and legally obliged to ensure the quality, safety and efficacy of our medicines, vaccines, medical devices and consumer health products. Over and above regulatory requirements, the responsible use of animals is essential in the research and production process. An example of our proactive approach is our objective of obtaining certification for all our sites in 2020 from AAALAC International, an internationally-recognized body. Animal testing is a small but integral part of our global research and analytical control strategy, which also includes non-animal methods and clinical research.

We are committed to complying with regulations and standards on the use and welfare of animals, and to developing alternative approaches. We also subscribe fully to the “3Rs” (Replacement, Reduction and Refinement) principle on the use of animals in research and production. This means that (i) we do not use animals unless there are no adequate alternative methods that can achieve the same purpose (replacement); (ii) we minimize the number of animals used to the extent compatible with good science (reduction); and (iii) we minimize pain and suffering through good housing and husbandry (refinement). Sanofi uses animals only if the scientific and regulatory case for animal experimentation has been clearly established, and within strict ethical guidelines.

We promote an “animal welfare culture”, the core value of which is to adopt a responsible approach to animal testing. Where animals are necessary, we commit to following high-quality programs for their welfare and use.

Our animal protection policy means that we encourage a shared vision of how we treat animals across our organization. In line with our long-standing commitment to the “3Rs”, this policy applies to all animals used by Sanofi for research; testing and producing medicines; investigational medicines; vaccines; medical devices; and active ingredients. This policy also applies to those who breed, supply and transport animals for use in research, trials or production, and to third parties who use animals under our instruction.

Our in-house laboratory animal experts carry out periodic audits of third-party suppliers to make sure that they are complying with the principles of our animal protection policy.

4.2.4.4.3. Performance indicators

4.2.4.4.3.1. Medical ethics and clinical trials

None of the 72 inspections conducted on our clinical research activities in 2018 resulted in regulatory action.

4.2.4.4.3.2. Transparency of medical and clinical data

- **Sharing clinical data:** 60 clinical trials were registered and 62 clinical trial results posted in 2018. These data are accessible to the public.

  Between January 1, 2014 and December 31, 2018, Sanofi received 69 requests from 12 countries to share data relating to 176 clinical trials. Of those 176 clinical trials:

  Data sharing was approved for 56 clinical trials:

  – data from 28 clinical trials were released under a data sharing agreement (the research projects involved are ongoing or completed), 5 of which have led to publication;

  – data from 6 clinical trials are being prepared for sharing; and

  – for the other 22 clinical trials, data sharing agreements have been rejected or abandoned by the researchers making the request.

  A total of 104 clinical trials have been excluded from the data sharing program for legal and/or data protection reasons. Reasons for exclusion may include: Sanofi is not the sponsor of the clinical trial; Sanofi is not legally entitled to share the data; or it is not possible to provide adequate protection for patients’ personal data.

  Finally, 16 clinical trials are being assessed for a potential data sharing agreement.

- **Scientific papers published in 2018:** 664 scientific and medical papers sponsored or signed by Sanofi were included in the PubMed database, which referenced over 5,200 journals in 2018.

4.2.4.4.3.3. Animal welfare

The acquisitions of Ablynx and Bioverativ in 2018 brought two more sites that use laboratory animals into the Sanofi scope of consolidation. One industrial site closed following the replacement of testing on rabbits with an alternative method that does not use animals (in line with the "3Rs" principle). At the end of 2018, 18 Sanofi sites in eight countries were using animals. Of these, 14 have obtained accreditation from AAALAC International, an internationally-recognized body, and one more is awaiting a decision on initial accreditation.

In 2018, 49 contracted research organizations or universities conducting tests on animals, and nine suppliers of animals and animal-derived products were subject to an evaluation and required to comply with our animal welfare principles (there were no critical discrepancies).

Reduction in the number of animals used by Sanofi over the last four years (2013-2017): 25.6%.

4.2.4.5. Biopiracy

Sanofi is committed to complying with conventions on the protection of biodiversity and combatting biopiracy, and in particular to respecting the intellectual property rights of indigenous populations. We monitor our compliance with international standards by carrying out due diligence and conducting investigations, for example when we use a new product developed from natural sources by Sanofi R&D.

Other risks of adverse impacts on local communities include the environmental impact of our operations, and in particular risks relating to environmental releases (see Section 4.2.4.8.) and to the use of water resources (see Section 4.2.4.9.).

4.2.4.6. Personal data protection

For Sanofi, it is essential that we protect the personal data of our employees and of patients, healthcare professionals and other partners with whom we interact. This is especially important in light of current developments in information and communication technologies.

Sanofi operates a global privacy and personal data protection policy that applies to all our activities (see Item 3. – "Risks relating to legal and regulatory matters" in our 2018 Annual Report on Form 20F). We are committed to protecting personal data and to use them only as permitted by currently applicable legislation.

The term "personal data" refers to any information liable to establish a direct or indirect link between an individual and an identification number or at least one factor specific to that individual's social, cultural, economic, mental, physiological or physical identity (examples include name, date of birth, social security number, physical characteristics, e-mail address, computer ID, and genetic or health-related information).

4.2.4.7. Employee health and safety

Sanofi has a risk management framework. Our Global Health, Safety & Environment (HSE) function applies a methodology and reporting process to guarantee that all significant HSE risks are identified, flagged and managed. The aim of this mapping process is to obtain a comprehensive overview of the level of control over the principal HSE risks to which Sanofi is exposed.

Results of HSE risk assessments are collated in a summary document at site level.

Each site has a comprehensive risk evaluation program covering all its activities. Sites systematically identify all HSE hazards and evaluate the associated risks and effects. The evaluation methodology aims to identify and quantify hazards and assess the level of risk in light of the extent to which the risk is controlled.

Depending on the nature of the site, some of the following issues may be more relevant than others:

- process safety and risk of explosions;
- fire risks;
- exposure to natural disasters (assessed with insurers if necessary);
- work-station risks;
- road safety;
- asphyxiation risks;
- biological risks;
- occupational disease risks; and
- environmental risks.

Each type of risk evaluation has its own methodologies, scope, and tools for determining priorities and acceptability (usually in the form of a risk matrix).

Risk evaluations are reviewed annually, and whenever there is a material change.

In deciding which risk mitigation techniques to use, the following hierarchy of preventive measures is used:

- firstly, elimination/substitution;
- secondly, prevention and/or protection using technical or organizational measures;
- and finally the use of collective (or failing that, individual) protection measures.

Results from the evaluations are collated in a summary document, which identifies all types of risk associated with the site or activity and determines an acceptable level of risk. Mapping is then used to prioritize those risks for action.

Risk mapping is carried out an a full scope basis, both on initial preparation and in subsequent updates; it is signed off by management at site and business unit level.

Each site establishes and maintains its own emergency response plan, adapted to reflect site-specific risks and the internal or external resources that would be deployed or called upon in response to those risks.

Special case: sites with "Seveso" classification (major risks):

The five European sites classified as Seveso III establishments have specialized response resources, implemented by standby crews and employees who have received second response training.

The chemical manufacturing sites in Aramon, Sisteron and Vertolaye (France), the facilities at our industrial platform in Frankfurt am Main (Germany), and our chemical production facility in Budapest (Hungary) are all classified as Seveso III (from the name of the European directive relating to potentially hazardous sites, providing a list of activities and substances and

the associated classification thresholds). In accordance with French law on technological risk prevention, the three French sites mentioned above are subject to more stringent safety inspections due to the toxic or flammable materials stored on the sites and used in their operating processes.

4.2.4.7.1. Organization

The HSE department, which is responsible for managing HSE risks, covers all business segments and all geographies, and the entire life cycle of Sanofi products. Its remit is to set up processes to control HSE risks and impacts and embed the Sanofi HSE culture at all levels of the organization, in a spirit of constant improvement.

In deploying the HSE strategy, our global HSE organization is based on three pillars, all under the direction of our Global Head HSE:

- global expertise: the global expertise functions support the activities of Sanofi and its partners by providing scientific and technical expertise, and develop global strategies;
- Business Partners: the HSE Business Partners within the Global Business Units (GBUs), R&D and Industrial Affairs are tasked with implementing specific strategies and monitoring performance;
- regions: regional HSE managers provide operational support aligned on global and business-specific strategies and on local regulations.

The global HSE function is backed up by:

- a dedicated HSE department within each of our industrial, research and tertiary sites, representing around 700 employees in total across 45 countries who run and implement HSE programs at site level;
- professional firefighters, at sites where this is required (such as those classified as “Seveso” because of hazardous substances); and
- occupational health services, either in-house or outsourced, offering medical coverage appropriate to the nature of occupational risks. Internationally, the HSE department has a leadership team of eight Key Medical Doctors (KMDs), based in the regions of the world where we operate, who develop and harmonize occupational risk prevention and medical surveillance activities within Sanofi in compliance with local regulations. In France, a collective agreement on the creation of an occupational health service at Sanofi has been in operation since it was approved in November 2015. The aim is to standardize medical surveillance of our employees by increased coordination of medical services, without impairing the independence of occupational physicians.

Our HSE department heads up a number of expert committees that assess the impacts and hazards of substances and biological agents (see Section 4.2.4.7.5.2.1., “Managing risks associated with manufactured substances”).

Sanofi also has in-house analytical laboratories, such as the Aramon laboratory in France staffed by a team of experts. Their occupational health role includes classifying people’s level of exposure to active substances. From a safety standpoint, they assess hazards associated with processes, and classify types of dust and equipment. The Aramon laboratory also develops specific analytical methods.

4.2.4.7.2. Policies and action plan

As a global healthcare player, we are committed to providing a safe and healthy workplace for all employees and contractors working at our sites, while minimizing the environmental footprint of our activities and products. To deliver on this commitment, Sanofi has developed an HSE strategy based on a management system that is consistent with the issues faced by the company in its activities, and involves the whole organization. The policy is established by our HSE department and signed off by our senior management.

All of Sanofi’s activities are subject to regulations, and also to ever-growing expectations on the part of stakeholders, in the field of HSE. To address these challenges, and to reiterate our commitment to our employees and to the environment, we issued an updated HSE policy in May 2017. The policy was signed by our Chief Executive Officer, and was issued and promoted to all our activities throughout the world.

A cornerstone of the Sanofi HSE strategy, this policy is integral to our commitment to corporate social responsibility.

In implementing the policy, Sanofi has defined a series of HSE ambitions for 2025, which are being applied across all of our activities with a focus on four key areas:

1. Encourage change in attitudes to safety within Sanofi: a unified safety culture means we can commit to protecting life by ensuring that all our people enjoy safety in the workplace and arrive home safe and sound every day.
2. Make Sanofi a healthy community: protect the health of everyone working at Sanofi, by developing programs like “Take Care & Bwel!” that attract people to join us and encourage them to stay.
3. Minimize our environmental footprint: leverage our Planet Mobilization strategy to make Sanofi a beacon of corporate environmental management.
4. Strengthen HSE as a partner of our business operations: using HSE programs and transverse cooperation, transform HSE challenges into opportunities for our businesses and in our markets.

In all sites and all countries, our HSE department has established a framework that covers all aspects of HSE: safety in the workplace, process safety, occupational health, and protection of the environment. These documents are reviewed on a regular basis, and distributed on all Sanofi sites.

The framework includes regulatory requirements and internal rules, the results of risk/opportunity analysis, and expectations on the part of stakeholders – including customers, NGOs, investors and civil society – and is translated into a set of compulsory standards and methodological guides.

The HSE department carries out regular audits of Sanofi entities and subcontractors to check that the rules established centrally are being applied locally. Information relating to the audit process is set out in Section 4.2.4.7.4., “HSE compliance and audit” below. In addition, all assignments performed by the HSE department to establish, implement and check the application of HSE policy may be subject to audit by our Internal Audit department.

4.2.4.7.3. HSE training and awareness initiatives

We invest in training and awareness programs designed to embed environmental protection, and the prevention of health and safety risks, into everything we do.

In general, each new joiner receives initial HSE training appropriate for their job profile so that they can perform their work in strict compliance with the rules. Depending on their jobs, employees may then follow other training modules specifically related to what they do (such as eco-driving for medical and sales reps, or chemical risks for employees handling chemical products).

Founded in 2012, the Sanofi HSE Academy enables all employees to access the training programs developed and approved by our HSE department (other than regulatory training).

Number of participants[(a)]	2018	2017
Leadership training	7,610	2,912
Technical training	1,802	1,211
Driver training	3,096	3,329
Other e-learning modules	1,733	159

(a) The total number of participants may be higher than the total number of employees. For example, if one employee takes part in three training sessions, that counts as three participants.

In 2018, we rolled out a new "Managerial Safety Visits" program across all our sites worldwide, along with new e-learning modules (including a safety module) at our logistics centers.

4.2.4.7.4. HSE compliance and audit

In addition to the regulatory watch role carried out by our global experts within their sphere of competence, individual sites also monitor local HSE regulations and compliance with local administrative and HSE requirements.

4.2.4.7.4.1. Internal audit

The HSE department runs audit programs to assess compliance with internal HSE rules.

The purpose of these audits is to:

- help our sites and activities establish HSE priorities and action plans;
- measure site performance against our internal rules and regulatory requirements;
- provide senior management with an objective and documented overview of how HSE policy is being applied, and of the performance of our sites and subsidiaries;
- identify, promote and organize good practices developed by our sites and subsidiaries; and
- check that HSE management systems and HSE programs are being implemented.

These HSE audits are performed throughout the year by Sanofi Lead Auditors certified by the International Register of Certified Auditors (IRCA). The Sanofi Lead Auditors are supported by other staff members who have recognized HSE experience and have followed a dedicated training program accredited by IRCA. Some of our internal auditors have individual IRCA accreditation.

Alongside the audits organized by the HSE department itself, some Sanofi Internal Audit team members have received HSE audit training so that they can incorporate HSE issues into their general audits.

	2018	2017
Number of internal HSE audits, including Biosafety	50	47
Number of auditors with IRCA accreditation	27	25
Number of auditors involved in audits	87	85

Through our HSE policy and internal audits, we encourage adherence to our HSE standards, which are specifically tailored to our activities. By complying with these standards, sites may if they wish obtain official recognition of their commitment through international certifications: ISO 14001 (Environmental Management) and OHSAS 18001 (Occupational Health & Safety).

To further our commitment to energy management, we also encourage our sites to obtain ISO 50001 (Energy Management).

Similarly, we have been tightening our road safety policy since 2017 by encouraging our sites to obtain ISO 39001 (Road Traffic Safety).

International standards	Number of sites certified in 2018
ISO 14001 (Environmental Management)	46
OHSAS 18001 (Occupational Health & Safety)	29
ISO 50001 (Energy Management)	25
ISO 39001 (Road Traffic Safety)	2

In addition to internal verifications and audits, Sanofi sites are also subject to regular inspections by local authorities and to regulatory verifications by third parties on specific issues. For example, 217 visits were carried out by technical experts on behalf of Sanofi's insurers during 2018.

4.2.4.7.5. Workplace health and safety programs

We have rigorous policies to identify and evaluate safety risks and to develop preventive measures, and methods for checking their efficacy. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Preventive measures are designed primarily to reduce the number and seriousness of occupational injuries and to minimize the exposure of permanent and temporary Sanofi employees as well as our subcontractors.

The health and safety programs followed by Sanofi employees are based partly on an analysis of the risks associated with the substances we manufacture (including active ingredients and medicines), and partly on the nature of the work done by all employees and contractors at our sites.

4.2.4.7.5.1. Occupational injury prevention programs

4.2.4.7.5.1.1. Preventing occupational injuries

Each project, whether in research, development or manufacturing, is subject to evaluation procedures incorporating the data on substances and on chemical and biological processes issued by the COVALIS and TRIBIO committees, as described in Section 4.2.4.7.5.2.1., "Managing risks associated with manufactured substances". Risk assessments of processes and installations are drawn up according to standards and internal guidelines that incorporate the best state-of-the-art benchmarks for the industry and international standards. Particular attention is paid to any risk-generating changes, such as process or installation changes, as well as changes in production scale and transfers between industrial or research units.

Sanofi has implemented a sophisticated real-time monitoring tool that alerts management as soon as possible after an accident has occurred, and tracks frequency rates. A monthly report is issued to operational managers, and a quarterly report is sent to the Chief Executive Officer and the Executive Committee members.

Periodic analysis of occupational injuries is used to guide the implementation of specific preventive programs, both locally and globally.

These programs may include technical, organizational and human measures. The Sanofi "Safety Culture" program urges all employees to take an active interest in their own safety and that of their colleagues by raising their awareness of the hazards and risks in their day-to-day environment and in their tasks, actions and practices.

The program encourages employees to flag up dangerous situations and near misses, alongside safety inspections and the sharing of good practice.

Topic	Ambition	Progress 2018	Progress 2017	Contribution to SDGs
Health and safety in the workplace				
Decent work	– Reduce the total occupational injury frequency rate (any employee) below 2 by 2020	2.4	2.7	**SDG 8: Decent work and economic growth**
	– Reduce the lost time injury frequency rate (any employee) below 1.4 by 2020	1.8	1.9	**SDG 8.8:** Protect labor rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment.

4.2.4.7.5.1.2. Prevention of serious or potentially serious accidents

Our HSE department has established criteria for determining the potential seriousness of occupational accidents. This has enabled us to take more targeted action to reduce the number of potentially serious accidents, and to take human and organizational factors into account for an in-depth analysis of such accidents. The ultimate aim is to focus our efforts on ways to prevent potentially serious accidents, rather than simply reacting after the event. Potentially serious accidents are systematically identified and reported, and are subject to in-depth analysis.

We have also taken steps to reinforce our preventive measures and fine-tune the analytical methodology used to assess the root causes of serious or potentially serious accidents. The goal is to prevent any recurrence of these events, and to gradually embed a safety culture for all Sanofi employees, independent contractor staff and temporary staff.

4.2.4.7.5.1.3. Learning from experience (LEX)

To achieve further improvements in accident prevention, we have set up a learning from experience process aimed at achieving the following objectives:

- identify the contributing factors of incidents by going back to the root causes;

- prevent recurrence by analyzing past events, taking corrective action and sharing lessons from the experience;
- improve performances across the board by changing operating methods, sharing good practice, and taking account of all technical, human and organizational factors through collective in-depth analysis of incidents;
- value the positive contribution made by operational staff to the safety of work tasks, operations and installations.

Learning from experience is based on a dedicated reporting datasheet (known as LEX Alert or Vigilance) containing an analysis of the incident, the immediate and root causes, and actions to be taken (some of which, if the issue is serious enough, will have to be completed within a specified time-frame). The datasheets are prepared by experts and disseminated through the entire HSE network, and to operational and site managers (R&D, industrial and administrative).

A total of 36 datasheets were distributed in 2018.

4.2.4.7.5.1.4. Road safety

In 2018, each of our subsidiaries throughout the world bolstered its road safety program with joint initiatives by HSE managers, sales managers designated as “Road Safety Chair”, and vehicle fleet buyers. To persuade drivers to take more care at the wheel, we used a video with the message that if we treat other road users as we would treat our nearest and dearest, we naturally change our behavior, saving lives by driving more responsibly. The video was shown to our sales teams worldwide, to raise awareness that we can take control of our own safety.

Hands-on training courses offered every three years help sales forces improve their techniques for emergency braking and driving in slippery conditions, and to better assess safe distances, while practicing on a closed track in a safe environment. Similar courses adapted for motor-cyclists have been used in countries like India and Vietnam. These initiatives are backed up throughout the year by online courses to refresh awareness of key road safety principles. A pilot scheme in Turkey used a virtual coach to let medical reps analyze their journeys and provide them with feedback on how to drive more safely.

In April 2018, during a ceremony at the Carrousel du Louvre in Paris attended by senior executives from Sanofi, our Road Safety Committee presented awards to the best-performing medical reps (from Brazil, France, India and the United Kingdom), to regional managers (from India, Kazakhstan and Ukraine) and to HSE managers (from Spain, Greece and India) in recognition of their exemplary attitude to road safety.

4.2.4.7.5.1.5. Occupational injury indicators

	2018	2017
Lost time injury frequency rate[(a)] – Sanofi personnel	1.6	1.6
Lost time injury frequency rate[(a)] – any employee[(b)]	1.8	1.9
Total occupational injury frequency rate[(c)] – Sanofi personnel	2.2	2.3
Total occupational injury frequency rate[(c)] – any employee[(b)]	2.4	2.7
Number of deaths[(d)]	0	0
Number of occupational diseases reported	**21**	**30**

(a) Number of accidents resulting in lost time of one day or more within a 12-month period, per million hours worked. For non-mobile personnel, accidents occurring during the home-workplace commute are not included in this indicator. However, they are included for travelling medical reps, in accordance with reporting rules. In the interests of comparability, the figures for 2017 have been restated to reflect the scope of the Sanofi group at the end of 2018.

(b) “Any employee” includes Sanofi employees, temporary workers and subcontractors.

(c) The total occupational injury frequency rate represents the number of reported occupational injuries with and without lost time within a 12-month period, per million hours worked. Occupational injuries without lost time are those that meet certain severity criteria established by Sanofi to distinguish them from accidents that required no more than first aid, which are not logged as reportable accidents.

(d) Although outside the scope of reported accidents, two deaths occurred in 2018 involving employees traveling by taxi or minicab (one in the USA, the other in Japan).

The majority of lost time injuries are due to employees falling or slipping, or to accidents while travelling. A new campaign was launched in 2018 to prevent accidents of this kind.

The number of occupational diseases is decreasing.

We have decided not to publish the severity rate calculated using the criteria defined by French regulations. Because this rate is calculated solely on the basis of the number of days of lost time, it does not reflect the actual severity of injuries from an international standpoint. This is because for a given injury, the number of days of lost time may vary considerably from one country to another depending on the applicable regulations and compensation systems. Consequently, we have decided to publish the total occupational injury frequency rate. This indicator takes into account occupational injuries with and without lost time (i.e. all serious accidents), thereby avoiding the discrepancies arising from country-specific regulatory systems as mentioned above.

4.2.4.7.5.2. Health programs

4.2.4.7.5.2.1. Managing risks associated with manufactured substances

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continually assess the effects of products on human health, especially that of our employees. This expertise is deployed through committees responsible for chemical and biological risk assessments, which are used to determine adequate risk prevention and protection measures for employees. These committees are convened at global level, and pool the resources of our network of international experts; they rely on Sanofi standards and policies.

The COVALIS committee is responsible for hazard determination and classification for all the main active pharmaceutical ingredients and synthesis intermediates handled or manufactured at our sites. This includes all active ingredients subcontracted to

third parties under the Sanofi label. The COVALIS committee sets limits for workplace exposure that apply to all Sanofi sites.

The TRIBIO committee establishes the methodology for evaluating, classifying, consolidating and disseminating validated information about all biological agents handled within Sanofi facilities. The committee provides management with guidance on risks, preventive measures, controls, personal protection equipment, medical surveillance, and specific training programs associated with biological agents.

In addition, specific resources are allocated to the implementation of the European Union regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). In compliance with the European CLP regulation on the classification, labeling and packaging of chemical substances, we have registered the relevant substances with the European Chemicals Agency (ECHA).

4.2.4.7.5.2.2. Managing work-station health risks

Each site prepares its own health risk analysis, and then defines and implements risk prevention programs and occupational health practices in accordance with Sanofi's HSE rules. This mainly involves containment measures, as well as individual and collective protection against exposure at all work-stations where chemical substances or biological agents are handled. Other risk factors associated with issues such as noise, vibration and ergonomics are also examined.

All personnel are monitored under medical surveillance programs that are based on the results of occupational risk assessments linked to their duties.

4.2.4.7.5.2.3. Occupational diseases

Occupational diseases and their causes are divided into categories based on international standards. For the purposes of prevention, the number of occupational diseases is consolidated for Sanofi as a whole on an annual basis, with the aim of improving the reporting of data based on local regulations that may vary greatly from country to country.

In line with European statistics (in particular those for France, Italy, Belgium and Spain), the principal type of occupational diseases recognized within Sanofi during 2018 was musculoskeletal disorders.

4.2.4.8. Environmental releases

Our R&D and manufacturing operations – and the storage and transportation of raw materials, products and waste – are associated with various potential risks relating to the release of toxic chemicals or biological pathogens that may adversely affect the environment or human health. We must ensure that we comply with regulations and with our own internal directives, and anticipate new and emerging regulations relating to the release of contaminants into the environment in every country where we operate.

4.2.4.8.1. Organization

Our Environment department is part of our HSE department. Consequently, information about our organization in this area is presented in Section 4.2.4.7.1 of the "Employee health and safety" section.

4.2.4.8.2. Policies and action plans

4.2.4.8.2.1. Managing pharmaceutical contamination and combatting microbial resistance to antibiotics

Pharmaceutical substances, including antibiotics, may be found in the environment as a result of effluent from manufacturing sites; medicines taken by patients and then excreted; and inappropriate disposal of unused or date-expired medicines. Our products are available in more than 170 countries, so we need to make sure that we apply regulations and our own internal directives on pharmaceutical substances in the environment, as well as anticipating the impacts of new and emerging regulations in this area.

We are careful to ensure that the processes we use, and the way we operate our sites, limits the potential for releasing pharmaceutical substances into the environment.

Alongside this, we have developed and are rolling out a global program to manage the potential environmental impacts of our production sites, with a particular focus on the discharge of pharmaceutical substances in effluents. At site level, this translates into dedicated discharge management plans that include a profile of discharges and emissions, the application of environmental thresholds, and the implementation of any risk management measures that may be necessary. Following an initial pilot study in 2012-2015 that targeted our chemical and biochemical facilities, this new global program has been rolled out gradually since 2016, and was implemented at four sites in 2018.

We have also signed up to the "AMR Roadmap 2020" to help combat microbial resistance to antibiotics. This initiative brings together 13 major players in the pharmaceutical industry to collaboratively produce guidance and reference frameworks for the sustainable management of antibiotics within the industry. It includes a specific commitment relating to antibiotics manufacturing sites operated by signatories and their suppliers, involving the definition and implementation of a common framework for managing potential discharges and the setting of environmental limits.

4.2.4.8.2.2. Managing other types of wastewater discharge

Directly related to our policy on managing pharmaceutical substances in the environment is our commitment to managing wastewater discharge. We have various programs in place for:

- online monitoring of trends in the concentration of pollutants in the natural environment;
- reducing at source the volumes and quantities discharged;
- installing state-of-the-art treatment facilities at sites, where necessary.

Wastewater generated by our operations is always treated before being discharged into the natural environment, either directly using our own installations or indirectly under agreements with municipal or industrial partners to use their treatment facilities.

Our own in-house treatment plants are subject to a rolling program of maintenance, monitoring, reporting and performance optimization. This includes equipment upgrades, and improvements to flow management such as treatment at source, flow segregation and dedicated treatment processes. Sites can call upon support from centers of excellence at our corporate headquarters and in our analytical laboratory.

Onsite HSE teams are responsible for checking that our discharges comply with all relevant licenses and agreements. They are also tasked with implementing environmental and public health impact assessment programs. These programs involve:

- profiling flows of pollutants (sources, quantities and composition);
- developing specific pollution management strategies (reduction at source, segregation, outsourcing, and dedicated or centralized treatment facilities; and
- monitoring discharge and performance at treatment facilities.

4.2.4.8.2.3. Managing airborne emissions: optimizing the use of solvents and control over emissions of volatile organic compounds

Solvents (primarily used in the production of active ingredients, and in their transformation into pharmaceutical products) are governed by company-wide recommendations on their use.

Solvents used in the production process are either purchased (consumed quantities), or regenerated at Sanofi sites. We encourage process optimization, regeneration (when possible) and waste-to-energy technology in an effort to reduce consumption.

Controlling volatile organic compound (VOC) emissions from drug synthesis and manufacturing activities is a priority for Sanofi. An integrated approach is applied at each stage of product development, from research to production, aimed at:

- reducing organic solvent usage by implementing green chemistry techniques, and through the use of key process performance indicators by our R&D teams;
- reducing emissions at source through specific adjustments to manufacturing processes and maximum containment of solvent use; and
- capturing and treating residual VOC emissions at special treatment facilities using the best available techniques for the specific physico-chemical properties of the VOCs emitted (cryogenic capture, gas scrubbers, thermal oxidizers, etc.).

4.2.4.8.2.4. Managing hazardous waste

Managing waste (both hazardous and non-hazardous) is one of the priority areas in our Planet Mobilization program. Our commitments on waste are described in Section 4.1.3.1., “The Planet Mobilization roadmap”.

At end 2018, our reuse/recycle/recovery (“3R”) rate was 73%. This rate does not include solvents recycled onsite.

The volume of hazardous waste fell by 12% in 2018 relative to 2017, and the 3R rate for hazardous waste was 68% in 2018. Refer to the table in Section 4.1.3.5.2., “Waste generated”.

4.2.4.8.3. Performance indicators

4.2.4.8.3.1. Managing releases of pharmaceuticals into the environment

Following an initial pilot study in 2012-2015 that targeted our chemical and biochemical facilities, the new global program has been rolled out gradually since 2016. The program was implemented at four pharmaceutical production sites in 2018, which means that pharmaceutical contamination assessments have now been conducted at 14 production sites.

4.2.4.8.3.2. Managing wastewater discharge

The data reported correspond to effluents after internal and/or external treatment. Chemical oxygen demand (COD) is the primary environmental indicator of effluents. If no information on external treatment is available, a conservative purification rate of 50% is applied as a default.

The data reported cover all Sanofi sites (other than tertiary and logistics sites, which contribute only marginally to COD releases).

Wastewater discharge (tonnes)	2018	2017
COD	2,005	2,421

Various reasons underlie the significant year-on-year reduction of 17% in COD released into the environment:

- a better understanding of how third-party treatment facilities are performing, which means that in many cases the elimination rate has been revised upward;
- the implementation of various programs to reduce discharge of some substances at source, resulting in a reduced concentration in the effluents discharged;
- the start-up of new onsite treatment facilities, including both complete treatment plants (such as at Geel, Belgium) or enhancements to existing facilities, in particular activated carbon adsorption units (such as at Sisteron, France).

Many other projects to extend wastewater treatment facilities are under development around the world.

4.2.4.8.3.3. Managing airborne emissions: optimizing the use of solvents and control over volatile organic compound emissions

Optimizing the use of solvents:

(tonnes)	2018	2017
Solvents used	192,562	207,816
Percentage of regenerated solvents	65%	65%

Control over volatile organic compound emissions:

(tonnes)	2018	2017
VOCs (estimated)	3,378	3,296

(tonnes of SO_x)	2018	2017
Direct emissions	116	110

(tonnes of NO_x)	2018	2017
Direct emissions	424	406

4.2.4.8.4. Remediation

4.2.4.8.4.1. Programs and resources devoted to preventing environmental risks and pollution

In accordance with our own HSE policy and regulatory requirements, all our sites are equipped with containment systems and/or systems for collecting accidental releases to prevent them from penetrating the soil. All containment systems are built to the highest standards and are covered by appropriate maintenance programs to ensure the integrity of the sites' effluent collection systems. Our sites are also equipped with emergency spill control kits wherever potentially hazardous substances are stored or handled.

We also have a systematic multi-year soil and groundwater monitoring and evaluation program for our sites, both for those with ongoing operations and those being sold. Where necessary, remediation work is carried out following detailed evaluations.

Capital and operating expenditures incurred on preventing environmental risks and contamination form part of the overall expenditures incurred on the implementation of Sanofi's HSE policy.

Environmental fines imposed on Sanofi in 2018 were immaterial.

4.2.4.8.4.2. Provisions and guarantees for environmental risks

Applicable environmental laws and regulations may require Sanofi to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past, and may still occur or be discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned at Mount Pleasant, East Palo Alto and Portland in the United States; Barceloneta in Puerto Rico; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Beaucaire, Valernes, Limay, Romainville, Neuville and Vitry in France; and at a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d to our consolidated financial statements, included at Item 18 of our 2018 Annual Report on Form 20-F. In 2018, Sanofi spent €62 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision.

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to €680 million as of December 31, 2018, compared with €685 million in 2017. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto, are described in Note D.22. to our consolidated financial statements, included at Item 18 of our Annual Report on Form 20-F.

4.2.4.9. Water resource management

Specific operating measures are in place to optimize water supply management and use of water in the manufacture of medicines and vaccines (see Section 4.1.3.3., "Water management").

4.2.4.10. Human rights

We employ over 100,000 people in many countries and work with a large number of suppliers and subcontractors. This gives us a duty to respect the human rights of workers both in our own operations and in our supply chain. Human rights in this context refers to fundamental rights embodied in International Labour Organization (ILO) conventions, and more specifically to the abolition of child labor and forced labor, the elimination of discrimination, and the recognition of freedom of association and collective bargaining.

Sanofi must comply with regulatory obligations on human rights; these include international standards such as the United Nations Guiding Principles on Business and Human Rights, and national regulations such as the French Duty of Vigilance law.

We need to identify the nature and extent of potential human rights violations in every country in which we, our suppliers and direct subcontractors operate, and prevent any breach of the rules or of our own internal policies.

A description of our risk mapping, organization, policies, action plans and performance monitoring in respect of human rights is provided below.

4.2.4.10.1. Human rights risk mapping

The following risks have been specifically identified as salient for Sanofi as regards the fundamental rights of employees:

1) For sales, R&D and support function activities: psychosocial risks, and the risk of isolated practices that may be prejudicial to freedom of association and the principle of non-discrimination.
2) For manufacturing and logistics activities: risk of employing migrant workers in situations that may be tantamount to forced labor; risk of excessive working hours; risk of wages below decent wage levels; risk of hazardous work being carried out by children aged under 18; and the impossibility for Sanofi to meet its commitments on freedom of association and non-discrimination in at-risk countries.

The risk factors used to define human rights risks are linked to the characteristics of the workforce.

To evaluate the criticality of risks, we determined a number of inherent risk factors: level of qualification, working conditions, potential presence of vulnerable workers, and the characteristics of countries where we operate (such as legislation that is inadequate or contrary to international standards, widespread human rights violations, or a large presence of vulnerable populations in the country). Because we classify our employees by what they do (industrial, sales, support functions, etc.), we were able for each risk to determine its probability and severity (the seriousness of the potential risk and the number of people potentially affected, and whether the potential violation is systemic or isolated). This methodology was developed in consultation with our Risk Management department.

4.2.4.10.2. Organization

Sanofi has for many years adopted a proactive vigilance approach to prevent our activities having negative impacts on human rights. Three of our support functions play key roles in this approach. Our CSR department provides expertise in embedding human rights into our activities; our HR function implements policies and action plans; and the Internal Control and Internal Audit functions check that the policies are being implemented and complied with.

4.2.4.10.3. Policies and action plans

We pay particular attention to respect for the fundamental rights of employees, whether employed directly by Sanofi or indirectly by parties with whom we do business.

In 2015, we approved and rolled out three internal policies on freedom of association, prohibition of forced labor and prohibition of child labor. These policies reiterate our commitments to employees, and establish processes to translate those commitments at operational level by identifying and controlling the risk of infringements of these rights and requiring the implementation of due diligence. Our policies are based on ILO conventions, and in particular on:

- ILO Conventions 87 and 98 on freedom of association, protection of the right to organize and collective bargaining;
- ILO Conventions 138 and 182 on child labor; and
- ILO Conventions 29 and 105 on forced labor.

To ensure that these policies are properly implemented, specific control points have been built into our internal control system covering respect for freedom of association and the right to collective bargaining, the elimination of all forms of forced labor, and the abolition of child labor. We strengthened our existing processes in 2018:

- we updated our "Human and Labor Rights" risk profile to improve the way in which we rank human rights risk (which we define as the risk of violating the human rights of workers) and how we assess severity in terms of the seriousness of the impact on employees; and
- we classified risks relating to the fundamental rights of workers and ranked them by criticality (see section 4.2.4.10.1., "Risk mapping"), and revised our existing policies to make risk assessment questionnaires compulsory and more operational, and to ensure that data are reported up to the CSR department.

An action plan for 2019 has been drawn up to respond specifically to the operational risks identified. This action plan aims to:

1) improve the classification of risk causes and situations, and identify sensitive areas with precision (for example: collecting data on the types of job most likely to be done by people aged under 18, and reporting of psycho-social and discrimination risks by HR managers, etc.); and
2) manage risks, by more rigorous implementation of our internal policies on the fundamental rights of workers (raising awareness at entity level, training for HR staff and auditors, and compliance audits in at-risk countries) and by ensuring that people at the operational level are familiar with the alerts management system.

4.2.4.10.4. Performance indicators

In ensuring that our human rights policies are implemented across our subsidiaries, we will pay particularly close attention to:

- subsidiaries that have not implemented these policies;
- subsidiaries that have only partially implemented them; and
- policies that are particularly difficult to implement (forced labor, child labor, freedom of association, non-discrimination, etc.).

4.2.4.11. Ethics and business integrity

Our commitment to behave ethically and with integrity extends beyond mere compliance with laws and regulations. Each employee must have a sound ethical approach to what they do, and the good judgement needed to identify risks and manage difficult situations appropriately. As a business with a wide range of activities spread across many countries and involving a large number of partners, we pay the closest attention to ethical standards in the way we conduct our operations, especially in our interactions with third parties.

Typical situations may include:

- unethical behavior in interactions with third parties, including (but not limited to) government representatives, customers, healthcare professionals, patients, and patient rights groups;
- inappropriate promotional and/or marketing practices;
- fraud (misappropriation of assets, false accounting, corruption); and
- conflicts of interest.

4.2.4.11.1. Organization

4.2.4.11.1.1. Background

Sanofi operates in more than 100 countries across the globe and is committed to respect the highest standards of ethics and integrity in business conduct.

Embedding ethical values into what we do every day is essential if we are to remain faithful to our commitments to patients, physicians, the scientific community, our partners and investors, and society as a whole. It is also essential to protecting our image and reputation, and our employees.

To sustain our commitment, we have implemented a robust governance structure, backed by clear rules that comply with the legal frameworks applicable in each country where we do business. We also have a rigorous internal control system in place.

The cornerstone of this approach is our Ethics & Business Integrity (E&BI) department, which works closely with a number of other departments including (but not limited to) Internal Control & Processes; Internal Audit and Risk Management; Global Quality; Medical Affairs; Legal Affairs; Procurement; and Health, Safety & Environment (HSE).

4.2.4.11.1.2. Ethics and Business Integrity Program

The Sanofi Ethics and Business Integrity Program, developed and implemented by our dedicated E&BI department, is supported by our Code of Ethics; internal policies and standards; education and training initiatives; monitoring procedures; a specific alerts procedure backed by internal investigations; and the implementation of corrective and/or disciplinary measures, if needed.

The core mission of E&BI is to promote a culture of ethics and integrity at every level within Sanofi. E&BI's role is to act as a partner for our business units and support functions and to help achieve our business objectives while ensuring compliance with laws, regulations, industry codes, ethical standards and values, and our own internal policies and standards.

4.2.4.11.1.3. Ethics and Business Integrity (E&BI) department

E&BI provides our Global Business Units (GBUs) and support functions with the assistance needed to identify, evaluate and mitigate risks potentially associated with our operations.

E&BI has a dedicated team working on our approach to ethics and business integrity. This team reports to our Global Compliance Officer and is present at both global and local level, providing support across the whole of Sanofi: headquarters, GBUs, support functions, regions and countries.

Global Compliance Officer reporting to our General Counsel and to our Chief Executive Officer	Provides strategic compliance expertise to Sanofi's Executive Committee and Board of Directors. Monitors the implementation and management of our Ethics & Business Integrity Program.
E&BI department staffed by more than 140 people	E&BI managers within our GBUs and support functions, and at region and country level, who: ♦ ensure that the fundamental aspects of the Ethics & Business Integrity Program are in place and working properly at every level in the organization; and ♦ provide support in the day-to-day conduct of our business.
Global center of excellence	Dedicated team working on risk assessment, developing and distributing policies and standards, training, and awareness campaigns.
Specific managers with responsibility for (i) fraud prevention and (ii) internal investigations	Tasked with developing and applying a full-scope fraud risk management program built on four pillars: prevention, detection, investigation, and analysis/reporting. Supported by a dedicated team, who also conduct internal investigations.
A network of 960 "Compliance Champions", made up of volunteers from each country, GBU and support function	Communicate and reinforce compliance messages developed by E&BI. Support the implementation of E&BI initiatives. Monitor in real time participation in compulsory training programs. Act as a contact point for employees, encourage alerts, and promote a culture of ethics and business integrity.
Compliance Executive Committee, chaired by the Chief Executive Officer	Evaluates, recommends and monitors all initiatives intended to support and improve the Ethics & Business Integrity Program, and promotes ongoing adherence by our employees to the Sanofi core values: team spirit, courage, respect and integrity.

4.2.4.11.2. Policies and action plans

4.2.4.11.2.1. Code of Ethics, policies and standards

The Sanofi Code of Ethics defines the standards of ethical conduct that employees must apply when working for Sanofi. It is a key resource and practical tool, providing guidance to each employee about the attitudes to adopt in interactions within and outside the company. The Code of Ethics has been translated into 29 languages, ensuring that it can be accessed and understood by everyone, everywhere in the world. All employees are required to follow training on the Code of Ethics, which consists of a series of chapters under three main headings:

- Respect & protection of people and the environment
- Integrity in managing company information
- Integrity in our business practices

To support effective application of the principles contained in our Code of Ethics, we have developed a comprehensive set of policies and standards, designed to give guidance on a broad range of situations specific to our industry. In particular, our anti-corruption policy lays down guidance for employees, and for third parties who interact with Sanofi, to help them comply with laws and regulations and to promote a culture of ethics and integrity.

In addition, we conduct anti-corruption due diligence before doing business with a third party; before making any investment in a commercial entity not owned by Sanofi; and before signing any joint venture or partnership agreement.

4.2.4.11.2.2. Training and education programs

We have built an E&BI training program to raise employee awareness and deliver continuing education. Every year, Sanofi employees must complete compulsory ethics and business integrity training. Tools include e-learning modules and short videos based on real-life situations that could expose employees to various types of risk including corruption, conflicts of interest, fraud, and data confidentiality breaches. In addition, an online library of training modules, some of them available in 19 languages, can be accessed by all employees who want to self-train. All E&BI policies are backed up by specific training tools, including frequently asked questions.

4.2.4.11.2.3. Alerts management

A secure compliance helpline with a toll-free number and a dedicated web page are available 24/7 in 28 languages. In the United States, a helpline has been set up for Sanofi employees which is guaranteed to be independent and protect anonymity, in accordance with local regulations and practices. This system can be used by any employee who encounters a problem or who believes in good faith that a breach has occurred or is about to occur of any law, regulation, industry code of conduct, Sanofi standard or policy, or of any principle contained in the Code of Ethics. Employees will not be disciplined or penalized as a result of reporting to the helpline, provided that they act in good faith and without malicious intent, even if the facts turn out to be inaccurate or no further action is taken. Sanofi employees are encouraged to identify themselves when reporting an incident, as this helps the investigation process. However, if they prefer not to disclose their identity, they can report anonymously. The system is also open to third parties interacting with Sanofi. Each alert, whether received through the compliance helpline or any other channel, is investigated internally using a methodological protocol set out in our alerts management policy. If, after the internal investigation, the alert is substantiated, corrective and/or disciplinary measures are initiated. To ensure that such measures are determined consistently and uniformly, Sanofi has issued a policy formally documenting an overall framework for corrective and/or disciplinary actions.

4.2.4.11.3. Performance indicators

In 2018:

Training:

- 91,782 employees received Code of Ethics training; and
- 63,911 employees received anti-corruption training.

Compliance helpline:

- 775 alerts were reported to E&BI. After investigation, 353 cases were substantiated. They resulted in 110 dismissals or resignations related to misconduct.

4.2.4.12. Tax policy

Sanofi applies the law and regulations in force in the countries where it does business, files the relevant tax declarations on time with the tax authorities, and pays the taxes determined on that basis.

The Sanofi Tax department is responsible for establishing and implementing our tax policy. The Audit Committee, the Risk Committee, Internal Audit and the external auditors regularly check compliance with procedures and policies and the effectiveness of tax risk management within Sanofi. Our tax policy is published on our corporate website. Our policies and procedures relating to taxes and duties are accessible to all our employees.

Sanofi seeks to develop and maintain an open, transparent and collaborative approach to its dealings with the tax authorities and other governmental bodies worldwide. In particular, Sanofi files its country-by-country report annually with the French tax authorities. In line with OECD recommendations and French regulations, this document is forwarded to more than 60 foreign tax administrations.

Sanofi is regularly subject to tax audits in most of the countries where it operates. Sanofi seeks assurance from and works constructively with the tax authorities in the event of tax uncertainties or divergent positions.

In the transfer pricing area, Sanofi applies the OECD guidelines, French legislation and any country-specific legislation to its inter-company transactions, targeting “arm’s length” remuneration for all Sanofi entities. Sanofi’s transfer pricing policy is duly documented and supported by economic analysis.

Sanofi’s tax strategy is based on the economic reality of its operations, and is aligned with its values and the business strategy defined by Sanofi’s management, which all prohibit tax evasion.

Income taxes are described in detail in our consolidated financial statements, included at Item 18 of our 2018 Annual Report on Form 20F, and specifically in Note B.22., “Income Tax Expense”; Note D.14., “Net deferred tax position”, and Note D.30., “Income tax expense”. The tax information disclosed in our financial statements is subject to independent external audit.

4.2.4.13. Procurement and subcontracting

Sanofi buys raw materials, goods and services all round the world, and uses a diversified panel of suppliers reflecting the diversified nature of our activities. Our Procurement function is centralized, and acts on behalf of all Sanofi entities (including our Global Business Units and support functions). This structure delivers synergies, in terms of both expertise and procurement costs.

Sanofi's procurement policy, which applies to all our employees, is based not only on economic principles but also on ethical, environmental and social principles.

Procurement key figures	2018	2017
Procurement spend (€ billion)	15.6	14.6
♦ in OECD countries	13.3	12.2
♦ in non-OECD countries	2.3	2.4
Number of suppliers	86,000	87,400
Number of countries where we have suppliers	157	156

Sanofi is a member of the Pharmaceutical Supply Chain Initiative (PSCI), which aims to improve practices at industry-specific suppliers by establishing common standards, providing support and training programs for suppliers, and arranging shared audits.

We have also signed up to the Together for Sustainability (TfS) initiative, a worldwide program to evaluate and improve sustainable procurement practices adopted by suppliers. Under the TfS initiative, supplier evaluations and audits are carried out and the results shared between TfS members via a collaborative online platform.

Our Responsible Procurement approach requires our suppliers to adhere to Sanofi's commitments on human rights, health and safety and the environment via our Suppliers Code of Conduct. In addition, we conduct anti-corruption due diligence before doing business with at-risk suppliers.

All 250 procurement categories were evaluated during 2018 and rated on a scale from 1 to 4 in terms of their inherent risk to health and safety, the environment, and human rights. Inherent risk is defined as the external, business-related risk (regardless of the country where that business is carried on) that suppliers in a given procurement category will endanger health and safety, violate the human rights of their workers, or cause harm to the environment.

The risk rating reflects:

- for health and safety: the number of people potentially affected, and the severity and irreversibility of the accidental or chronic harm caused;
- for the environment: the extent and irreversibility of the negative consequences (in terms of pollution and consumption of natural resources) on the environment, communities and biodiversity (not necessarily limited to the site itself); and
- for human rights: the characteristics of the labor force (level of qualification, headcount, extent of reliance on temporary labor), and the human rights sensitivity of the products used (supply chain).

An overall composite rating was calculated for each procurement category, and 44 were regarded as inherently high-risk in terms of environmental protection, health and safety, and human rights. Those 44 categories were associated with waste management, demolition, depollution, major construction works, hazardous products, active ingredients, natural products, pharmaceutical subcontracting, clinical trials, transport and distribution, site operations, security services, travel and events, and recruitment agencies.

This new risk mapping exercise enabled us to determine response typologies for each category identified as being at risk, with reference to the vigilance plan (health and safety, environment and human rights). The response depends on the risk rating, the country of activity, the characteristics of the service provided (such as on/offsite, the service-provider's organizational structure, recurrence, etc.) and the volume of spend. Examples of potential risk management responses include audits (by our internal auditors, or via PSCI or TfS sector initiatives), assessments, prevention plans or specific awareness actions.

Suppliers identified as being in the highest risk categories have their CSR performance assessed by an external service-provider. The results of those evaluations are fed back into the procurement risk management process, driving constant improvement among our supplier base. The process covers more than 200 suppliers a year, with the aim of covering 100% of our high-risk strategic suppliers by the end of 2020.

We assessed 211 suppliers in 2018. Of those, 36 did not achieve the required level and will have to follow a corrective action plan; a further assessment will be conducted in 2019 to see whether that corrective plan is working.

We also aim to have completed audits of all our providers of high-risk critical active pharmaceutical ingredients (APIs) and all our contract manufacturing organizations (CMOs) by the end of 2020, under a phased plan that reflects the level of risk:

- 2017-2019: focus on all providers of antibiotics and hormones; and
- 2018-2020: focus on providers of feedstock (synthesis intermediates).

	2018	2017
Number of Sanofi CMO audits	64	70
Number of API supplier audits	90	88

Results from these audits showed that one-quarter of the suppliers failed to meet the required standard; these were mainly suppliers based in India and China. All of these suppliers will have to follow a corrective action plan. Of the suppliers audited in 2017 and 2018, 60 suppliers have been issued with a corrective action plan, and more than half of those have improved their performance.

4.2.5. Other vigilance plan issues

4.2.5.1. Oversight

Our vigilance approach is under the joint control of our heads of CSR and HSE. Global coordination is provided by the CSR department, who ensure that there is a good fit between the various measures in the vigilance approach, and that those measures are implemented.

The CSR department works closely with our HSE, Procurement, Legal Affairs and Ethics & Business Integrity departments in our inter-departmental Vigilance Working Group, whose remit includes global oversight of Vigilance Plan implementation. Monitoring of risk management policies and alerts systems is the responsibility of the specific departments concerned, such as HSE.

4.2.5.2. Dialogue with stakeholders

We have discussed the content of, and progress on, our Vigilance Plan with employee representative bodies: the European Works Council (in June 2018) and the French Group Committee (in September 2018). These discussions led to the formation of a working group, mandated by the Group Committee to discuss in greater detail three specific issues covered by the Plan: human rights at work, responsible procurement, and the alerts management system.

We recognize the importance of these issues, and are determined to build a robust and sustainable approach to vigilance, especially on human rights. That is why we have shared the content of our approach with external stakeholders such as "*Entreprises pour les droits de l'homme*" (Businesses for Human Rights), a French not-for-profit organization that supports businesses as they make progress on human rights (www.e-dh.org); Together for Sustainability (TfS); and the Pharmaceutical Supply Chain Initiative (PSCI). We have also shared our approach with French bodies including AFEP (the French employers' federation), and international bodies such as the International Organization of Employers (IOE) and the 2018 United Nations Business and Human Rights Forum.

4.2.5.3. Alerts management and report-handling

An alerts management system has been in operation at Sanofi since 2006, enabling any employee to report any breach of our Code of Ethics at any time.

Sanofi employees are encouraged to report any breach directly to our Ethics & Business Integrity department via the relevant Compliance Officer, or by using the compliance helpline. Employees will not be disciplined or penalized as a result of using the alerts system, provided they do so in good faith and without malicious intent, even if the report turns out to be inaccurate or no further measures are taken. Our Ethics & Business Integrity department will carry out the necessary investigations into the reported allegations, with assistance from other Sanofi departments if required. If those investigations confirm the allegations, we will remedy the situation by taking disciplinary action and/or corrective measures, and by instigating all the legal proceedings we judge necessary.

When we revised our Code of Ethics in March 2018, we accompanied it with an information campaign for all our employees highlighting the existence of the alerts management system.

Alongside this global alerts system, Sanofi has specific mechanisms in place for patients to flag up issues and give early warnings about drug safety.

4.3. Methodological note on data reporting

4.3.1. Scope of consolidation

Unless otherwise specified:

Social data:

- HR data are consolidated for all Sanofi companies worldwide that are (i) fully consolidated for financial reporting purposes and (ii) have been integrated into the Workday Global HR system, regardless of their activity (industrial, research, commercial or administrative); and
- health and safety data (occupational injuries) are consolidated worldwide for all Sanofi companies fully consolidated for financial reporting purposes. In some tables, the term “any employee” includes Sanofi employees, temporary workers, and subcontractors.

Environmental data:

- environmental data (including expenditures) are consolidated for all industrial, R&D and administrative sites, for all Sanofi companies fully consolidated for financial reporting purposes; and
- the environmental impact of CO_2 emissions from our vehicle fleet covers all Pharmaceutical Operations subsidiaries (field sales force, but excluding management).

Scope 1 CO_2 data (apart from the vehicle fleet), scope 2 CO_2 data and water data are reported on a proforma constant scope basis.

Vigilance Plan:

The Vigilance Plan covers the operations of (i) Sanofi, (ii) all Sanofi companies fully consolidated for financial reporting purposes, and (iii) Tier 1 suppliers and subcontractors of all companies included in (i) and (ii).

For a list of companies fully consolidated by Sanofi for financial reporting purposes, refer to Note F to our consolidated financial statements, included at Item 18 of our 2018 Annual Report on Form 20F.

4.3.2. Changes in scope

Bioverativ and Ablynx were acquired in 2018.

Ablynx was fully integrated into the Workday Global HR system as of January 1, 2019, but data for Ablynx was manually consolidated for inclusion in the 2018 workforce numbers and movements. Bioverativ has been only partially integrated into Workday: its employees in Japan and Australia (21.1% of Bioverativ’s total workforce) will be integrated in the second quarter of 2019. Consequently, those employees were not consolidated in the 2018 workforce numbers and movements.

Environmental, health and safety data for Ablynx and Bioverativ will be included in the reporting scope from 2019 onwards.

4.3.3. Reporting methods

- **Social data**:

  Workday was rolled out between 2015 and 2017 with the following key objectives:

  - integrating our processes and systems in a two-tier architecture (global/local), such that the global level becomes the master application for most data but local legal requirements could also be addressed;
  - simplifying and standardizing processes across business units and support functions;
  - centralizing data management on a single, unified platform, to significantly improve the quality of HR data and reporting;
  - introducing self-service to enhance the user experience for employees and managers and help them engage better with HR issues;
  - improving talent management and staff mobility; and
  - streamlining IT mapping.

  In 2018, the Workday Global HR platform replaced the Convergence platform as the tool used to record workforce numbers and movements. The Core HR processes were rolled out in waves across successive geographies during 2016 and 2017. In addition to these core processes, the Organization Management, Talent & Performance, Recruitment, Onboarding, Compensation and Grading modules have also been rolled out. Workday is used by all Sanofi employees and managers in Employee Self-Service (ESS) and Manager Self-Service (MSS) modes. Specific work on data quality was carried out during the rollout, and is continuing through maintenance and ongoing improvements to the system.

- **HSE data**:

  We apply standard reporting frameworks for safety and environmental information, so that the indicators monitored across all our entities are consistent and reliable. Those frameworks specify the methodologies to be applied for reporting indicators throughout Sanofi and include definitions, methodological principles, calculation formulae and emission factors. We also use standard data collection tools:

  - Health and Safety: we used the SHERPA system to collect and consolidate safety data for 2018 across our entire reporting scope.
  - Environmental data:

    We use the SHERPA system to collect and consolidate environmental data.

    The reporting period for our environmental indicators for a given calendar year runs from October 1 of the previous year through September 30 of the current year, except for VOCs which are reported for the calendar year. Environmental indicators are collected during an annual campaign, except for indicators relating to energy/water consumption and waste, which are collected quarterly.

In 2017, the tertiary sites included in the scope of the Planet Mobilization plan were limited to those located in France. In 2018, all tertiary sites worldwide were included in the scope.

The method used to integrate companies acquired since 2015 into the 2015-2025 Planet Mobilization plan is as follows (illustrative example): a company acquired in 2018 is included in the baseline year (2015) and the intervening years (2016 and 2017) on the basis of its 2018 data, so as to report data on a constant scope basis.

4.3.4. Additional information and methodological limitations

The methodologies applied for some HR and HSE indicators may be subject to limitations as a result of:

- the lack of nationally and/or internationally recognized definitions, in particular for different types of employment contract;
- the need to rely on estimates and on representative rather than actual metrics, and the limited availability of external data required for calculations;
- practical arrangements for the collection and input of data:
  - our change in HR platform from Convergence to Workday: in terms of movements, the reasons for staff departures ("layoffs", "resignations" and "by mutual consent") are more comprehensive in Workday than in Convergence. In calculating the resignation rate on permanent contracts, the 2017 figures include resignations only, whereas the 2018 figures also include departures by mutual consent at the employee's request. It was not possible to recalculate the 2017 figures to align on this new calculation method. It will however be possible to make like-for-like comparisons next year (2019 versus 2018).
  - The 2017 figures for layoffs comprised the following categories: "layoffs", "death", "disability", and all "departures by mutual consent" (whether at the request of the employee or the employer). By contrast, the 2018 figures for layoffs comprise "layoffs", "death", "disability", and "departures by mutual consent at the employer's request". The calculation method will be standardized for the next reporting period to ensure strict comparability between 2018 and 2019 figures. We will also create a new "Other" category, which we will use to record departures due to death and disability, and departures by mutual consent. This is why to the extent possible, we specify the definitions and methodologies used for each of the indicators listed below, and any margin of uncertainty.

4.3.5. Social indicators

4.3.5.1. Worldwide workforce

Employees under contract include all employees who have a contract with Sanofi, including apprentices.

Employees are treated as "under contract" if they have an employment contract (permanent or fixed-term) with a Sanofi company on the last calendar day of the year. The figures are expressed in numbers of employees, regardless of hours worked or the date of hiring during the month.

4.3.5.2. Regions

The regions shown in the workforce data tables are defined as follows:

- Europe: Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).
- Emerging Markets: World excluding United States, Canada, Europe, Japan, South Korea, Australia, New Zealand and Puerto Rico.
- Other Countries: Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

4.3.5.3. New hires and departures

New hires and departures for Sanofi as a whole exclude all intra-group movements such as international, inter-company or inter-site transfers.

Data on movements (new hires and departures) cover more than 99% of the reporting scope, and include new hires and departures for companies that were consolidated for the first time or acquired during the year, except for Bioverativ employees in Japan and Australia (21.1% of that company's total workforce) who have not been integrated into Workday. Bioverativ's Japanese employees will be integrated into Workday in the second quarter of 2019. The Japanese and Australian employees of Bioverativ were not consolidated in the 2018 workforce numbers or movements.

Conversions of fixed-term contracts into permanent contracts are not counted unless there is a gap of more than one day between the two contracts, in which case they are counted as a departure and a new hire.

4.3.5.4. Training hours

In 2017 Sanofi installed iLearn, a single training platform intended to house all our existing systems. Migration of our existing systems began in 2017 but is not complete, meaning that we cannot yet consolidate our figures on a global basis.

For 2017, the training hours reported derive from two significant training systems:

- Le@rn, a system dedicated to training in good pharmaceutical practices at Sanofi, which is deployed worldwide; and
- Foederis, a system specific to employees located in France, which covers training in a number of fields: Business, Regulatory, and Transverse (Management & Leadership / Personal Development / Languages / Office Applications).

For 2018, the training hours reported derive from the following training systems:

- iLearn, which delivers all compulsory and support function training:
  - Compliance: Ethics & Business Integrity and Pharmacovigilance

- Quality
- Workplace First-Aiders
- Business Development, Management and Leadership.

- Learning Gateway, which provides our North American employees with compulsory and technical training, alongside personal and professional development programs.
- Isotrain, which delivers training to Sanofi Pasteur employees in France, North America and Global R&D.
- Syfadis, a 100% online platform.
- Peps, a training system for our German employees.
- Foederis, a dedicated platform for employees located in France which covers training in various areas (business, regulatory and cross-disciplinary).

4.3.5.5. Definition of grades

Executive posts

- Executive Level 2: in charge of alignment on corporate strategy, with a critical impact on return indicators and corporate image, and a solid contribution to Executive Committee orientations.
- Executive Level 1: in charge of translating and implementing corporate strategy, with a critical impact on the results and competitiveness of a Global Business Unit or Global Support Function and an important impact on the overall results of Sanofi.

Senior Leaders Includes Executive Committee members, executive posts, and Grade 5 posts. Grade 5 posts are people with senior management responsibilities in Product Innovation, Processes or Services, who implement policies within their function. They have an impact on the attainment of financial objectives.

This category was created when we set up our new grading system in 2018. Consequently, figures for 2017 are not available.

Managers Employees who manage direct subordinates.

4.3.6. Safety indicators

4.3.6.1. Lost time injury frequency rate

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

For employees working in a fixed location, accidents occurring during the home-workplace commute are not included in this indicator. However, they are included for travelling medical reps, in accordance with our internal reporting rules.

If additional accidents are identified that had not yet been recorded by the end of the reporting period, or if the classification of an accident is changed after the end of the reporting period, the frequency rate is adjusted retrospectively.

4.3.6.2. Total occupational injury frequency rate

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

This is because for a given injury, the number of days of lost time may vary considerably from one country to another depending on the applicable regulations and compensation systems. Consequently, we have decided to publish the total occupational injury frequency rate.

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

4.3.6.3. Motor vehicle accidents

A motor vehicle accident is any accident that occurs when the driver is at the wheel (driving or parking).

This indicator covers all road traffic accidents involving vehicles owned or leased by Sanofi, or owned by an employee and regularly driven for work purposes (medical reps).

Accidents in public transport or taxis are excluded from our reported data, because they are not considered to be Sanofi's responsibility.

4.3.7. Environmental indicators

4.3.7.1. Carbon footprint

Direct emissions are calculated on the basis of Greenhouse Gas (GHG) Protocol data. Indirect emissions from other energy sources purchased from external suppliers are accounted for as follows:

- emissions from electricity generation: emission factors are obtained from data published by the International Energy Agency during the current year, which define emission factors for the year before last. Consequently, emission factors are applied to data for the current year and the two previous years (data from more than two years ago are not amended);
- emissions generated by the production of steam are calculated on the basis of site-specific factors, or estimated using our own internal standards; and
- emissions from our medical rep vehicle fleet are included in Scope 1.

Indirect Scope 3 emissions are calculated in accordance with GHG protocol recommendations. We have updated emission factors by using factors from the ecoinvent V3.3 database.

Emissions relating to purchased goods and services (category 1) are based on our full-year budget for the current year. This approach was adopted because it allows for optimal modelling of this category (which is our biggest Scope 3 emitter).

The calculation of our CO_2 footprint is reviewed by the Independent Third Party.

Carbon neutrality is defined as zero greenhouse gas emissions. This can be achieved by the use of renewables, by generating energy directly, or by purchasing energy. The carbon-neutral objective covers Scopes 1 and 2, i.e. it includes production sites, R&D sites and tertiary sites, plus the medical rep vehicle fleet.

4.3.7.2. Wastewater discharge

The data presented correspond to effluents after internal and/or external treatment. In the absence of information on the effectiveness of external treatment, a conservative purification rate of 50% is assumed for the purpose of calculating chemical oxygen demand (COD).

The data reported cover all Sanofi sites (other than tertiary and logistics sites, which contribute only marginally to COD releases).

4.3.7.3. Waste

The distinction between hazardous and non-hazardous waste corresponds to that used in European regulations for European Union member countries (Decision 2000/532/EC of May 3, 2000), and that used in local regulations for other countries. Waste arising from soil decontamination operations is not included in the published total for our operating activities. The recovery rate corresponds to waste that is recycled, or incinerated off-site using waste-to-energy technology.

The reuse/recycle/recovery ("3R") rate used for the Planet Mobilization project is defined as the sum total of waste recycled externally plus waste subject to energy recovery, as a proportion of the total amount of waste. Waste includes both hazardous and non-hazardous waste.

4.3.8. Other indicators

Animal welfare:

The "Number of animals used by Sanofi" indicator for 2018 was not yet available at the time of publication of this report. The one-year time-lag in publication does not undermine our strategy of seeking to reduce the extent to which we use animals in research and manufacturing.

4.3.9. Consolidation and internal controls

Data are consolidated by our global HR and HSE functions on the basis of information provided by industrial and R&D sites, Sanofi subsidiaries and tertiary sites throughout the world.

Where sites house more than one function, environmental impact is either attributed to the one with the greatest impact or shared among all the functions. Safety and environmental data are systematically checked by HSE coordinators within each activity before being submitted for consolidation. In addition, our global HR and HSE functions perform consistency controls on data during the consolidation process.

These controls include comparisons with prior-year data; any significant variances are investigated.

To ensure that site correspondents have properly understood the HSE indicators and that the right data are being reported, controls over selected HSE reporting data are performed during internal audits conducted at Sanofi sites.

Workforce data are compared with consolidated data in the finance database.

4.4. Independent third party's report

Year ended on December 31st, 2018

Independent third party's report on the consolidated statement of extra-financial performance presented in the management report

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

To the shareholders,

In our quality as an independent third party, accredited by the COFRAC under number n° 3-1050 (whose scope is available at www.cofrac.fr), and as a member of the network of one of the statutory auditors of the company Sanofi (hereafter "entity"), we hereby report to you on the consolidated statement of extra-financial performance for the year ended on December 31st, 2018 (hereinafter the "Statement"), included in the management report pursuant to the legal and regulatory provisions of articles L. 225 102-1, R. 225-105 et R. 225-105-1 of the French Commercial Code (*Code de commerce*).

Responsibility of the entity

It is the responsibility of the Board of Directors to establish the Statement in compliance with the legal and regulatory provisions including a presentation of the business model, a description of the main extra-financial risks, a presentation of the policies applied regarding these risks as well as the results of these policies, including key performance indicators.

The Statement and the information selected by the entity (hereafter the "Selected Information") have been prepared in accordance with the entity's procedures (hereinafter the "Criteria"), the main elements of which are presented in the Statement and available on request at the Entity's headquarters.

Independence and quality control

Our independence is defined by regulatory requirements pursuant to the provisions of the article L. 822-11-3 of the French Commercial code and the Code of Ethics of our profession. In addition, we have implemented a quality control system, including documented policies and procedures to ensure compliance with ethical standards, professional standards and applicable laws and regulations.

Responsibility of the independent third party

On the basis of our work, our responsibility is to provide a report expressing a limited assurance conclusion on:

- The compliance of the Statement with the provisions of article R. 225-105 of the French Commercial Code;
- The fairness of the information provided pursuant to paragraph 3 of I and II of Article R. 225 105 of the French Commercial Code, namely the results of the policies, including key performance indicators, and the actions related to the main risks, hereinafter the "Information".

It is also our responsibility to express, at the entity's request and outside the scope of our accreditation, a limited assurance conclusion that the Information Selected by the entity and identified in Appendix 1 has been prepared, in all material respects, in accordance with the Criteria.

Nonetheless, it is not our responsibility to express any form of conclusion on:

- The entity's compliance with other applicable legal and regulatory provisions, particularly the French Duty of Vigilance law and anti-corruption and tax evasion legislation;
- The compliance of products and services with the applicable regulations.

1. Report on the compliance and the fairness of the Statement

Nature and scope of the work

Our work described below has been performed in accordance with the provisions of articles A. 225 1 et seq. of the French Commercial Code determining the conditions in which the independent third party performs its engagement and with the professional guidance applicable in France to such engagements, as well as to the international ISAE standard 3000—Assurance engagements other than audits or reviews of historical financial information.

The work that we conducted allows us to assess the compliance of the Statement with regulatory provisions and the fairness of the Information:

- We took note of the entity's activities and of all the companies included in the scope of consolidation, the statement of the main social and environmental risks related to this activity, and, where applicable, the impact of this activity on compliance with human rights and anti-corruption and tax evasion legislation, as well as the resulting policies and their results;
- We assessed the suitability of the Criteria with respect to their relevance, completeness, reliability, neutrality and understandability with due consideration of industry best practices, where appropriate;
- We verified that the Statement includes each category of social and environmental information set out in article L. 225-102-1 III of the French Commercial Code, as well as information regarding human rights and the anti-corruption and tax evasion legislation;
- We verified that the Statement includes an explanation for the absence of the information required by the 2nd paragraph of III of Article L. 225-102-1 of the French Commercial Code;
- We verified that the Statement presents the business model and the main risks associated with the activity of all the entities included in the scope of consolidation; including where relevant and proportionate, the risks associated with their business relationships, their products or services, as well as their policies, measures and results, including key performance indicators;
- We verified, when relevant to the main risks or the policies presented, that the Statement presents the information provided for II in Article R. 225-105 II of the French Commercial Code;

- We assessed the process used to select and validate the main risks;
- We inquired about the existence of internal control and risk management procedures the entity has put in place;
- We assessed the consistency of the results and the key performance indicators with respect to the main risks and policies presented;
- We verified that the Statement covers the consolidated scope, i.e. all the companies included in the scope of consolidation in accordance with article L. 233-16 of the French Commercial Code, within limitations set out in the Statement;
- We assessed the data collection process implemented by the entity to ensure the completeness and fairness of the Information;
- For the key performance indicators and other quantitative outcomes that we considered to be the most important presented in Appendix 1, we implemented:

– analytical procedures to verify the correct consolidation of the collected data as well as the consistency of their evolutions;

– substantive tests using sampling techniques, in order to verify the proper application of the definitions and procedures and reconcile the data with the supporting documents. This work was carried out on a selection of contributing entities listed hereinafter: LATAM Region, including Campinas – Medley and Suzano sites (Brazil), as well as Pilar site (Argentina); Europe A Region, including the sites of Marcy l'Etoile, Elbeuf and Ambarès (France), which cover between 55% and 83% of the consolidated data selected for these tests (quantitative environmental information presented).

- We consulted documentary sources and conducted interviews to corroborate the qualitative information (measures and outcomes) that we considered the most important presented in Appendix 1;
- We assessed the overall consistency of the Statement based on our knowledge of the entity.

We believe that the work carried out, based on our professional judgement, is sufficient to provide a basis for our limited assurance conclusion; a higher level of assurance would have required us to carry more extensive procedures.

Means and resources

Our verification work mobilized the skills of eleven people and took place between September 2018 and the signature date of this report on a total duration of intervention of about twelve weeks.

We conducted about thirty interviews with the persons responsible for the preparation of the Statement representing the sustainable development, human resources, product quality and safety, bioethics, ethics and business integrity, HSE and procurement departments.

Conclusion

Based on our work, we have not identified any significant misstatement that causes us not to believe that the statement of extra-financial performance complies with the applicable regulatory provisions and that the Information, taken together, is fairly presented, in compliance with the Criteria.

Comments

Without qualifying our conclusion above and in compliance with the provisions of Article A. 225-3 of the French Commercial Code (Code de Commerce), we draw your attention to the following point:

- For some components of the main risks, such as product quality and waste management, a review is under way to complement the policy results with other key performance indicators.

2. Limited assurance report on the Selected Information

Nature and scope of the work

Concerning the Information Selected by the entity, identified in Appendix 1, we conducted work of the same nature as described in paragraph 1.

Our work has been performed in accordance with the international ISAE standard 3000 (International Standard Assurance Engagements) and with the professional guidance applicable in France.

The selection of contributing entities covers between 24% and 36% of the total workforce and between 54% and 74% of the quantitative environmental information presented.

We believe that the work carried out is sufficient to provide a basis for our limited assurance conclusion on the Selected Information.

Conclusion

Based on our work, we have not identified any significant misstatement that causes us not to believe that the Selected Information, taken together, has not been fairly prepared in compliance with the Criteria.

Paris-La Défense, March 8th, 2019

French original signed by:

Independent third party
ERNST & YOUNG et Associés

Partner, Sustainable Development
Caroline Delerable

Partner
Jean-François Bélorgey

Appendix 1: Information considered as the most important

Social Information	
Quantitative Information (including key performance indicators)	***Qualitative Information (actions or results)***
Lost time injury frequency rate – Sanofi employees* Lost time injury frequency rate – Any employee* Total occupational injury frequency rate – Sanofi employees* Total occupational injury frequency rate – Any employee* Number of occupational diseases reported* Employees under contract as of December 31, 2018 and breakdown by region, activity, gender, age and contract type* Number of new hires and departures (all reasons)* Resignation rate on permanent contracts* Turnover rate of employees on permanent contracts* Proportion of women in senior leadership positions* Proportion of women in executive positions*	Occupational health and safety conditions* Measures undertaken to promote diversity*

Environmental Information	
Quantitative Information (including key performance indicators)	***Qualitative Information (actions or results)***
Total quantity of hazardous waste, quantity of reused/recycled/recovered and non-reused/recycled/recovered hazardous waste, hazardous waste reuse/recycle/recover rate Wastewater discharge (Chemical Oxygen Demand, number of production sites assessed for discharge of pharmaceutical substances in 2018 and since 2016) Airborne emissions (total solvents used, percentage of regenerated solvents, emissions of volatile organic compounds) Total water consumption, and breakdown by water source* Total energy consumption, and breakdown by type of energy* Direct and indirect greenhouse gas emissions (scopes 1 & 2)* Significant greenhouse gas emissions generated as a result of the company's activities, including the following scope 3 categories: purchased goods and services (Category 1), use of sold products (Category 11), downstream transportation and distribution (Category 9), capital goods (Category 2), waste generated by operations (Category 5), fuel and energy related activities (Category 3)*	Measures to prevent, recycle and dispose of hazardous waste Measures to prevent, reduce or offset airborne emissions (management of volatile organic compounds), water (management of releases of pharmaceutical substances into the environment) and soil Water consumption and water supply according to local constraints* Percentage reduction in water consumption compared to the baseline year (2015)* Measures undertaken to improve energy efficiency and to promote the use of renewable energy* Percentage reduction in direct and indirect greenhouse gas emissions (scopes 1 & 2) compared to the baseline year (2015)*

Societal Information	
Quantitative Information (including key performance indicators)	***Qualitative Information (actions or results)***
Number of suppliers assessed on their CSR performance by an external service-provider in 2018 Number of audits of suppliers and subcontractors (Sanofi Contract Manufacturing Organizations, Active Pharmaceutical Ingredients suppliers) Number of Ethics & Business Integrity managers Number of "compliance champions" Number of alerts reported to the Ethics and Business Integrity Department and number of associated dismissals and resignations on grounds of misconduct Number of substantiated alerts relative to total number of alerts reported to the Ethics and Business Integrity Department Number of internal audits (GQA) Number of regulatory inspections Number of pharmacovigilance safety signals assessed Number of clinical trials Number of scientific publications Number of sites using animals Percentage decrease in the number of animals used by Sanofi	Actions in favor of human rights, in particular respect for the ILO fundamental conventions Consideration of environmental and social issues in procurement policies (results of CSR performance assessments, results of supplier and subcontractor audits) Measures undertaken in terms of ethics and business integrity Pricing measures undertaken Actions implemented with regard to access to healthcare* Measures undertaken with regard to product quality Measures undertaken with regard to product safety (pharmacovigilance) Measures undertaken with regard to medical ethics and bioethics Measures undertaken with regard to animal welfare

* *information that the entity has chosen to prepare and present outside its Statement in its management report*

4.5. Corporate social responsibility cross-reference table

The cross-reference table below shows the disclosures required pursuant to Articles L.225-102-1 and R.225-104 to R.225-105-2 of the French Commercial Code.

4.5.1. Statement of extra-financial performance (SEFP)

SEFP topic	Cross-reference to 2018 Chapter 4 or to the 2018 Annual Report on Form 20F	Page(s)
Business Model		
Business Environment		
a) Customers		
Distributors/wholesalers, pharmacies, hospitals, clinics, public bodies	♦ 20F: Item 4, B.6.1., "Marketing and distribution"	45
Marketing practices: direct sales, tenders	♦ 20F: Item 18, Note B.13., "Revenue recognition"	F-28
b) Prescribers	♦ 20F: Item 4, B.6.1., "Marketing and distribution"	45
c) Competition	♦ 20F: Item 4, B.6.2., "Competition"	45
d) Regulatory framework	♦ 20F: Item 4, B.6.3., "Regulatory framework"	46
e) Payers		
Government health insurance systems	♦ 20F: Item 4, B.6.4., "Pricing and reimbursement"	56
Private insurers (e.g. in the United States)		
f) Number of countries in which Sanofi products are sold	♦ 20F: Item 4, B.6.1., "Marketing and distribution"	45
g) Net sales		
3-year trend in net sales	♦ 20F: Item 18, "Consolidated income statements"	F-4
Net sales by segment and geographical region	♦ 20F: Item 18, Note D.35.1, "Segment results" ♦ 20F: Item 18, Note D.35.3, "Information by geographical region"	F-106 F-111
Organization and Structure		
Sanofi		
a) Number of employees		
Total, and split by segment, geographical region, gender, and type of contract	♦ 20F: Item 6.D., "Employees" ♦ Chapter 4.1.2.6., "Workforce"	187 370-371
Split by function	♦ 20F: Item 6.D., "Employees"	187
b) Sanofi sites		
Number of countries in which Sanofi operates	♦ 20F: Item 4, B.6.1., "Marketing and distribution"	45
Location and number of production/R&D/tertiary sites	♦ 20F: Item 4, B.8., "Production and raw materials" ♦ 20F: Item 4, D.1., "Overview" ♦ 20F: Item 4, D.6., "Description of our sites"	66 71 71
c) Operations and product life cycle		
Research & Development	♦ 20F: Item 4, B.5., "Global Research & Development"	34

SEFP topic	Cross-reference to 2018 Chapter 4 or to the 2018 Annual Report on Form 20F	Page(s)
Production: biological, chemical, pharmaceutical, vaccines	♦ 20F: Item 4, B.8., "Production and raw materials" ♦ 20F: Item 4, D.1., "Overview" ♦ 20F: Item 4, D.6., "Description of our sites"	66 71 71
Sales and Distribution	♦ 20F: Item 4, B.6.1., "Marketing and distribution"	45
End of life cycle management	♦ Chapter 4.1.3.4., "Managing pharmaceutical products in the environment"	378
d) Therapeutic areas and associated products		
Pharmaceuticals **Consumer Healthcare** **Vaccines**	♦ 20F: Item 4, B.2., "Main pharmaceutical products" ♦ 20F: Item 4, B.3., "Consumer healthcare" ♦ 20F: Item 4, B.4., "Vaccine products"	24 31 32
Number of products	♦ 20F: Item 4, B.2., "Main pharmaceutical products" ♦ 20F: Item 4, B.3., "Consumer healthcare" ♦ 20F: Item 4, B.4., "Vaccine products"	24 31 32
Product types (vaccines, biologic medicines, pills, injectables)	♦ 20F: Item 4, B.2., "Main pharmaceutical products" ♦ 20F: Item 4, B.3., "Consumer healthcare" ♦ 20F: Item 4, B.4., "Vaccine products"	24 31 32
e) Global Business Unit (GBU) structure		
Overview of GBUs	♦ 20F: Item 5, A.2.1, 2/ "Net sales by Global Business Unit"	88
Net sales by GBU	♦ 20F: Item 5, A.2.1, 2/ "Net sales by Global Business Unit"	88
Suppliers/Subcontractors		
Total amount of purchases **Number, type and location of suppliers**	♦ Chapter 4.2.4.13., "Procurement and subcontracting"	402
Partnerships and Alliances		
Regeneron and Bristol-Myers Squibb agreements **Alliance with Alnylam**	♦ 20F: Item 18, Note C, "Principal alliances"	F-34
Financial Performance		
Management report	♦ 20F: Item 5, "Operating and Financial Review and Prospects"	74
Trends, Objectives and Strategies		
a) Trends	♦ 20F: Item 4, B.1., "Strategy – The market context for Sanofi" ♦ 20F: Item 4., B.6.3.7., "Transparency and public access to documents"	80 52
b) Objectives and Strategy	♦ 20F: Item 4, B.1., "Strategy – Implementing the strategic roadmap"	22
Main Extra-Financial Risks		
♦ **Information about how the reporting entity takes account of the social and environmental consequences of its operations, and about the effects of those operations on human rights and the fight against corruption and tax evasion**	♦ 4.2., "Statement of Extra-Financial Performance and Vigilance Plan"	381

SEFP topic	Cross-reference to 2018 Chapter 4 or to the 2018 Annual Report on Form 20F	Page(s)
Other Topics Cited in Article L225-102-1 III of the French Commercial Code		
Consequences for climate change of the reporting entity's operations, and of the use of the goods and services it produces	♦ 4.1.3., "Environment"	373
Societal commitments in support of sustainable development	♦ 4.1.1., "Access to healthcare for the underserved"	358
Circular economy	♦ 4.1.3.5., "Waste management"	379
Reducing food waste	♦ 4.1.3.5.3. "Initiatives to reduce food waste"	380
Combatting food insecurity and promoting responsible, fair and sustainable food	♦ Not applicable	—
Respect for animal welfare	♦ 4.2.4.4.2.3., "Animal welfare"	389
Collective agreements entered into within the reporting entity, and their impacts on the entity's economic performance and on the working conditions of its employees	♦ 4.1.2.4., "Social dialogue"	368
Initiatives to combat discrimination and promote diversity, and measures to support disabled people	♦ 4.1.2.2., "Diversity and inclusion"	365

4.5.2. Duty of vigilance

Duty of Vigilance Topic	Cross-reference to Chapter 4	Page(s)
Identification and evaluation of risks generated by operations		
	♦ 4.2.3., "Presentation of risks and issues"	382
Regular evaluation procedures		
Product safety for patients and consumers	♦ 4.2.4.3.1., "Organization" ♦ 4.2.4.4.1., "Organization"	386 388
Biopiracy	♦ 4.2.4.5., "Biopiracy"	390
Personal data protection	♦ 4.2.4.6., "Personal data protection"	390
Employee health and safety	♦ 4.2.4.7.2., "Policies and action plans" ♦ 4.2.4.7.5.2., "Health programs"	391 395
Environmental releases	♦ 4.2.4.8.2., "Policies and action plans"	395
Use of water resources	♦ 4.1.3.3.1., "Water resource management plan"	377
Human rights	♦ 4.2.4.10.1., "Human rights risk mapping"	398
Procurement and subcontracting	♦ 4.2.4.13., "Procurement and subcontracting"	402
Appropriate actions to mitigate risks or prevent serious harm		
Product safety for patients and consumers	♦ 4.2.4.3.2., "Policies and action plans" ♦ 4.2.4.4.2.1., "Medical ethics and clinical trials"	387 388
Biopiracy	♦ 4.2.4.5., "Biopiracy"	390
Personal data protection	♦ 4.2.4.6., "Personal data protection"	390
Employee health and safety	♦ 4.2.4.7.5.1., "Occupational injury prevention programs" ♦ 4.2.4.7.5.2, "Health programs"	393 395
Environmental releases	♦ 4.2.4.8.2., "Policies and action plans"	395
Use of water resources	♦ 4.1.3.3.1. , "Water resource management plan"	377

Duty of Vigilance Topic	Cross-reference to Chapter 4	Page(s)
Human rights	♦ 4.2.4.10.3., "Policies and action plans"	399
Procurement and subcontracting	♦ 4.2.4.13., "Procurement and subcontracting"	402
Alerts systems and report-handling		
	♦ 4.2.5.3., "Alerts management and report handling"	403
Arrangements for monitoring the measures taken and evaluating their effectiveness		
Product safety for patients and consumers	♦ 4.2.4.3.3., "Performance indicators" ♦ 4.2.4.4.3.1., "Medical ethics and clinical trials"	387 389
Biopiracy	♦ 4.2.4.5, "Biopiracy"	390
Personal data protection	♦ 4.2.4.6., "Personal data protection"	390
Employee health and safety	♦ 4.2.4.7.4.1., "Internal audit" ♦ 4.2.4.7.5.1.5., "Occupational injury indicators" ♦ 4.2.4.7.5.2., "Health programs"	392 394 395
Environmental releases	♦ 4.2.4.8.3., "Performance indicators"	396
Minimizing the use of water resources	♦ 4.1.3.3.2., "Water consumption"	378
Human rights	♦ 4.2.4.10.4., "Performance indicators"	399
Procurement and subcontracting	♦ 4.2.4.13. "Procurement and subcontracting"	402

SANOFI

54, rue La Boétie 75008 Paris – France – Tel.: +33 (0)1 53 77 40 00 – www.sanofi.com