

CORPORATE SOCIAL RESPONSIBILITY

CHAPTER 4 OF 2020
DOCUMENT D'ENREGISTREMENT UNIVERSEL

2020



SANOFI



Forward-Looking Statements

This report contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

CHAPTER 4.

CORPORATE SOCIAL RESPONSIBILITY

Chapter 4 of 2020 Document d'Enregistrement Universel*

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*This is a free translation into English of the "Chapitre 4, Responsabilité Sociale, Environnementale et Sociétale" of our 2020 Document d'enregistrement universel issued in French. It is provided solely for the convenience of English-speaking readers.

4.1. Statement of extra-financial performance

This chapter sets out for 2020 [GRI 102-51] the material issues facing Sanofi in terms of corporate social responsibility (CSR) and the identified risks, in accordance 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 the 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 section 4.7, "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 by Sanofi in 2015. Some GRI indicators are identified in the body of this report within square brackets. A full cross-reference table, the "GRI Content Index", is available via the Document Center at www.sanofi.com.

Sanofi is also a signatory of the United Nations Global Compact, and as such discloses annually the progress achieved against the principles contained in the Compact.

A methodological note on how we report our data is provided in section 4.5.

This 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 4.6.

4.1. Statement of Extra-Financial Performance

[GRI 102-11]

4.1.1. Methodology for selecting risks and issues for the Statement of Extra-Financial Performance (SEFP)

The principal SEFP risks and issues were identified by our Corporate Social Responsibility (CSR) department, in collaboration with our Risk Management department, on the basis of (i) Sanofi's material risks and issues and (ii) material issues identified in the industry-specific standard (Biotechnology & Pharmaceuticals) issued by the Sustainability Accounting Standards Board (SASB).

Our materiality and extra-financial risk matrices were updated by an independent third party in 2020 as part of a review of our CSR strategy. This review identified issues that have assumed higher importance in light of the Covid-19 crisis. The outcome of that process is a list of eight SEFP risks and four SEFP issues, as summarized in the table in section 4.1.2.

Policies and action plans for each of those risks are described in section 4.2.

A cross-reference table showing all the information required in the SEFP, including the presentation of the business model, is provided in section 4.7, "Corporate social responsibility cross-reference tables".

4.1.2. Table of SEFP risks and issues

[GRI 102-46, GRI 103-1]

Category	Field or activity	Type	Description	Risk mentioned in Item 3.D, "Risk Factors", of our 2020 Annual Report on Form 20-F	Section in this chapter
Social	Human capital	Issue	We rely on the commitment and expertise of our people to attain our strategic objectives in a fast-changing, highly competitive environment.		4.2.1. Human capital
	Attracting and retaining talent	Risk	Risk that we will be unable to attract, integrate or retain people with the necessary profiles and skillsets, which could adversely affect our ability to implement our strategy and attain our objectives.	x	4.2.1. Human capital
Societal	Access to healthcare	Issue	An integrated approach to access to healthcare, combined with philanthropy, can generate opportunities for growth, innovation, and unique partnerships.		4.2.2. Access to healthcare
	Product pricing	Risk	Risk that our pricing policy will mean access to our products does not meet the expectations of certain stakeholders and/or the market, undermining our commitment to patients and the healthcare system.	x	4.2.2. Access to healthcare
	Product quality *	Risk	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, or that other quality issues will arise that could have an adverse effect on patients or healthcare professionals.	x	4.2.3. Product quality
	Product safety for patients and consumers *	Risk	Risk of product safety breaches, from first administration in clinical trials on humans through to the end of the product's life cycle, that could have an adverse effect on patients or healthcare professionals.	x	4.2.4. Product safety for patients and consumers
	Animal protection *	Risk	We must comply with ethical standards and principles that are essential to the responsible use of animals in scientific and medical activities.		4.2.11. Animal protection
	Supply chain continuity *	Risk	Risk of supply chain interruptions, product recalls or loss of inventories due to unforeseen events, which could harm society (patients and healthcare professionals) and damage our reputation.	x	4.2.6. Supply chain continuity
	Local Communities	Issue	With operations in more than 100 countries worldwide, we must manage our economic, social and environmental impact so that we make a positive contribution to the places around our sites and support the sustainable development of communities.		4.2.7. Communities and places
Environment	Ethics and business integrity	Risk	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.	x	4.2.8. Ethics and business integrity
	Climate change and carbon footprint	Issue	Climate change generates risks as diverse as the impact of extreme weather events on our infrastructure and supply chain; scarcity of resources; carbon taxes, and their financial impact; and the direct or indirect repercussions for human health.		4.2.10.2. Climate change: towards carbon neutrality
	Environmental releases *	Risk	Risk that discharges and emissions from our industrial and R&D operations will adversely affect the environment or human health, or will not be appropriately managed by our own staff or by our suppliers or subcontractors.	x	4.2.10.5. Environmental releases

* Indicates risks that apply not only to our own operations, but also to those of our suppliers, subcontractors and partners. See section 4.3.14, "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. Detailed description of SEFP issues and risks

[GRI 103-1, GRI 103-2, GRI 103-3]

4.2.1. Human capital

Our ambition to 2025 is for Sanofi to reinforce its position as an innovative global biopharmaceutical leader focused on human health, supported by digital solutions, and delivering growth for our three Global Business Units (Specialty Care, Vaccines and General Medicine) and our standalone Consumer Healthcare entity.

To achieve this ambition, we face major challenges in terms of human resources, such as anticipating and delivering changes to the skillsets of our employees in a fast-changing environment. Striking the right balance between science, innovation, technological progress and personal commitment is key.

4.2.1.1. Strategy and organization

In January 2020, our senior management outlined the new “Play to Win” strategic roadmap to the Group Works Council. The strategy is underpinned by four key objectives:

- focus on growth by leveraging our high-potential assets, Dupixent® and our vaccines portfolio;
- lead with innovation, prioritizing six therapies with the potential to transform patients’ lives;
- accelerate our operational efficiency; and
- reinvent how we work, by structuring our business into three fully accountable global business units (GBUs) – General Medicines, Vaccines and Specialty Care – plus a standalone Consumer Healthcare (CHC) entity.

In this fast-changing environment, Human Resources functions both as a strategic partner and as a catalyst for change.

Following the announcement of Sanofi’s new strategic roadmap, our Human Resources (HR) function has evolved to provide optimal support through the process of organizational change and cultural transformation.

Our HR function operates on global lines, with harmonized processes and shared tools deployed across the whole of Sanofi. The four key objectives of the new “Play to Win” strategy feed into an HR roadmap, with four pillars:

- a clean, efficient organizational structure: Sanofi is an agile, competitive organization that meets the needs of patients and the market, drawing on a solid pool of talent with good skillsets;
- meaningful career journeys: fulfilling, life-enhancing experiences at work help our people to progress and grow;
- a decisive culture: our corporate culture allows our people to flourish, and to contribute to our success;
- diversity that sets us apart: our ability to draw maximum strength from the diversity of our people and our partners helps our business outperform.

Alongside objectives relating to Sanofi’s annual performance and individual objectives, the variable portion of the compensation awarded to members of our Executive Committee is 20% linked to human capital objectives such as gender balance in senior executive roles, individual career development plans, and talent and key skills management.

Sanofi’s HR function maps onto the new “Play to Win” organizational structure, with separate HR departments responsible for:

- the four GBUs (General Medicines, Vaccines, Specialty Care, and the standalone Consumer Healthcare GBU);
- four newly re-defined regions (North America, Europe, International and China), as well as France;
- three global functions (Research & Development, Industrial Affairs and Support Functions); and
- four Centers of Excellence (Talent Management, Rewards & Performance; Organizational Development; Culture & People Development; and Diversity & Experience).

Our HR function is staffed by around 1,150 people, 50% of whom are HR Business Partners who support our business operations. The other 50% work in our Centers of Excellence, dealing with matters such as compensation and employee benefits, talent management, analytics and systems, training and development, and trade union relations.

4.2.1.2. Workforce

[GRI 102-8, GRI 405-1]

Sanofi had 99,412 employees under contract at the end of 2020, 1% fewer than at the end of 2019. The reduction reflects a policy to control the size of the workforce by hiring fewer external candidates and prioritizing internal candidates.

External staff represented a total of 7,742 full-time equivalents in 2020 (6,809 in 2019), comprising 6,193 temporary staff (5,220 in 2019) and 1,549 third-party sales forces staff (1,589 in 2019).

Distribution of employees under contract by region

Employees under contract as of December 31	Worldwide		Europe ^(a)		United States		Rest of the world	
	2020	2019	2020	2019	2020	2019	2020	2019
Employees under contract	99,412	100,409	46,761	46,236	12,972	12,592	39,679	41,581
%	100.0%	100.0%	47.0%	46.0%	13.0%	12.5%	39.9%	41.4%

(a) For a list of countries included in the Europe region, refer to section 4.5.2.1.2., "Regions".

Distribution of employees under contract by activity

Employees under contract as of December 31	Worldwide		Pharmaceuticals		Vaccines		Consumer Healthcare		Other ^(a)	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Employees under contract	99,412	100,409	64,604	66,379	15,676	15,285	9,127	7,735	10,005	11,010
%	100.0%	100.0%	65.0%	66.1%	15.8%	15.2%	9.2%	7.7%	10.1%	11.0%

(a) The "Other" column comprises employees of our global support functions (Medical Affairs, External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.).

Distribution of employees under contract by global function

Employees under contract as of December 31	2020	2019	2018	2017
Production	37,935	37,873	38,790	40,417
Research and development	15,446	15,538	15,140	14,764
Sales force	25,203	26,178	28,914	30,284
Marketing and support functions	20,828	20,820	21,382	21,101
Total	99,412	100,409	104,226	106,566

Distribution of employees under contract by age bracket

Distribution of employees under contract by age bracket	Worldwide	
	2020	2019
Under 21 years	0.3%	0.2%
21 to 25 years	4.5%	4.8%
26 to 30 years	10.8%	11.2%
31 to 40 years	30.4%	30.8%
41 to 50 years	29.4%	29.4%
51 to 60 years	21.5%	21.1%
Over 60 years	3.2%	2.5%

The average age of our employees in 2020 was 42.1 years (versus 41.7 years in 2019).

4.2.1.3. Agile and efficient organization

[GRI 102-41, GRI 403-4]

Sanofi has an agile, competitive organizational structure that meets the needs of patients and the market, while developing skillsets and allowing the next generation of talent to emerge.

4.2.1.3.1. Organizational change

We need the teams at each of our Global Business Units (GBUs) and support functions to play a full part in implementing the strategy set by senior management. This involves improving our operational performance and reinventing how we work, so we can better serve the interests of our patients, our customers and our people over the long term.

This reorganization project includes headcount adjustment measures, resulting not only from new technologies but also from better task-sharing and prioritization, and from streamlining our organizational structures and processes. It also includes a commitment to hire 100 new people with skills in emerging or developing fields.

Making Sanofi CHC a world-beating Consumer Healthcare organization

To deliver on this ambitious goal, we need to make Sanofi CHC more agile and responsive, so that it can operate effectively in the specific market context of the pharmaceuticals industry. That's why it was decided to create a standalone CHC entity, which nonetheless remains one of Sanofi's four GBUs.

Creating EUROAPI a new independent European active pharmaceutical ingredient company

We expect EUROAPI, a specialist company developing, manufacturing and selling active pharmaceutical ingredients (API) to become the world's second-largest API producer, in a constantly growing but fragmented market. Sanofi would remain the principal shareholder and biggest customer of the new entity, giving it the best chance of success.

These reorganization projects in no way undermine our objectives and resource allocations in terms of training and skills development, especially within the framework of the strategic workforce planning process.

4.2.1.3.1.1. Promoting 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 our employees; see the Vigilance Plan, section 4.3.6, "Fundamental human rights at work".

In Europe, Sanofi's European Works Council (EWC), which includes 40 members and 40 alternates, represents employees who work in European Union countries. In 2020, the EWC met in June, September, November and December. At the meeting on June 26, Sanofi's Executive Committee outlined the strategic roadmap for implementing the "Play to Win" strategy. At subsequent meetings, the EWC was informed about the projects contained in the strategic roadmap, including the proposal for CHC to become a standalone entity within Sanofi, and the EUROAPI project.

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

4.2.1.3.1.2. Organizational change and social dialogue in France

The organizational change needed to support our new "Play to Win" strategy will result in the loss of no more than 700 posts. The scheme is entirely voluntary, and gives the employees concerned the opportunity to be supported as they embark on a personal project or take retirement.

Employee representatives were consulted about the terms and timing of the proposals, and collective termination agreements were signed in November 2020 within Sanofi-Aventis Groupe, Sanofi Aventis France, Sanofi Chimie and Sanofi Winthrop Industrie, the entities that house our GBUs and support functions.

The proposal for CHC to become a standalone entity within Sanofi is expected to create more than 200 new posts in France, with priority given to internal candidates. Sanofi has committed to maintaining the existing terms of employment and collective agreements. In France, the employee consultation process began in November 2020 and is scheduled to be completed in the first quarter of 2021, ahead of implementation in the second half of the year.

The EUROAPI project, announced in February 2020, was presented to the French employee representative bodies on November 5, 2020; it will be implemented by 2022, once the consultation process has been completed. It would have no impact on jobs. In France, it affects sales and central support function teams based in Paris, as well as the Vertolaye and Elbeuf sites.

In France, Sanofi runs “Career Lab”, a support platform to help employees reposition themselves within or outside the company if their roles are in decline or changing. More than 160 people signed up to the Career Lab in 2020.

4.2.1.3.1.3. Organizational change and 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 so as to strike a balance between the interests of the employees and of the company. During 2020, negotiations were conducted with these bodies on a range of issues:

- reorganization projects affecting global support functions, the Primary Care business unit, and senior management roles in subsidiaries. In R&D and Industrial Affairs, negotiations with local and central Works Councils concerned the loss of around 800 jobs and related impacts;
- the proposed transfer of the Sanofi Genzyme organization (apart from sales forces) from the Berlin and Neu-Isenburg sites to the Frankfurt Industriepark site, with Neu-Isenburg closing at the end of the year;
- ongoing enhancements to our new systems – such as new skillset applications (such as HR) in Workday, and the One LMS learning management system – with the Central Works Council agreeing to the rollout of new functionalities;
- consultation with the Central Works Council on the creation of new marketing job profiles for all our Global Business Units;
- agreement on a new salary structure for non-managerial staff, aligned on Sanofi’s global staff grades, and negotiations on the implementation of new collective agreements for “Arbeiten 4.0”.

As in previous years, Sanofi 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.

4.2.1.3.2. Developing the skills needed for growth

4.2.1.3.2.1. Talent and key skills management plan

To meet the operational challenges arising from our transformation and product launches, we have since 2016 systematically used Strategic Workforce Planning (SWP) to determine the capabilities needed for future growth, assess our competencies, and develop appropriate learning solutions at every level of our organization.

The SWP process involves analyzing our strategic objectives, assessing how these will impact on our operations, and then making concrete plans to meet the identified needs in both quantitative and qualitative terms: what workforce will we need, with what skills and organizational structure, and in what location? The aim is to achieve the best possible allocation of resources to meet business needs in our Global Business Units and geographies.

A multi-level governance structure has been set up to optimize rollout of SWP projects. This is headed up by the SWP center of excellence, which:

- provides quarterly project progress reports to the Executive Committee on the most critical projects;
- heads up the network of SWP project managers working at GBU/activity level, in order to harmonize methodologies, share good practices and measure the impact of progress; and
- liaises with geographies affected by projects, to ensure they are successfully delivered locally and to share information with the HR and Finance functions who drive the local rollout.

This governance structure provides an enhanced interface and better communication between work areas on the one hand, and global/local organizations on the other.

For the 2020-2022 period, following on from past initiatives in major fields such as R&D, Medical Affairs, Marketing and Operational Support, five new fields have been put forward for specific SWP analysis to support the “Play to Win” strategic ambition, each with a specific pattern of delivery:

- three projects fall within the Specialty Care GBU and cover a specific product or therapeutic field: Dupixent[®], Rare Blood Disorders and Oncology;
- one project involves an analysis of four global support functions (Legal Affairs, Ethics & Compliance; Human Resources; Finance; and Digital/IT Systems) in around ten countries, representing approximately 80% of the workforce in those functions; and
- one project covers all sales teams, with one GBU (General Medicines) given priority.

4.2. Detailed description of SEFP issues and risks

These projects were appended to the Strategic Plan shared by our Executive Committee in July 2020. They aim to accelerate our roadmap by delivering on the following objectives:

- forecasting workforce needs and tracking changes over the next five years;
- preparing skillset lists for each field that build in forward-looking analyses of the skills and job profiles of the future;
- a programmed skillset analysis plan for each function;
- drafting action plans to bridge skills gaps (such as leadership or vocational training via the academies set up at global support function level, external hires or organizational changes), and to reallocate people between jobs according to the official SWP classification used by Sanofi (which splits job profiles into five categories: sensitive, stable, undergoing transformation, under pressure, and emerging);
- tracking trends in staff costs and resource allocation; and
- overseeing implementation of action plans at local level, in liaison with global management of the functions involved.

In line with the good governance practice we have applied since 2017, one of these strategic projects (Dupixent®) will count for 5% of the collective variable compensation of Executive Committee members.

SWP has been integral to our HR strategy since 2016. However, successful implementation of SWP in priority functions/geographies has paved the way for a transformation of HR, synchronizing it more closely with our business agenda and strengthening partnerships between HR and Finance.

Action plan	
2016 to mid-2018	Mid-2018 to 2021
<ul style="list-style-type: none"> • Define the overall SWP methodology and governance structure • Identify priority departments for analysis: Medical Affairs, Marketing, Market Access, Biology. • Executive Committee sign-off on priority areas, and on the SWP performance indicators to include in variable compensation of top management • Select IT solutions for quantitative and qualitative analysis 	<ul style="list-style-type: none"> • Engage with Human Resources teams to set up dedicated SWP structure and network • Liaise with Talent Acquisition, People Development, Human Resources Business Partners (HRBPs), and business units. • Measure the impact (including internal job transfers, training and talent pool) • Predictive workforce analysis for all departments, linked to the roadmap and operational needs • Adopt predictive workforce analysis as a standard human resources tool

Overall, our “Plan to Win” SWP process helps support the rollout of our “Play to Win” strategic plan, by identifying what we need to invest in human capital in the short and medium term. This extends from in-house performance and talent management, to optimizing staff allocation and hiring in new skillsets as needed. Our SWP approach also takes account of market dynamics around new working practices (such as teleworking, shared platforms and shared service centers) and new areas of expertise (such as digital and database management).

Within Sanofi, qualitative skills gap analysis helps optimize investment in training, especially for the in-house academies (training programs dedicated to a specific function and encourages job transfers between departments (see section 4.2.1.3.2.2., “Allowing the next generation of talent to emerge”). It can also help in calibrating the number of in-house or external recruits needed and the skillsets required, identifying target entities/geographies, and focusing on people who match the desired profile (see section 4.2.1.4.1.1., “Attracting and retaining talent”). The ultimate aim is to be able to anticipate changes in skillset requirements and be more aware of how each work area’s needs are evolving.

4.2.1.3.2.2. Allowing the next generation of talent to emerge

In 2020, we took our commitment to staff development to the next level with the launch of the Sanofi University, which provides learning solutions for our people that reflect the key skillsets and capabilities essential for our activities (in line with our Talent and Skillset Management Plan).

We are continuing to expand our catalog of learning solutions and making them easily accessible to all our people across the world through our iLearn shared platform. Through five newly created institutes, the Sanofi University offers learning resources focused on personal development, medical excellence, R&D, and digital. Other programs aimed at sales forces and marketing staff have also been successfully introduced. Around 13,000 medical reps and sales managers across 100 countries have followed a pathway to develop and hone their skills in business development, negotiation and sales techniques (face-to-face or online), thereby also making them more effective as individuals. We recently launched our Marketing Excellence program, which we developed out of an analysis of the skillsets needed in this field and delivered it to 2,000 of our marketing staff. Initial results show an engagement rate of over 90%, and a knowledge gain of close to 70%.

Our personal development program continues to encourage a holistic learning experience derived from the 70-20-10 model. This delivers benefits by a mix of formal training and informal learning through experience, projects, and mentorship. It is based on the fact that learning comes 70% from job-related experiences, 20% from interactions with others, and 10% from more formal training.

We continue to actively support learning and personal development for our employees everywhere in the world, so that they can meet the needs of our constantly changing business while fulfilling their personal aspirations. During 2020, we organized a number of events to support and engage our people in the learning sphere, for example a series of “#BeCurious & Stretch” events aligned on the new behaviors promoted by our “Play to Win” culture. Worldwide, 20,000 employees signed up for these events, joining the #BeCurious community on our in-house Yammer network (which has around 23,000 subscribers).

Thanks to the Sanofi University launch and to the commitment of our learners, we observed a rise of over 90% in the completion rate of the digital learning resources available in iLearn, and an increase of over 120% in training hours.

Training performance indicators ^(a) :	2020	2019
Number of employees receiving training (based on the iLearn system)	107,183	106,288
Number of training modules		
iLearn ^(b)	47,118	8,544
Le@rn ^(c)	10,552	8,954
Peps ^(d)	20,133	109,458
Number of training hours:		
iLearn	2,582,027	825,293
Le@rn	105,983	155,982
Peps	220,243	205,005

(a) These figures do not include training programs followed by subcontractors.

(b) iLearn delivers all compulsory and support function training:

- Compliance: Ethics and Business Integrity, Pharmacovigilance.
- Quality.
- Workplace First-Aiders.
- Business Development, Management and Leadership.

Ultimately, iLearn will deliver all Sanofi training programs.

(c) The Le@rn system is dedicated to training in Good Pharmaceutical Practices at Sanofi (such as Good Manufacturing Practices) and is deployed worldwide.

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

4.2.1.4. Meaningful career journeys

4.2.1.4.1. Developing Sanofi leaders

In parallel with the Sanofi University launch, the People Development Learning Institute was set up, bringing all our cross-disciplinary skills, management and leadership training solutions into a single institute. We responded rapidly to the COVID-19 crisis by adapting our training solutions to offer virtual learning experiences, including both self-study modules and sessions led by online trainers. As a result, we were able to deliver training to over 25,000 participants (including 2,800 Senior Leaders and 7,500 managers), 9% more than in the previous year.

Key developments during the year included:

- “Management Essentials”: we revamped this learning program, intended for local managers in every country where we operate. The program now offers a blend of virtual classes and self-study resources, with a wide range of modules to teach key managerial skills. 745 employees followed this program.
- “Leading through Change”: this training program uses a combination of virtual classes, self-study modules and a toolbox to support employees driving change within Sanofi. 4,210 employees followed this program.
- We also rolled out a suite of learning solutions to help people build and enhance cross-disciplinary skills in sync with Sanofi’s priorities; these included project management, storytelling and career management. The number of completed courses was double that of 2019.

4.2.1.4.1.1. Attracting and retaining talent

Build on recent actions to professionalize our practices in talent management and recruitment (both internal and external), we have now combined the two functions (Talent Management and Recruitment) under unified leadership, supported by a global center of excellence. The aim is to continue to invest in promoting our employer brand, while placing greater emphasis on internal career opportunities and diversity.

The employer brand created in 2018 has now been cascaded out into all geographies and all our Global Business Units via testimonies from Sanofi people, sharing their varied career journeys and highlighting our corporate culture. Our employer brand will be fine-tuned in 2021 so that it fully reflects the ambitions underpinning our “Play to Win” strategy and changes in what our talents expect of us, whether in terms of diversity or working practices (accelerated by the COVID-19 crisis).

We draw on candidate experience to guide what we do and how we invest. After launching our careers site for external hires in 2019, with advanced search features and a personalized candidate experience, 2020 saw the rollout of our first-ever in-house careers site, with similar user functionalities. In parallel, we continue to invest in digital solutions such as chatbots, automated candidate identification, AI pre-selection tools, non-discriminatory job descriptions, and candidate relationship management tools.

In 2020, Sanofi obtained global Top Employer accreditation for the third successive year, thanks to accreditations for 24 subsidiaries (Argentina, Australia, Brazil, China, Colombia, Egypt, France, Germany, Hungary, India, Italy, Kazakhstan, Malaysia, Mexico, Philippines, Poland, Russia, Singapore, Spain, South Africa, Turkey, United Kingdom, United Arab Emirates, Vietnam) and four regions (Europe, Middle

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East, Asia-Pacific, Latin America). “Top Employer” accreditation is awarded in recognition of efforts made by employers to improve working conditions for their employees.

Our strategy has paid off, with improvements in all our performance indicators: 40% of vacancies were filled through internal transfers (65% in France); managers expressed a 91% satisfaction rate on new hires (Gartner benchmark); and targeted marketing efforts reduced our dependence on external recruitment firms by 58% between 2015 and 2020. Our new tools, coupled with the professionalization of our in-house teams, give us the ability to hire quality people faster, and without reliance on third parties.

Despite an increase in the volume of new hires, the COVID-19 crisis did not have an adverse impact on the management or quality of recruitment at Sanofi.

Our performance indicators for external hires and internal job transfers/promotions are summarized in the table below:

	2020 targets	2020	2019
Internal transfers and promotions			
Senior leaders (in %) ^(a)			
Executive posts ^(b)	80%	87%	92%
Grade 5 posts ^(b)	70%	75%	66%
<i>total workforce excluding executive posts (in %)</i>		40%	36%
Other indicators			
Succession planning <i>Executive posts</i>		43%	49%
Inter-entity job transfers ^(c) (cross-GBU/GSF) <i>Employees eligible for variable compensation (STI)</i>		2,932	2,809
Staff turnover <i>Employees eligible for variable compensation (STI)</i>			
Voluntary ^(d)		6.0%	7.3%
Total ^(e)		9.5%	12.3%

(a) This indicator is included in the collective qualitative criteria for variable compensation of Executive Committee members (counts for 5%).

(b) See section 4.5.2.1.5., “Definition of grades”.

(c) Inter-entity job transfers also includes corrections to organizational data, and movements due to the reorganization of our GBUs and global support functions.

(d) Voluntary staff turnover = Voluntary departures of employees eligible for STI / Total number of employees eligible for STI at year-end.

(e) Total staff turnover = All departures of employees eligible for STI / Total number of employees eligible for STI at year-end.

4.2.1.4.1.2. Staff engagement

Our People Survey, rolled out Sanofi-wide in 2017 and repeated in 2018, provided benchmarks against which we could measure our future development. The survey data helped us identify and rank opportunities to improve employee engagement and our corporate performance. We outperformed the benchmarks in three areas: individual and team alignment with Sanofi objectives; engagement and pride in fulfilling our mission; and effective co-operation between teams.

However, despite some improvements, we still face key challenges in anticipating change, reducing bureaucracy, and cross-disciplinary co-operation within entities. In an ever-more difficult external environment, we need to become more agile if we are to be competitive.

Following the organizational changes under the “Play to Win” strategy, we did not repeat the People Survey in 2020. However, staff engagement remains high overall as shown by the voluntary staff turnover rate, which is less than 7%.

	2020	2019
Staff turnover <i>Employees eligible for variable compensation (STI)</i>		
Voluntary ^(a)	6.0%	7.3%
Voluntary - High Potential	6.9%	N/A
Total ^(b)	9.5%	12.3%
Total - High Potential	8.1%	N/A

(a) Voluntary staff turnover = Voluntary departures of employees eligible for STI / Total number of employees eligible for STI at year-end.

(b) Total staff turnover = All departures of employees eligible for STI / Total number of employees eligible for STI at year-end.

4.2.1.4.2. Compensation and employee benefits

4.2.1.4.2.1. Compensation policy

Our compensation policy is designed to reward employee performance, delivering fair, market-competitive rewards while ensuring alignment with Sanofi’s strategy via a strong link between corporate and employee performance. It aims to promote a culture of performance and employee development, contributing to the sustainable success of Sanofi.

The compensation arrangements of our Chief Executive Officer and the Chairman of our Board are described in Item 6.B., “Compensation” of our 2020 Annual Report on Form 20-F.

The key components of our compensation and benefits policy are:

- Fixed reward: base pay established according to the employee’s skills, level of contribution to the organization, and market practices. This aims to reward the value, key skills, competencies and potential of our employees.
- Short-Term Incentive (STI) compensation is our annual variable cash incentive compensation. STI rewards employees individually for their contribution to the attainment of Sanofi’s annual corporate goals. The overall STI budget is based on Sanofi’s annual performance, which in turn is derived from the annual performance of identified key performance indicators (KPIs), which may vary from year to year.
- Equity-based programs:
 - Long Term Incentive (LTI) compensation involves performance shares, designed to build loyalty and motivate critical employees and key talents towards achieving Sanofi’s long-term goals. Along with STI, this is a key component of our compensation programs. Awards of performance shares are approved by our Board of Directors, and delivery of the shares is contingent on Sanofi attaining performance criteria over three financial years.
 - Employee Stock Purchase Plan (ESPP): this is a company-run program in which employees can become Sanofi shareholders by acquiring our shares on preferential terms.
- Employee Benefits: these are primarily plans providing for retirement benefits, reimbursement of medical expenses, and death and disability benefits.

(€ million)	2020	2019	2018
Net sales	36,041	36,126	34,463
Personnel costs	9,076	9,139	9,269
Ratio of personnel costs to net sales	25,2%	25,3%	26,9%

4.2.1.4.2.2. Employee benefits

Sanofi strives to ensure that all employees worldwide receive high-quality benefits covering health, old age, incapacity, disability and death. Those benefits comply with national regulations, are adapted to local cultures and provide the coverage that best meets employees’ needs. On a regular basis, we take part in a comprehensive market survey, conducted in over 70 countries, to ensure that the employee benefits we offer are in line with current local practices. We also make sure that our employee benefit plans are designed for the long term. In all countries, employees (as well as, in general, their spouses and children) receive a good level of reimbursement of medical expenses as well as death benefits.

In the vast majority of countries, Sanofi also offers benefits covering temporary or permanent incapacity. In France for example, all Sanofi employees, irrespective of the type of contract they hold (fixed-term or permanent, part-time or full-time), are entitled to the same medical and welfare benefits from the moment they are hired.

In order to limit employee-related liabilities, Sanofi prefers defined-contribution plans (where the employer’s commitment is restricted to paying the amount of its annual contribution) over defined-benefit plans (where the employer’s commitment is to pay the amount of the future benefit).

As regards “insured” plans, Sanofi seeks to optimize funding and reduce administrative costs by using programs such as insurance pooling or through the use of a captive insurance company. These plans not only offer economies of scale for the subsidiaries, they are also designed to ensure financial oversight and optimal governance. Sanofi has had a dedicated Employee Benefits Steering Committee since 2010. The remit of the Committee, which is chaired by our Chief Financial Officer and our Executive Vice President, Human Resources, is to:

- review and approve Sanofi’s overall employee benefits strategy;
- review and approve the implementation or amendment of any defined-benefit pension plan; and
- review and approve the implementation or amendment of any defined-contribution pension plan above a limit set in advance by the Committee.

Whenever possible, Sanofi provides personalized employee benefit programs (medical, vision, dental, etc.) that allow employees to adjust their coverage according to their family situations and personal needs. These types of programs have been instituted in China, the United States, the United Kingdom and Ireland, for example.

In some countries, medical benefits also include programs focusing on prevention, vaccinations, screening (e.g. diabetes and skin cancer), nutritional advice, well-being, etc. In the United States and many other countries, employees can sign up to “Take Care & Bwel!”, Sanofi’s complete employee wellness program.

This 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

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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.

The program operates in 62 countries and at 140 sites worldwide, representing 90% of audited sites with over 100 employees. Our goal is to continue with this program, supporting sites as they implement good practices adapted to a changing environment. Since 2017, we have developed 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, as recorded in a published scientific paper (Montagni, 2019: “Effectiveness of a Blended Web-Based Intervention to Raise Sleep Awareness at Workplace: The WarmUapp™ Pilot Study”, *Journal of Occupational and Environmental Medicine*). In 2019, we released a new digital app (“Walk Well”) that our employees can use to organize walking challenges at all our sites. Since then, numerous challenges have been completed by our employees, involving thousands of people. We have also been able to show that simple food labeling practices adopted in our corporate cafeterias are effective, and help our people make healthy eating choices in line with international nutritional recommendations (see “Using Positive Nudge to Promote Healthy Eating at Worksite: A Food Labeling Intervention”, Montagni et al, *Journal of Occupational and Environmental Medicine*, 2020).

During 2020, we adapted our wellness at work solutions in response to the COVID-19 pandemic. This included widely available online resources (exercise classes, stretching and relaxation sessions, and mindfulness), plus webinars offering psychological support and healthy lifestyle tips. We also intensified our distribution of online newsletters and advice to reach as many of our people as possible, with extra support for teleworkers, salespeople and shift workers.

4.2.1.5. Decisive culture

Like many other great companies, we value teamwork, respect, integrity and courage. What makes us special is how we are focusing on living those values through our “Play to Win” behaviors: Stretch, Take action, Act for patients and customers, Think Sanofi first¹.

A culture shift takes more than posters and slogans. It involves changing our behaviors every day, everywhere: how we interact together, how we treat each other, what we do and don’t tolerate, and how we keep holding each other accountable. This is a long-term project, with a three-to-five-year time horizon, which will permeate gradually within our organization.

Our four “Play to Win” behaviors emerged from a cultural diagnostic review conducted in November 2019, and from our “Play to Win” priorities as announced by our Executive Committee at the Capital Markets Day in December 2019. This collaborative effort, carried out at the annual meeting of the 250 Sanofi Leaders in February 2020, provided the answer to the question: “Based on the diagnostic review and our “Play to Win” priorities, what behaviors do we want to see?”. The outcome was a decision that “Stretch, Take action, Act for patients and customers, Think Sanofi first” would be our priorities in reinventing how we work together. So during 2020, we initiated a series of actions at four levels that we intend to embed in our culture well beyond 2020:

- ensuring our leaders are exemplars of the four “Play to Win” behaviors;
- identifying a network of informal influencers capable of creating a shift away from old habits towards the new behaviors at grassroots level;
- using personal testimony and lived experience to tell stories that demonstrate the four behaviors; and
- evolving our key systems (HR and Finance) so that they encourage everyone at Sanofi to adopt the four “Play to Win” behaviors.

We launched various initiatives in 2020, at both global and country level; these are intended to continue beyond 2020, and further actions will be developed in 2021.

4.2.1.6. Diversity that sets us apart

4.2.1.6.1. Diversity and inclusion

[GRI 405-1]

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

¹ Think about the interests of Sanofi ahead of those of individual GBUs, support functions, or your own team.

The strategic pillars of our global Diversity & Inclusion department are:

- work on inclusion and engagement;
- promote cultural diversity in the workplace; and
- support our business and enhance our reputation.

4.2.1.6.1.1. Gender balance

Promoting gender balance is at the heart of our strategy. Bringing more talented women on board is one of the individual variable remuneration objectives for Executive Committee members. We have committed to achieving gender balance in our population of Senior Leaders and 40% of women in our Executive population by 2025.

In terms of governance, our Gender Balance Board consists of 10 senior executives (5 women and 5 men), 4 of whom are Executive Committee members. They support regional networks around the globe, sponsor initiatives to promote gender balance within Sanofi, and serve as role models. Our Gender Balance Board members are role models within Sanofi, leading by example in gender balance within their own teams and inspiring others through their behaviors and career journeys. They also act as spokespersons, both within and outside Sanofi.

Our Gender Balance Board and Gender Balance network, alongside our Executive Committee members, show their commitment through participation in events such as International Women's Day, the Women's Forum and the World Economic Forum and our own in-house awareness campaigns like "I'm in" and "Challenge Your Bias". They also back local initiatives, such as mentorship and coaching programs.

To meet our objective of achieving gender balance by 2025, we are focusing on three priorities:

- the "I'm In" awareness program;
- mentorship and leadership training programs to prepare women to assume senior executive roles, including "Elevate", which is wholly devoted to the development and progression of women through the organization; and
- a more welcoming and inclusive workplace environment, as illustrated by the International Women's Day webcast, "Women@Sanofi" posts on the intranet, and a dedicated Yammer group.

Gender balance	Performance indicators	
	2020	2019
Ambition Our ambition is to achieve gender balance in Sanofi Senior Leaders ^(a) by 2025.	38.8% women	37.2% women
Action plan Policy requiring women to be integrated into the recruitment process for executive roles. Since 2018, we have been running "Elevate", a new program intended to prepare women to assume Senior Leader roles within Sanofi.	Policy rolled out Number of sessions: 1 Number of women who have followed the "Elevate" program: 43	Policy rolled out Number of sessions: 2 Number of women who have followed the "Elevate" program: 93
Ambition Our ambition is to achieve 40% of women in our Executive population (approximately 500 posts) by 2025. This ambition requires women to represent at least 50% of appointments executive posts in the 2021-2025 period.	31.3% women	29.9% women
Action plan Targeted development of 100 female leaders (Grade 5) for specific posts Gender-balanced shortlists and interview panels Build gender diversity into performance indicators	Commitments Half-yearly reviews of high-potential women, risk-taking in promotions with personalized career development 60% (minimum) of short-listed candidates for external hires 50% women on all interview panels Add gender diversity in management teams to the performance criteria for our Executive population	

(a) This indicator is included in the collective qualitative criteria for variable compensation of Executive Committee members (counts for 5%).

Equal pay

Our compensation policies and practices aim to ensure fair treatment of all our people and are subject to annual audit.

We aim to avoid any discrimination (e.g. based on gender) in the compensation paid in respect of a given position at equivalent levels of individual performance. Where disparities exist, we may allocate specific budgets to rebalance compensation levels. For example, in France 0.1% of total payroll is allocated to adjustments, such as reducing the pay gap between men and women.

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And Sanofi once again ranks in the top third of companies in the official French gender balance index, achieving scores ranging from 75 to 99 out of 100 in the latest index (published March 2020) and a headcount-weighted average of 90; this compares with an average of 87/100 for all companies with more than 1,000 employees. In France, companies now have a legal obligation to deliver equal pay for equal work; previously, the only obligation was to have measures in place to achieve this. That obligation was introduced in new French legislation on freedom of career choices, adopted in September 2018. The Gender Balance Index enables companies with more than 1,000 employees to benchmark their performance. The index awards scores out of 100 on five key gender balance criteria: pay gap (basic and variable pay plus bonuses); gap in distribution of individual pay rises; gap in distribution of promotions; percentage of female employees receiving a pay rise on return from maternity leave; and number of women in the ten highest-paid employees.

Gender balance by grade

Employees under contract as of December 31	Worldwide		Non-manager		Manager ^(a)		Senior leader ^(a)		Executive posts ^(a)		Executive Committee	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Employees	99,412	100,409	80,419	81,043	18,993	19,366	2,219	2,066	514	488	12	14
% women	46.8%	46.2%	47.9%	47.4%	42.2%	41.4%	38.8%	37.2%	31.3%	29.9%	25.0%	21.4%
% men	53.2%	53.8%	52.1%	52.6%	57.8%	58.6%	61.2%	62.8%	68.7%	70.1%	75.0%	78.6%

(a) See section 4.5.2.1.5., "Definition of grades".

4.2.1.6.1.2. Inclusive work environment

Our inclusive work environment relies on working practices that strengthen our corporate culture, and that bring out the best in our people so they can engage and progress. It values, respects, and draws benefits from the richness of diversity, and focuses on five areas:

- people with disabilities;
- LGBTI (lesbian, gay, bisexual, transgender and intersex) communities;
- gender balance;
- multi-cultural, multi-generational and multi-background; and
- providing an inclusive workspace.

During 2020, a range of internal and external initiatives tackled these issues:

- The Global Flexible Work Culture initiative: signed off by our Executive Committee, this supports flexible working through two global policies: Flex at Work (flexible hours, homeworking, etc.) and Flex From Work (time off for family reasons, parental leave, carers, etc). So far, these flexible working policies have been adopted by Sanofi in over 75 countries.
- Inclusion Nudges: these are embedded in our HR processes to encourage managers to be inclusive, for example in job interviews, and performance or career development evaluations.
- Proud to be me: this global Inclusion & Diversity (I&D) Day event was streamed live worldwide from our corporate HQ in France and our Cambridge site in the United States; it highlighted our aspiration to create an inclusive workplace and promote a culture where differences are a source of strength in what we do. The event was an opportunity to showcase local I&D initiatives, and to share feedback from our Executive Committee.
- Global Pride webinar: this was organized and streamed worldwide. Participants in this LGBTI event included our CEO, the Executive Committee member with responsibility for our Consumer Healthcare GBU, and LGBTI CRG leaders from various countries. It was an opportunity to launch our "One Face One Story" video, with over 3,700 participants, across all our social networks.
- Challenge Your Bias: this training and awareness program has been followed by over 4,030 employees (including 70% of executive posts and 36% of Senior Leaders);

We have developed a range of resources to support our managers and other employees in navigating this new, more inclusive and diverse environment. These include guides and a playbook; quarterly Global I&D Insights forums; an online platform to educate and inform about inclusion and diversity, confront bias, and learn how to communicate in a multi-cultural environment; an I&D Playlist of thought-provoking discussions; and recent articles and white papers on encouraging inclusivity in the workplace.

The arrival of our new Chief People Officer in August 2020 gave significant new impetus to inclusion and diversity within Sanofi. She has created a new post – Chief Diversity + Experience Officer – as part of her management team and plans to set out a global Inclusion & Diversity Strategy in 2021; this will harmonize the various local initiatives, bringing them together as part of a common global I&D strategy.

4.2.1.6.1.3. Focus on diversity and inclusion in France

Collective efforts are ongoing in France to support major initiatives, with our employees in the forefront. These include supporting young talents through apprenticeships; "Tackling Cancer at Work" helpdesks; the "PAQTE" program for deprived urban areas; and programs to provide employment for people with disabilities.

Diversity

We are committed to equal rights and fair treatment for all, whatever their sexual orientation or gender identity; to helping and supporting all our people to feel included, respected, and valued; and to providing an inclusive environment where everyone can be the person they want to be.

In November 2020, Sanofi France signed up to the Charter of LGBT+ Commitment, developed by the "L'autre cercle" non-profit organization, in the presence of the Chairman of Sanofi France and the Head of Human Resources for Europe and France. The company also signed up to #StOpE, a campaign to stamp out everyday sexism at work.

Cancer at work

Our "Tackling Cancer at Work" initiative supports and improves the lives of employees directly and indirectly affected by cancer, at all Sanofi sites in France. This initiative follows on from Sanofi France's May 2017 signature of the French National Cancer Institute (INCa) charter, when the company signed 11 commitments to help support employees affected by cancer and to promote health.

This is delivered through a network of 30 listening booths where people can talk freely about cancer-related issues, staffed by multi-disciplinary teams with different types of expertise: occupational health, social care and human resources professionals, plus an employee with experience of being a carer and a manager who has provided cancer-related support.

These booths (which operate online in a teleworking context) are confidential, and open to any Sanofi employee directly or indirectly affected by cancer. They can be accessed at any time on request by any employee. Participants work with the employee to develop solutions and pathways tailored to his or her situation.

Our people have shown long-term commitment to this scheme; the network now numbers over 150 volunteers, who have helped over 210 employees. Barely two years after the network was set up, the network has proved a resounding success: in a satisfaction survey, 98% of respondents found it helpful, and 100% would recommend it to a colleague.

We are also working to change perceptions of cancer. Our short film on the theme of tackling cancer at work, *Le choix du lien*, was a prize-winner at both the *Grand Prix Stratégies de la Production Publicitaire* awards and the Deauville Green Awards in 2019.

And in 2020, we opened up two new lines of research that will raise awareness and help our teams develop transformative practices to reconcile work and wellness:

- we are funding a thesis on "Cancer: Vulnerability and Performance" to help identify levers and brakes; and
- we are developing and piloting a back-to-work module for our "Cancer at Work" initiative, as part of the "Breast Cancer at Work" program led by researchers at Le Nouvel Institut and funded by the INCa, the DGT (Department of Labor), and AGEFIPH (an organization dedicated to employment opportunities for people with disabilities).

Equality of opportunity

In France, we are stepping up our commitment to the government's PAQTE program to support deprived urban areas, through the many initiatives already in place on our sites. The focus is on four key areas:

- awareness: we are familiarizing youngsters with workplace life through work experience for 14-year-olds, sponsorship and tutorials;
- training: helping young people find work, especially through apprenticeships;
- hiring: encouraging non-discriminatory recruitment by providing training to hirers; and
- purchasing: buying goods and services from SMEs in deprived urban areas to stimulate economic growth.

We feel it is essential to broaden the educational experience by opening our doors to young people. That's why we welcomed nearly 200 school students from deprived urban areas onto our French sites in 2020. Our employees have also invested time in sponsorship initiatives focused on equal opportunity, sponsoring 217 young people from deprived urban areas across France: 58 in association with Nos Quartiers ont des Talents, a non-profit organization that helps youngsters from deprived neighborhoods to find jobs; 69 with the Institut Télémaque, which supports talented and motivated young students from underprivileged backgrounds; 40 with Capital Filles, which supports girls from deprived urban and rural areas; 12 with Sport dans la Ville, which helps struggling young people find their place in society and begin their careers; 8 via the P-TECH project (in conjunction with IBM at Montpellier), which uses tutoring and internships to help vocational students train in science and technologies; and 19 in link-ups with other local non-profits, including Maison Gaia and Proximité. Finally, 11 of our employees visit schools in deprived neighborhoods under the auspices of the Énergie Jeunes educational program.

People with disabilities

We continued 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;
- the continued hiring of employees with disabilities, regardless of the nature of their disability;
- better communication and information, via awareness campaigns including a call for disability project ideas from employees, and involvement of Sanofi sites in European Disability Employment Week and DuoDay;

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- ongoing actions to provide better accessibility to workspaces and information, such as making the Tadéo® IT solution available to deaf or hearing-impaired employees; and
- maintaining ties with the sheltered employment sector.

A network of 29 on-site disability contacts provides local support.

In 2020, Sanofi opened negotiations with employee representative bodies with a view to renewing its fifth collective agreement on disabilities.

In France, Sanofi had 1,434 employees with registered disabilities in 2020 ⁽²⁾.

4.2.1.7. Additional workforce information

[GRI 102-8, GRI 405-1]

4.2.1.7.1. Workforce trends

Workforce in main countries where Sanofi operates

Workforce in main countries where Sanofi operates														
Employees under contract as of Dec. 31	Worldwide		France		United States		Germany		China		India		Brazil	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Employees under contract	99,412	100,409	25,337	25,174	12,972	12,592	8,979	9,113	7,777	8,098	4,805	5,412	3,152	3,374
% of total employees	100.0%	100.0%	25.5%	25.1%	13.0%	12.5%	9.0%	9.1%	7.8%	8.1%	4.8%	5.4%	3.2%	3.4%

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

Employees under contract as of December 31	Worldwide		Europe ^(a)		United States		Rest of the world	
	2020	2019	2020	2019	2020	2019	2020	2019
Distribution of employees under contract by gender								
Employees under contract	99,412	100,409	46,761	46,236	12,972	12,592	39,679	41,581
% women	46.8%	46.2%	48.6%	48.5%	50.5%	50.2%	43.4%	42.5%
% men	53.2%	53.8%	51.4%	51.5%	49.5%	49.8%	56.6%	57.5%
Distribution by type of contract, work time and gender								
Permanent contracts	88.9%	88.7%	93.6%	93.8%	99.8%	99.8%	79.9%	79.7%
% women	46.2%	45.7%	48.5%	48.5%	50.4%	50.2%	41.3%	40.3%
Fixed-term contracts	11.1%	11.3%	6.4%	6.2%	0.2%	0.2%	20.1%	20.3%
% women	51.2%	50.5%	50.4%	49.6%	67.9%	75.9%	51.5%	50.8%
Part-time employees	3,719	3,809	3,533	3,684	136	60	50	65
Full-time equivalents	2,891	2,943	2,739	2,851	113	40	38	52
% women (full-time equivalents)	86.2%	87.3%	87.4%	87.5%	59.6%	85.1%	83.1%	78.6%

(a) For a list of countries included in the Europe region, refer to section 4.5.2.1.2., "Regions".

Number of interns and apprentices hired (excludes apprentices in Germany):

	2020	2019
Apprentices	1,302	1,190
Interns	2,845	2,776

⁽²⁾ Source: disabilities data declared in the monthly employee Data Return (Déclaration Sociale Nominative).

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4.2.1.7.2. New hires and departures

New hires and departures by region ^(a) Workforce as of December 31	Worldwide		Europe ^(b)		United States		Rest of the world	
	2020	2019	2020	2019	2020	2019	2020	2019
Employees under contract	99,412	100,409	46,761	46,236	12,972	12,592	39,679	41,581
Permanent staff ^(c)	88.9%	88.7%	93.6%	93.8%	99.8%	99.8%	79.9%	79.7%
Total number of new hires	11,873	12,494	4,229	3,700	1,997	1,581	5,647	7,213
of which permanent contracts	5,965	5,917	1,771	1,376	1,976	1,570	2,218	2,971
of which permanent contracts %	50.2%	47.4%	41.9%	36%	98.9%	99.3%	39.3%	39.5%
Total number of departures	12,710	16,467	3,787	4,347	1,589	2,486	7,334	9,634
of which permanent contracts	7,839	10,167	2,136	2,576	1,578	2,474	4,125	5,117
of which permanent contracts %	61.7%	61.7%	56.4%	59.3%	99.3%	99.5%	56.2%	53.1%
Resignation rate on permanent contracts ^(d)	4.2%	5.4%	1.7%	2.1%	7.7%	10.5%	6%	7.8%
Turnover – permanent contracts ^(e)	7.8%	9.0%	4.5%	5%	13.7%	16.1%	10%	12.4%

(a) Data on movements (new hires and departures) cover more than 99% of the reporting scope. Internal transfers are not included.

(b) For a list of countries included in the Europe region, refer to section 4.5.2.1.2., "Regions".

(c) Employees on permanent contracts.

(d) Resignation rate on permanent contracts = Voluntary departures of permanent staff / Total permanent staff at year-end.

(e) Turnover of employees on permanent contracts = [(New hires of permanent staff + departures of permanent staff)/2] / Total permanent staff at year-end

Population of millennials	2020	2019
New hires of people aged 30 or under as a % of total new hires	53%	55%

Sanofi hired 11,873 new employees in 2020, 50.2% of them on permanent contracts.

Departures were due to resignations (47.5%), layoffs (31.8%), expiration of fixed-term contracts (15.4%), and retirement (4.3%):

Based on employees under contract as of December 31	Worldwide	
	2020	2019
Total number of departures	12,710	16,467
Resignations:	47.5%	46.9%
Of which voluntary departures: fixed-term contract employees ^(a)	39.1%	37.5%
of which voluntary departures: permanent contract employees	60.9%	62.5%
Layoffs	31.8%	37.8%
Expiration of fixed-term contracts	15.4%	11.3%
Retirement	4.3%	3.2%
Other (death and incapacity) ^(b)	1.0%	0.8%

(a) 76.3% of these were in China, where all new hires are generally on fixed-term renewable contracts.

(b) From 2019 onwards, employees leaving by mutual agreement have been split between resignations (initiated by the employee) and layoffs (initiated by the employer).

4.2.2. Access to healthcare

[GRI 203-1]

4.2.2.1. Context and approach

Access to healthcare is at the heart of what we do. We focus our programs on the most important public health needs, in line with our areas of expertise and corporate strategy, with a view to delivering sustainable and measurable outcomes.

Access to healthcare is embedded in our corporate strategy, and implemented within each of our Global Business Units, regions and countries and in specific entities like Global Health and the Sanofi Espoir Foundation.

Our access to healthcare strategy has three core objectives:

- contributing to the control, elimination and eradication of certain infectious diseases through our vaccines portfolio and focusing on diseases where we can make a tangible contribution, such as polio and sleeping sickness;
- serving the needs of patients with non-communicable diseases and relieving the growing burden of such diseases in developing countries, with the emphasis on diabetes and cardiovascular diseases, pediatric oncology, mental health and epilepsy; and
- providing treatments for patients with life-threatening or seriously debilitating rare diseases everywhere in the world.

Access to healthcare involves a complex set of inter-connected issues. That's why Sanofi promotes a holistic, integrated approach covering the entire healthcare journey: from prevention and detection to early diagnosis and patient access to treatment and care. Where we have identified a need, we work with public and private sector partners and NGOs to develop programs that deploy one or more levers to improve access: innovation and patent management (section 4.2.2.2.); availability (section 4.2.2.3.); product pricing (section 4.2.2.4.); and quality care and patient support (section 4.2.2.5.).

These programs must meet the following criteria:

- meeting public health needs in the target country, in a field where Sanofi has expertise;
- targeting underserved populations, such as:
 - the poorest socio-economic categories;
 - patients excluded from healthcare cover;
 - people in remote or underserved areas; and
 - vulnerable populations (seniors, children, pregnant women, people with disabilities, etc.).
- based on solid partnerships, in collaboration with credible stakeholders and/or key players (such as the Ministry of Health, central government, NGOs or a private sector partner).
- building in a long-term future for the program and allowing for an exit strategy; and
- including clear, achievable public health objectives and appropriate metrics, targets and indicators for monitoring delivery against these objectives.

Our commitments are consistent with international healthcare priorities and with United Nations Sustainable Development Goals (SDGs). By delivering on our commitments, we contribute to meeting SDG 3 (Good health and well-being) and SDG 17 (Partnership for the goals).

4.2.2.2. Innovation and patent management

4.2.2.2.1. Innovation

As a global healthcare leader, Sanofi is committed to promoting access to healthcare through innovative R&D to develop sustainable solutions and address unmet needs.

Disease & global context	Target	Sanofi action	Progress in 2020
Sleeping sickness			
Sanofi has worked with the World Health Organization (WHO) since 2001 to tackle sleeping sickness, which threatens millions of people in 36 sub-Saharan African countries. Since the start of Sanofi's collaboration with the WHO, the number of cases of sleeping sickness has fallen from 26,950 in 2001 to 980 in 2019, dropping below 1,000 for the second consecutive year.	Help eliminate sleeping sickness by 2020, and sustainably eliminate it by 2030.	<p>Since 2009, we have been working with the NGO Drugs for Neglected Diseases Initiative (DNDi) to develop fexinidazole, a new all-oral monotherapy, which has received a positive opinion from the European Medicines Agency (EMA) and was approved in the Democratic Republic of Congo (DRC) at the end of 2018 following successful clinical trials. While previous treatments required long-stay hospitalization and intravenous administration, this new all-oral monotherapy reduces treatment to a once-daily dose of fexinidazole over 10 days and is effective in both the first and second phases of the disease in adults and children aged 6 years and over and weighing 20 kg and over. Fexinidazole received WHO pre-qualification in March 2019 and was submitted for approval by the Ugandan health authorities in April 2019. It was added to the WHO essential medicines list in July 2019 and to WHO guidelines for the treatment of sleeping sickness in August 2019, as a first-line treatment for first-stage sleeping sickness and non-severe second-stage cases.</p> <p>Sanofi has partnered with the WHO since 2001 to support the program against neglected tropical diseases, especially sleeping sickness. In 2020, we contributed a total of \$100 million to this WHO program.</p> <p>The program includes controls over the quality and use of the products, as well as distribution, which is handled jointly with Médecins Sans Frontières (MSF).</p>	<p>The first objective - eliminating sleeping sickness by 2020 - is on track, and the WHO is expected to confirm this in 2021.</p> <p>January 28, 2020 saw the first-ever dose of fexinidazole to be administered to a patient in DRC. This was a key success for all the partners in the program, and a major milestone on the road to sustainably eliminating this neglected disease, which is fatal if not treated.</p> <p>In September 2020, Sanofi and DNDi announced that they are jointly developing acoziborole. This new chemical entity is currently being tested in Phase II/III clinical trials. If it proves a success, then acoziborole - in association with a rapid diagnostic test - could be administered immediately, at the same time as the test. This would be a game-changer in the bid to sustainably eliminate sleeping sickness.</p> <p>In December 2020, we renewed our long-standing partnership with the WHO to combat neglected tropical diseases, and to sustainably eliminate sleeping sickness by 2030. Under the new partnership agreement, we will contribute \$25 million (\$5 million a year) towards the prevention and treatment of neglected tropical diseases.</p>
Malaria:			
In 2019, there were 229 million recorded cases of malaria, and over 400,000 died from the disease. Children aged under 5 are the most vulnerable and accounted for nearly 70% of malaria-related deaths worldwide.	Continue research into the technical life cycle for the pediatric indication of primaquine.	We are currently working to make a dispersible primaquine tablet available for children. Primaquine, which is widely used as a radical cure for Plasmodium vivax malaria, is also recommended as a transmission blocker in the elimination of Plasmodium falciparum malaria. For accurate dosing by body weight and ease of use, it is vital that appropriate dosages and formulations of this essential drug are made available.	In 2020, Sanofi adjusted the dose per tablet in line with the specifications issued by the WHO. We also defined the type of data required and the broad outlines of the protocol needed to meet the WHO specifications.
Tuberculosis:			
In 2019, 10 million people contracted tuberculosis (TB) worldwide. Excluding people with HIV, 1.2 million people died with TB, along with a further 200,000 deaths among the HIV-positive community.	Work with our partners to develop new regimes that will reduce the length of treatment for TB.	We are partnering with the US Centers for Disease Control and Prevention (CDC) to develop TB treatments. In November 2014, the US Food and Drug Administration (FDA) approved rifapentine for the treatment of latent TB infection (LTBI), in combination with isoniazid. Now approved in seven countries, it was added to the essential medicines list and granted WHO pre-qualification in 2017. Phase III trials are under way in the treatment of active TB, with a view to developing a shorter and simpler dosing regimen. Studies are also under way for fixed-dose combinations dispersible in water, for the treatment of LTBI in children.	In 2020, the CDC published initial 12-month results from the Phase III trial demonstrating that four months of daily treatment with a strong, optimized dose of rifapentine in combination with moxifloxacin is just as effective and carries no extra risk versus the current standard six-month treatment for patients with active TB.

4.2. Detailed description of SEFP issues and risks

4.2.2.2. Patent management

Patents should not be an obstacle to access to healthcare, and we believe that being transparent and flexible with our patents can help in responding to urgent health challenges in developing countries. In December 2019, we publicly disclosed the patent status of our essential medicines and vaccines in developing countries and confirmed that we would not file or enforce patents in Least Developed Countries (LDCs) or Low-Income Countries (LICs). This also applies to some lower-middle and upper-middle income countries. The disclosures are provided in full in the “Access to Healthcare” factsheet, available in the Document Center on www.sanofi.com.

4.2.2.3. Availability

We believe there is no room for compromise on the quality of medicines and vaccines and are committed to supplying patients with the right product, at the right time and in the right place. We constantly look to improve our processes to ensure that we can deliver safe, high-quality medicines and vaccines. We also support the WHO pre-qualification program.

Disease & global context	Target	Sanofi action	Progress in 2020
Polio			
<p>Polio mainly affects children under the age of 5. One infection in 200 causes irreversible paralysis.</p> <p>Polio has been classified by the WHO as an absolute priority since it launched the Global Polio Eradication Initiative (GPEI) in 1988.</p> <p>GPEI estimates that without its eradication efforts, 200,000 to 250,000 cases of polio would be diagnosed each year, causing paralysis in four million children over the next 20 years. If polio is not eradicated, significant financial and operational resources will be required to continue monitoring and controlling the disease.</p>	<p>Eradicate polio, in line with the objectives of the Global Polio Eradication Initiative.</p>	<p>Sanofi Pasteur has partnered with the Global Polio Eradication Initiative (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, thereby eradicating polio.</p> <p>The polio eradication program is a remarkable success story: the number of countries where polio is endemic has fallen from 125 in 1988 to just two in 2020. The number of cases continued falling through 2019, raising the world’s hopes of progress towards eradication. However, the epidemiology has worsened since then, and the COVID-19 crisis has had negative repercussions for polio eradication programs.</p> <p>Sanofi has played a pivotal role in the polio eradication campaign from the outset and has supplied vast numbers of doses of oral polio vaccine (OPV) – over 14 billion in total – to support the GPEI.</p> <p>In preparation for the final stage in the campaign against wild polio, we have made substantial investments in our industrial capacity during the last decade; we are now able to supply 50% of the injectable polio vaccine (IPV) doses required by UNICEF, even in the two-dose regimen currently recommended by the WHO. This is an unparalleled effort among the various suppliers that support the GPEI. We sell to UNICEF at the lowest possible price, so that the program can be affordable for all.</p>	<p>In 2020, Sanofi supplied 66 million IPV doses to UNICEF for GAVI-eligible countries, enabling around 66 million children (or 87% of the children born in GAVI countries) to be vaccinated.</p> <p>Sanofi Pasteur also supplied 33 million doses to Brazil, India, Indonesia and the Philippines for their national polio vaccination campaigns.</p>
COVID-19			
<p>COVID-19 is a disease caused by a novel coronavirus, SARS-CoV-2. Most people who develop symptoms recover without requiring hospital treatment. About 15% of patients become seriously ill and require oxygen therapy; around 5% develop critical infections and require intensive care. COVID-19 is the disease that has caused the ongoing global pandemic.</p>	<p>In October 2020, Sanofi and GSK signed a Statement of Intent committing to make available up to 200 million doses of their COVID-19 vaccine to the COVAX Facility. COVAX – which is co-led by the WHO and GAVI, the Vaccine Alliance – aims to ensure fair and equitable access to COVID-19 vaccines in every country in the world.</p>	<p>In response to the pandemic, Sanofi partnered with GSK to develop an adjuvanted COVID-19 vaccine. Given the extraordinary humanitarian and financial challenges of the pandemic, the two companies believe that global access to COVID-19 vaccines is a priority. So they have pledged to make their adjuvanted recombinant protein-based vaccine affordable to the public, using mechanisms that offer fair access to people in all countries.</p>	<p>In December 2020, Sanofi and GSK announced a delay in their adjuvanted recombinant protein-based COVID-19 vaccine program, in order to improve the immune response in the elderly.</p> <p>A new Phase IIb of an optimized vaccine candidate was launched in February 2021. If results are positive, a global Phase III study could begin in the second quarter of 2021. If the vaccine meets clinical safety and efficacy requirements, it could (subject to regulatory approval) be launched in the fourth quarter of 2021.</p>

4.2.2.4. Product pricing

Making products, treatments and associated services more affordable is a crucial aspect of improving access to healthcare. We are committed to working with governments to strengthen national healthcare systems and ensure that people can access affordable care and medicines.

Disease & global context	Target	Sanofi action	Progress in 2020
Malaria	Maintain a price cap on some malaria treatments, such as ASAQ Winthrop®, at less than \$1 for adults and \$0.50 for children.	ASAQ Winthrop®, a drug developed with the non-profit Drugs for Neglected Diseases initiative (DNDi), is distributed at preferential prices in compliance with the relevant local regulations. ASAQ Winthrop® has been used to treat over 515 million cases of malaria since it was launched in 2007, including more than 210 million babies and children aged under five thanks to our special pediatric formulation.	In 2020, more than 15 million ASAQ Winthrop® malaria treatments were sold at preferential prices, despite a slowing of demand under major programs caused by COVID-19.
Tuberculosis	Contribute directly and indirectly to raising from 50,000 to 3 million the number of people with access to a short, effective preventive therapy against tuberculosis (TB).	In 2019, Sanofi, Unitaïd and the Global Fund to Fight AIDS, Tuberculosis and Malaria negotiated a ground-breaking volume-based agreement that reduces the public-sector price of a three-month course of rifapentine by nearly 70% in 100 low-income and middle-income countries affected by TB and by TB/HIV co-infection. The agreement was implemented in 2020 and has enabled many countries and programs to offer patients access to effective and shorter treatments for latent TB.	In 2020 alone, nearly 80,000 courses of rifapentine were distributed at preferential prices. That figure is below our aspirations, because the diversion of resources to tackling the COVID-19 pandemic had a disastrous and very concerning impact on local anti-TB programs, and regulatory issues temporarily curbed our capacity to deliver rifapentine.
Rare Diseases	Rare diseases are serious, chronic conditions that are severely debilitating and potentially fatal. More than 300 million people globally live with one or more of the 7,000 identified rare diseases. Most rare diseases are genetic, and the majority start in childhood. As well as physical symptoms, rare diseases are often accompanied by a significant psychological burden for patients and their families.	<p>Even in countries with developed healthcare systems, patients may encounter difficulties accessing treatments for rare diseases due to limited health insurance cover, non-reimbursable treatments, and for many other reasons ranging from the severity of the condition to age and immigration status. To address such cases, Sanofi Genzyme operates a humanitarian program to supply free treatments to people with lysosomal disorders, while also working with governmental authorities, patient groups and health sector decision-makers to develop sustainable access solutions.</p> <p>The first Charitable Access Program was launched in the United States in 1991, a year after the treatment was first commercialized.</p> <p>The program has since been extended to other countries via the International Charitable Access Program, and specific initiatives in Egypt, India and China.</p>	In 2020, a total of 110,000 vials were donated, enabling more than 1,000 patients with rare diseases to receive treatment. The program now reaches patients in 70 countries – primarily India, Egypt and China. It has now been extended to even more countries following the first approvals of donations to treat people in Mozambique and Senegal.
Diabetes and cardiovascular diseases	Every year diabetes and cardiovascular diseases together kill nearly 20 million people worldwide, which represents nearly half of deaths due to non-communicable diseases.	<p>Test the Ngao Ya Afya pilot program in Kenya, aimed at improving the management of diabetes and hypertension by providing quality care and treatment at affordable prices.</p> <p>Early in 2018, we engaged in a partnership with PharmAccess and CarePay to develop and pilot a new commercial solution to provide digital access to care for non-communicable diseases in Kenya. The aim: trying out a new way to leverage accessibility and growth for patients in Africa. This commercial solution was also registered with Access Accelerated.</p> <ul style="list-style-type: none"> Number of patients reached by the pricing system (2020): At present, 650 patients have access to reduced-price diabetes and/or hypertension treatments thanks to the M-TIBA health portfolio. They also have access to self-dosing devices and systems, and free access to the "Afya pap" app. Number of patients being treated (2020): over the last three months, more than 300 patients (out of 650) accessed clinics and are receiving treatment for diabetes and/or hypertension. 	<p>In light of the COVID-19 pandemic, we extended our funding to September 2020, to ensure continuity of patient management during lockdown.</p> <p>Our co-operation with our partners ended as planned at the end of September 2020.</p>

4.2. Detailed description of SEFP issues and risks

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 offering solutions to access issues by adopting differentiated approaches in developed countries and emerging markets.

4.2.2.4.1. 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. Our Global Health organization does not share the same reporting lines to senior management as our Market Access and Pricing teams, but they are complementary and work together insofar as Global Health focuses more specifically on accessibility in low to intermediate income countries.

4.2.2.4.2. 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 37.4% of our annual net sales, and is unusual among mature markets in that the authorities do not impose price controls.

Our pricing principles, first published in May 2017, have since been updated in May 2018, February 2019, and March 2020. They are available at www.sanofi.us/en/corporate-responsibility/access-to-healthcare.

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.

4.2.2.4.3. 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:
 - clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care;
 - economic value, or the extent to which the medicine reduces the need for other healthcare interventions (and the associated costs); and
 - 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 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.

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

If 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) of the US federal government.

If 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.

In March 2020, the CMS issued a projected US healthcare cost growth rate for 2020 of 5.2%⁽¹⁾.

During 2020, we increased the price of 50 of our 80 prescription medicines. All those price increases were in line with our pricing principles.

4.2.2.4.5. 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)
2017	+1.6%	-8.4%
2018	+4.6%	-8.0%
2019	+2.9%	-11.1%
2020	+0.2%	-8.0%

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

4.2.2.5. Patient care and support

The most effective way of eliminating the human and financial burden of disease is early prevention and detection; this enables patients to take control of their condition sooner, thereby avoiding complications (and the associated costs). We help to promote disease prevention and are committed to supporting healthcare systems with appropriate evidence-based solutions adapted to the needs and resources of individual countries, in particular by developing comprehensive healthcare programs.

Disease & global context	Target	Sanofi action	Progress in 2020
Oncology			
Worldwide, nearly 300,000 cases of cancer are diagnosed in children under 15 every year. 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).	By 2021, provide care to 100,000 children with cancer and train 30,000 healthcare professionals through the "My Child Matters" program.	<p>Since 2006, the Sanofi Espoir Foundation's My Child Matters program has been working to provide children with cancer with the same conditions for accessing healthcare whatever country they live in.</p> <p>The program provides improved access to early diagnosis and care.</p> <p>This involves working with local teams to deliver enhanced training for healthcare professionals; raise public awareness; improve the quality and speed of diagnosis; reduce defaulting from treatment; develop pain relief and palliative care; improve data collection through cancer registers, allowing for better epidemiological tracking; and appropriate advocacy with the healthcare authorities in the relevant countries.</p>	<p>In 2020, we supported five new initiatives for children with cancer in lower-income or middle-income countries: four in Africa, and one in Asia. That takes to 80 (in some 60 countries) the total number of projects supported under the My Child Matters program.</p> <p>At the end of November 2020, the Sanofi Espoir Foundation announced that it had reached its goal of 100,000 child cancer patients treated under the My Child Matters program. The Foundation also contributes to the training of healthcare professionals, over 30,000 of whom have benefited to date. That goal was initially set for the end of 2021 but was achieved over a year early, in November 2020. Under its 2019-2021 roadmap, the Foundation will also move up a gear by providing expertise and funding to five new initiatives to help children with cancer.</p>

4.2. Detailed description of SEFP issues and risks

Disease & global context	Target	Sanofi action	Progress in 2020
<p>Diabetes</p> <p>In 2019, the International Diabetes Federation estimated that 463 million adults and over one million children were living with diabetes. Rising rates of obesity and reduced physical exercise among young people in many countries mean that type 2 diabetes is affecting people at ever younger ages, making it a global public health issue with grave consequences.</p>	<p>Raise awareness among children and teachers about diabetes (and the associated complications) and about healthy lifestyles, by developing educational materials and working with partners to roll out our program in schools across a growing number of countries.</p>	<p>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.</p> <p>The KIDS project operates through partnerships with various agencies (governmental authorities, patient groups, learned societies, NGOs, etc.), depending on the country.</p> <p>Our partners organize briefings and schools-based activities, based on core messages delivered through educational material comprising information and awareness packs for teachers and school staff, and for schoolchildren aged 6-14 and their parents. The material is currently available in 18 languages. The educational material is supplemented by a nutritional guide, providing information about the importance of healthy, balanced lifestyles in managing and preventing diabetes, and is backed up by the “NutriQuiz” online game.</p>	<p>During 2020, the program was adversely affected by school closures due to the COVID-19 pandemic. However, virtual classroom sessions were used wherever possible. This enabled the Philippines to become the tenth country to join the program, after India, Brazil, the United Arab Emirates, Pakistan, Egypt, Poland, Japan, Hungary and Argentina.</p>
<p>Mental health</p> <p>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.</p>	<p>Improve healthcare access for people with mental disorders or epilepsy in low-income or middle-income countries through the Fight Against STigma (FAST) program.</p> <p>Specific programs are developed for each country, with qualitative and quantitative targets in terms of healthcare staff trained, public awareness campaigns, and the number of patients diagnosed and treated.</p>	<p>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 low-income or middle-income countries. The FAST program has partnered with the French Institute of Epidemiology and Neurology (IENT, UMR 1094 Inserm) to launch mental healthcare access initiatives in more than 20 countries in Africa, Asia and South America. Developed in collaboration with local public health authorities, experts and healthcare professionals, and with patient associations and NGOs, these programs are based on training healthcare staff, raising public awareness, and educating patients and their families.</p>	<p>Cumulatively, by the end of 2020 over 10,700 healthcare staff had received training, awareness campaigns had reached over 3.4 million people, and more than 133,000 people with mental disorders or epilepsy had been diagnosed and/or treated.</p> <p>For example, the program in Mali that began in 2018 has already enabled over 2,800 new patients to be diagnosed and treated by trained general practitioners, and is still under way with the aim of training a further fifty or so general practitioners via an e-learning platform. A new initiative with the Senegalese Ministry of Health will train 290 primary healthcare professionals, using a combination of an e-learning course and interactive webinars hosted by local psychiatrists.</p> <p>And in South Africa, after an initial phase that delivered training to 1,120 front-line healthcare staff, a further 500 are to be trained using a blend of face-to-face and online training.</p>

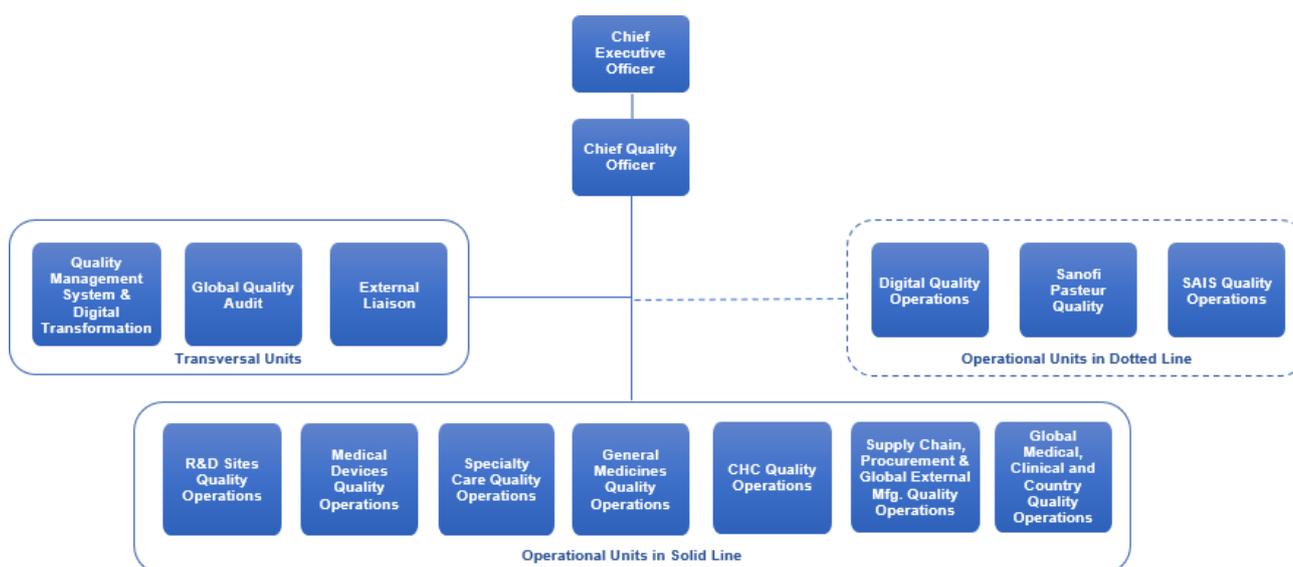
4.2.3. Product quality

4.2.3.1. Organization

Sanofi's dedicated Global Quality function is dovetailed with our operational entities and our global support functions.

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

Global Quality organization:



Global Quality implements our Quality policy across the entire life cycle (from discovery and development to manufacturing, 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 deliver on our commitment to allow patients access to safe, effective products that meet public health needs.

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 be sure that our products meet quality and regulatory standards.

4.2.3.2. 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 2019 and is available in 26 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 systems management; and
- organizational processes: quality systems management, quality audit, quality risk management.

Our quality management system has built-in flexibility, so that it can incorporate quality standards specific to each of our product families. 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 also incorporates all good practice rules – Good Clinical Practice (GCP),

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Good Distribution Practice (GDP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Pharmacovigilance Practice (GPVP) – as well as other regulatory requirements relating to human health.

Our Quality Policy and Quality Manual are the cornerstones of our 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, support functions, sites and country-level operations are subject to regular audits by a dedicated Global Quality Audit team, tasked with giving senior management a clear and impartial evaluation of compliance with the Sanofi quality management system. A risk-based approach is used to determine the frequency and duration of audits, and the number of auditors involved. The Global Quality audit team also handles preparations for official inspections. Our Global Quality Audit activities obtained ISO 17020:2012 certification in July 2019.
- Throughout the physical journey undertaken by Sanofi products, we maintain the same levels of quality, security and traceability for all our products. 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 serialization 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 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 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. To catalyze the impact on enterprise value, we founded our Quality Academy, which offers training programs to help ensure that our people are always properly trained and qualified. The Academy is complemented at operational level by practice communities, sharing and discussing quality-related issues and processes.

Highlights of 2020 were:

- [Nitrosamine risk assessment](#)

Sanofi set up a multi-disciplinary project team in October 2019 to address regulatory concerns about the risk of nitrosamines (carcinogenic impurities) being present in chemically-derived medicines. The team, overseen by a steering committee, is tasked with prioritizing and implementing the risk assessments needed to comply with the new regulatory requirements.

In September 2020, the project was extended to include biologically-derived products and vaccines.

The first responses to the regulatory authorities began in December 2020. The process of identifying and mitigating potential risks will continue in 2021 and beyond, in line with the timescale set by the regulators.

- [Global Quality Strategy](#)

In 2020, a new quality strategy aligned on our "Play to Win" corporate strategy was unveiled and validated. The strategy is based on four pillars:

- an effective, agile quality system, fully integrated from R&D through to sales, and managed centrally to ensure consistent standards;
- a strong quality culture across the entire organization, to ensure everyone makes good quality decisions every day;
- dedicated people who can develop their talents and skills to the full, so that we can meet our present and future quality needs;
- commitment to innovation and new technologies, to raise our performance levels while ensuring our products are compliant.

To deliver on this new strategy, our Quality operations are evolving from a static model to a more dynamic, real-time model supported by data science.

4.2.3.3. Performance indicators

	2020	2019	2018
Internal quality audits ^(a)	161	204	210
Regulatory inspections ^(b)	177	309	279
of which European inspections	55	70	
of which US FDA inspections	22	44	
Number of regulatory actions taken ^(a)	0	1	0
Recalls	39	45	44
of which Class 1 recalls ^(d)	2	4	3

(a) Significant reduction in 2020 due to travel restrictions as a result of the COVID-19 crisis.

(b) Significant reduction in 2020 due to travel restrictions as a result of the COVID-19 crisis. The lack of any regulatory action following inspections confirms an excellent level of compliance at Sanofi.

(c) US FDA Warning Letter, US FDA Consent Decree, suspension/withdrawal of GMP certificate.

(d) Definition as per EMA SOP/INSP/2018 and US 21CFR part 7.

4.2.4. 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; and
- report to the regulatory authorities on a timely basis, in accordance with international and local regulatory requirements and our own Global Quality standards.

4.2.4.1. Organization

The Chief Safety Officer (CSO) is responsible for our Global Pharmacovigilance (GPV) organization; this is supervised by our Chief Medical Officer (CMO)/Global Head of Development, who in turn reports to Sanofi's Global Head of R&D. This governance model ensures 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 safety and benefit/risk profile of the full spectrum of Sanofi products.

All pharmacovigilance activities relating to the use of the product portfolio report to GPV. Staff from GPV deploy their specialist expertise 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 signals, and for implementing risk minimization measures. This pragmatic, evidence-based benefit/risk approach protects patients and consumers by ensuring that our scientific communications are transparent, robust and credible. GPV also has a team of pharmaco-epidemiologists, tasked with 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 populations or patient groups, or via specialist databases.

A pharmacovigilance signal (or safety signal) is a hypothesis of a possible risk between taking a medicine and an adverse event, derived from data from one or more of many possible sources. In practice, a safety signal occurs when a parameter (such as the number, incidence or frequency of an adverse event) deviates from what is expected or accepted. This hypothetical deviation then needs to be analyzed, so it can be confirmed or rejected.

4.2.4.2. Policy and action plans

GPV proactively monitors national and international regulations and recommendations. A centralized regulatory watch unit within GPV analyzes changes in pharmacovigilance legislation in real time, so that we can always adapt our work processes to align on the latest requirements and good practices. GPV draws upon a worldwide network of local and regional managers trained in pharmacovigilance. GPV provides a range of services to this network; these include allocating sufficient resources and budgets to fulfil our mission; monitoring good practices; maintaining regulatory compliance; training; and access to the tools needed for the network to discharge its responsibilities in accordance with quality standards.

Sanofi systematically aligns on the most exacting standards of Good Pharmacovigilance Practices.

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

GPV is closely involved in many international initiatives such as 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, GPV has made significant strategic changes to its 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;
- delivering an ambitious technological development plan to automate and apply artificial intelligence to pharmacovigilance data. This was seen 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. 2020 saw the live rollout of the AI-based automated pharmacovigilance data management project, with highly satisfactory results in terms of data processing quality and accuracy, as well as productivity gains. During 2021, the technology will be ramped up as subsequent phases of the project are rolled out;
- extending our structured approach to benefit/risk profile evaluations, relying, if necessary, on population-based epidemiological statistics.
- optimizing the mechanisms used to detect and evaluate potential signals associated with the use of our products; and
- completing the refocusing of our in-house expertise on novel products with fast-changing benefit/risk profiles, by phasing in a new outsourced scientific platform dedicated to the monitoring of mature products or therapeutic classes. This model means 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. Performance indicators

Signals

Signals assessed	2020	2019	2018 ^(a)
Total signals	344	395	255
of which PRAC/HA signals ^{(b)/(c)}	125	204	110

(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.

Pharmacovigilance audits and inspections conducted in 2020:

- Number of audits: 33.
- Number of inspections: 5.

These audits and inspections are included in the figures reported in the Product Quality section (4.2.3.3., “Performance indicators”).

New performance indicator: quarterly submissions of individual pharmacovigilance cases to the European healthcare authorities by the regulatory deadline:

- Q1 2020: 98.2%.
- Q2 2020: 98.2%.
- Q3 2020: 99.5%.
- Q4 2020: 99.2%.

4.2.5. Medical ethics and bioethics

4.2.5.1. Scientific and medical integrity – Patient safety in clinical trials

4.2.5.1.1. Organization

Sanofi Bioethics Committee

Sanofi set up an internal Bioethics Committee in 2012 to ensure that we conduct our scientific and medical activities to high ethical standards, and with a view to constant improvement. The Committee is chaired by our Chief Medical Officer. Bioethics governance at Sanofi is reviewed regularly to ensure that we take greater account of stakeholder expectations and of the central role of patients, combined with better transparency. Our internal Bioethics Committee draws on recommendations from an Advisory Bioethics Council (ABC), set up in 2018 and consisting of independent, international members with acknowledged expertise in bioethics, which gives advice on key bioethics issues so we can improve our practices and anticipate potential ethical issues when developing innovative healthcare solutions.

The Bioethics Committee establishes Sanofi's positions on bioethics and ensures that its policies are implemented operationally. We have also reaffirmed our determination to move towards greater transparency, both on clinical trials and on the policies adopted by our Bioethics Committee, which are now publicly available on www.sanofi.com. Issues addressed by the Bioethics Committee are suggested by its members, based on the latest developments in the field or questions raised internally.

The independent bioethics experts who form the ABC have varied university backgrounds (medicine, law, philosophy), and work in Europe, Asia or North America. The ABC continued to operate remotely through 2020. The issues dealt with by the ABC are determined by consultation between ABC members and the Sanofi Bioethics Committee, and address bioethics issues arising in Sanofi's sphere of operations. Sanofi is committed to taking account of their recommendations, and to informing the Board of Directors that these recommendations are being implemented (or if not, of the reasons why).

During 2020, the ABC and the Bioethics Committee were involved in strategic thinking within Sanofi about product allocation, in particular during the COVID-19 pandemic.

4.2.5.1.2. Policy and action plans

Recommendations from our Bioethics Committee may lead us to implement policies and good practice guidelines, for which responsibility for applying rests with the relevant operating units.

4.2.5.1.2.1. Bioethics and research

Our Bioethics Committee takes a close interest in the ethical use of new technologies in our scientific activities. In particular, we have published a policy on gene editing and gene therapy technologies, which describes the opportunities for those technologies but also sets limits on their use.

4.2.5.1.2.2. Medical ethics and clinical trials

Clinical trials are a mandatory part of the approval process for any new healthcare solution. Their purpose is to collect data about the efficacy and safety of products in healthy subjects and patients, so that the benefit/risk profile can be evaluated. Sanofi organizes clinical trials all over the world. Clinical trials may also be carried out post-marketing approval to develop new indications for a drug or monitor its safety.

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 these 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).

We conduct clinical trials in lower-income and middle-income countries in certain very specific circumstances, applying the same quality and ethical standards as we do in higher-income countries (see also section 4.2.2, "Access to healthcare"). In particular, our Sanofi Pasteur vaccines business conducts trials of the pediatric hexavalent vaccine SHAN6, which was specifically developed for such countries. We also participate in the Clinical Research in Resource-Limited Settings working group of the Council for International Organizations of Medical Sciences (CIOMS).

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

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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 clinical trials of which Sanofi is the sponsor, in various countries and regions around the world. We also perform regular audits of subcontractors retained to improve clinical trial performance.

Finally, we are subject to inspections by health authorities to ensure that we are complying with ethical standards and legislation.

4.2.5.1.2.3. Transparency of medical and clinical data

We are committed to providing healthcare professionals, patients and the public with all useful information about our medical research, 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 4.2.5.1.3.1., "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 (<https://www.phrma.org/Codes-and-guidelines/PhRMA-Principles-on-Conduct-of-Clinical-Trials>). In addition to these core principles, we apply our own policy on sharing and transparency of clinical data. Our commitments are described (and fully accessible) on our corporate website.

4.2.5.1.3. Performance indicators**4.2.5.1.3.1. Medical ethics and clinical trials**

None of the 34 inspections conducted on our clinical research activities in 2020 resulted in regulatory action.

The number of regulatory inspections was around 50% lower in 2020 than in 2019. The COVID-19 pandemic, and the resulting lockdowns and travel restrictions, meant that procedures had to be adapted so that data and documents could be shared electronically, in accordance with the relevant requirements relating to confidentiality and data security.

4.2.5.1.3.2. Transparency of medical and clinical data

- **Sharing of clinical data:** Between January 1, 2014 and December 31, 2020, Sanofi received 142 requests from 17 countries to share data relating to 385 clinical trials.

Data sharing was approved for 121 clinical trials:

- data from 77 clinical trials were released under a data sharing agreement (the research projects involved are ongoing or completed), 10 of which led to publication;
- data from a further 19 clinical trials will be shared once the data sharing agreement has been signed off; and
- for the other 25 clinical trials, data sharing agreements are still being negotiated, or have been rejected or abandoned by the researchers making the request.

In addition, 20 clinical trials are under evaluation, and 244 were 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.

- Scientific papers published in 2020: 859 scientific and medical papers sponsored or signed by Sanofi were included in the PubMed database, which references over 5,200 journals.

4.2.6. Supply chain continuity

As a global healthcare leader, we are committed to organizing our supply chain so that it will deliver medicines and vaccines to the market without interruption, with the goal of protecting patients' health every day.

Global demand for medicines is rising, due to improved access to and development of healthcare in many regions of the world. While this is a good thing, it nevertheless raises issues about the capacity of manufacturing sites and their suppliers to adjust rapidly. Pressures on supplies of raw materials and active ingredients are intensifying, due in particular to more stringent environmental standards in China and other Asian countries. In the short term, this is causing the temporary shutdown of a number of manufacturing facilities, including some that supply active ingredients to the pharmaceutical industry. Tougher environmental regulations may temporarily reduce production capacity while manufacturing processes are upgraded. Finally, some of our products require long and complex production processes, and we may experience interruptions at any point in the chain.

We have for decades applied a regionalized production strategy in our network of in-house sites. Around two-thirds⁽³⁾ of the active ingredients in our products are manufactured within our in-house network, and our dependence on India and China is approximately 15%⁽¹⁾.

Our global service level on prescription products (general medicines and specialty care) is approximately 98.5%.

4.2.6.1. Organization and policy

Industrial Affairs at Sanofi have a governance structure that establishes the sourcing policy for our products; their core mission is to select and allocate the resources of our in-house and third-party manufacturing networks. The sourcing policy lays down rules for securing production of the principal active ingredients and currently marketed products, and on back-up sites for products in the launch phase (double or triple in-house/third-party sourcing).

We also have a supply chain continuity program in place that applies in priority to vital medicines, new and key products, and to pandemics and other major crises.

The program evaluates supply chain risks (from raw materials sourcing to active ingredient manufacture and product shipment) and includes fallback plans. It is integrated with our supply chain, and with our global risk management approach. We also have an ongoing multi-disciplinary process in place to analyze risks relating to the raw materials included in our products, and to the suppliers we source those materials from. This process is built into the governance of our supply chain continuity program, facilitating a coordinated approach to the referencing of suppliers and back-up manufacturing sites. This helps secure supply chain continuity by reducing mono-source risks and critical regional dependency.

Our Industrial Affairs Risk Committee, which includes representatives from our technological platforms and support functions (such as Quality, HSE, Procurement, Biological Platform, and Dispensing Systems Development), is tasked with identifying and evaluating major risks relating to our industrial operations, and with ensuring that action plans are implemented.

We have also set up a global operational committee to address the risk of product shortages; the committee coordinates and activates fallback solutions to reduce the risks and supports the process of notifying health authorities.

For vital products (i.e., Sanofi medicines and vaccines for which there is no therapeutic equivalent or local alternative available), we make every effort to ensure that they are always available in sufficient quantities. Our Global Medical Department has for several years been working with our subsidiaries to identify vital products in each country where we do business.

This list can then be used to determine production priorities and emergency responses in the event of a pandemic, or of a major incident (such as fire or natural disaster) at one of our production sites.

4.2.6.1.1. Ensuring day-to-day supply chain continuity

Sanofi has a range of instructions, tools and processes in place throughout the supply chain, which are subject to control and monitoring.

Sales & Operations Planning – Integrated Business Planning (S&OP – IBP) is the core tactical process operated within our organization. In this process, key players (marketing, sales, supply chain, industrial, finance, etc.) work together to identify, rank, decide, solve and plan actions to address the medium/long-term risks and opportunities around our portfolio.

It is based on sales forecasts (for up to 36 months) that are shared with all the stakeholders across the organization and includes an inventory policy that sets for each Sanofi subsidiary target inventory levels (of active ingredients, semi-finished and finished products) for all our products. The inventory policy is calibrated according to various criteria, such as product type (in particular, whether the product is identified as a vital medicine), the complexity of the manufacturing chain, or the number of sources of the various raw materials used. For example, a risk analysis conducted under the supply chain continuity program could lead us to constitute buffer stocks. The policy may also vary from one subsidiary to another, depending on specific circumstances in the country of operation.

⁽³⁾ This calculation relates only to chemical active ingredients, which tend to be manufactured in Asia. It does not include biological active ingredients or vaccines.

4.2. Detailed description of SEF issues and risks

At site level, sales forecasts are used to determine raw material and production needs for each product; careful resource planning is essential.

Once products have been manufactured and batch-released, they are shipped by our logistics organization, which combines in-house distribution centers and external service providers.

Our distribution centers deliver products through three main channels, depending on the country:

- directly to pharmacies;
- directly to hospitals; and
- to wholesalers.

To maintain a high level of customer service, we monitor a number of indicators throughout the supply chain that we can use to flag up potential risks or incidents with the various players.

In addition, we use long-term projections (from 36 months to 5-10 years) to inform our investment decisions by giving us visibility on sales for a product, a region or a specific technology.

4.2.6.1.2. Ensuring good distribution

In every country where we operate our own distribution centers, emergency plans are activated in the event of a supply chain interruption. All our distribution centers use the same information system, facilitating fallback solutions if one of our centers is temporarily out of action.

In countries where we outsource distribution, we apply rigorous selection procedures when referencing service providers, covering not only their financial health but also their service quality and compliance with HSE and CSR principles. If a potential risk is detected, we make sure we have alternative service providers. Over the last 10 years, we have only had three major incidents (in Venezuela, the Netherlands and Korea), with no impact on patients.

The freight companies we use are subject to an audit before they can work with Sanofi and continue to be audited throughout their service term.

We use state-of-the-art techniques to track shipments and confirm delivery to the customer, including GPS tracking, real-time GPRS tracking and electronic signatures. Each center has a fallback plan, including a list of freight companies that can step in at any moment and be operational within 24 hours.

4.2.6.1.3. Ensuring business continuity in a major crisis

We have continuity plans specific to our operations, so that in the event of a pandemic or major crisis (natural disaster, nuclear accident, humanitarian emergency, etc.) we can focus our efforts on simultaneously meeting all of the following objectives:

- guaranteeing and safeguarding continuity of our operations;
- ensuring that all our products meet the same quality standards;
- in the case of a pandemic, reacting as fast as possible to manufacture and distribute a pandemic vaccine in the affected regions;
- maintaining sufficient capacity in the development, production and distribution of medicines and vaccines to prevent or cure infections related to the pandemic in the shortest possible time-frame;
- maintaining business continuity so that we can supply all our medicines and vaccines to patients; and
- continuing to provide assistance to patients and healthcare professionals, in particular through fallback solutions, such as 24/7 call centers, while also monitoring any side effects (pharmacovigilance).

Our experience of past natural disasters, such as Fukushima in Japan, floods and earthquakes in Italy and the volcanic ash cloud in Iceland, has shown that we are capable of activating solutions, such as fallback manufacturing capacity or alternative transportation methods, in real time.

The COVID-19 crisis put our pandemic plan to the test. The 20,000 people employed in our industrial operations were able to continue working in compliance with public health restrictions, and all of our industrial sites continued operating. We also implemented additional measures:

- using alternative sources of raw materials to ensure continuity of supply when a particular region was affected by the pandemic; and
- immediate increase in output in response to recommendations in the treatment of COVID-19 and associated symptoms (injectable antibiotics, paracetamol, anti-thrombotics, hydroxychloroquine); and
- securing freight movements by activating a range of different modes of transport (air, sea, road).

4.2.7. Local Communities

[GRI 413-1]

As a major healthcare player, our priorities are to improve access to healthcare and develop new treatments. But we are also committed to supporting the local ecosystem wherever we operate, helping to make it more inclusive and sustainable and working with local stakeholders, including municipal authorities, non-profits and local residents.

In 2017, our international stakeholders committee encouraged us to go further on the issue of the local impact of our operations. It recommended developing an internal model for measuring our local footprint that could be rolled out across all our sites, so that they can work with local stakeholders to make a positive difference.

In 2018, a Sanofi-specific methodology was defined, and rolled out at six pilot sites that are representative of the diversity of sites we operate: the manufacturing sites at Aramon (2018), Swiftwater (2018) and Vitry-sur-Seine (2020); the R&D site at Chilly Mazarin (2018); and office sites at Gentilly (2020) and Bordeaux-Bègles (2020).

Local footprint metrics aim to capture the environmental, social, societal and economic impact of a site's operations in a specific locality, or in its most direct sphere of influence. The process involves putting a value on our community engagement, and hence our contribution to addressing local issues. Local footprint is measured for around twenty direct and indirect environmental, social, societal and economic impacts. Stakeholder perceptions are captured using questionnaires that evaluate the extent to which the site is involved in local issues.

At all the pilot sites, the results offer a fresh, all-round perspective of the site that is much appreciated by the onsite teams. And mapping the strategic issues facing each site against stakeholder expectations helps prioritize areas with positive impacts for both local communities and Sanofi, and potential for going even further.

A methodological guide has been produced to enable all Sanofi sites to evaluate their local footprint.

4.2.8. Ethics and business integrity

[GRI 102-16, GRI 205-1, GRI 205-2]

Our commitment to behave ethically and with integrity extends beyond mere compliance with laws and regulations. Everyone at Sanofi 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 encountered 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 marketing and/or promotional practices;
- fraud (misappropriation of assets, false accounting, corruption); and
- conflicts of interest.

4.2.8.1. Organization

4.2.8.1.1. Background

We have operations in more than 100 countries across the globe and are committed to meeting 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.

We have robust governance structures in place to ensure we deliver on our commitments, 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).

CHAPTER 4.

CORPORATE SOCIAL RESPONSIBILITY

4.2. Detailed description of SEF issues and risks

4.2.8.1.2. 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 whistle-blowing system backed by internal investigations; and the implementation of corrective and/or disciplinary measures where 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 corporate objectives while ensuring that we comply with laws, regulations, industry codes, ethical standards and values, and our own internal policies and standards.

4.2.8.1.3. 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: <ul style="list-style-type: none"> 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 1,690 "Compliance Champions" made up of volunteers from each country, GBU and support function.	Communicates and reinforces compliance messages developed by E&BI. Supports the implementation of E&BI initiatives. Monitors in real time participation in compulsory training programs. Acts as a contact point for employees, encourages whistle-blowing, and promotes 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.

4.2.8.2. Policy and action plans

4.2.8.2.1. 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 both a reference manual and a practical tool, providing each employee with guidance 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; and
- 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 now owned by Sanofi; and before signing any joint venture or partnership agreement.

4.2.8.2.2. 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 confidentiality breaches. In addition, an online library of training modules, some of them available in 19 languages, can be accessed by employees who want to self-train. All E&BI policies are backed up by specific training tools, including frequently asked questions. Since 2019, failure to complete certain compulsory training modules can have an adverse impact on an employee's annual evaluation.

4.2.8.2.3. Whistle-blowing

A secure hotline and dedicated web page are available 24/7. The hotline is accessed by a toll-free number and is available in 28 languages. In the United States, the helpline set up for Sanofi employees is guaranteed to be independent and to protect anonymity, in accordance with local regulations and practices. 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, can use this system to report it by whatever means he or she sees fit. Employees will not be disciplined or penalized as a result of using the whistle-blowing system provided they acted in good faith without malicious intent, even if the report turns out to be inaccurate or no further measures 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 report, whether received through the whistle-blowing system, or through any other channel, is investigated internally using a methodological protocol set out in our whistle-blowing policy. If an internal investigation confirms the allegations, corrective and/or disciplinary measures are taken. 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.

4.2.8.3. Performance indicators

In 2020:

Training:

- 92,512 employees followed at least one Ethics & Business Integrity training module.
- A total of 171,554 Ethics & Business Integrity training modules were followed in the year.

Whistle-blowing hotline:

- 718 incidents were reported to E&BI.
- After investigation, 352 of these were substantiated. As a result, 85 employees were dismissed or resigned on grounds of misconduct.

4.2.9. Tax policy

As a multinational company, we must apply the laws and regulations in force in countries where we do business and pay the appropriate amounts of taxes and duties under those laws and regulations. Our primary responsibility is to pay taxes and file tax returns with the tax authorities on time, in compliance with laws and regulations.

Responsibility for tax matters lies in the first instance with our Tax Department, supervised by our Chief Financial Officer, which implements and maintains robust tax policies and procedures that are signed off by Sanofi's Board of Directors and Audit Committee. A set of controls has been put in place to ensure that Sanofi's tax strategy is applied effectively.

Our tax policy is published on our corporate website.

We aspire to build and maintain open, transparent and collaborative relationships with tax authorities and other governmental bodies worldwide. Wherever possible, we engage in partnerships with tax authorities, and seek prior consent on complex issues and transfer pricing policies. We apply a similar open and cooperative approach to the regular tax inspections to which we are subject in most countries.

In transfer pricing, Sanofi applies the OECD guidelines and any country-specific legislation, with a view to applying arm's length terms for all intragroup transactions. Our transfer pricing policy is documented and supported by economic analysis.

Sanofi's tax strategy is driven by operational considerations and reflects the underlying reality of our activities. We do not engage in tax evasion or tax fraud. Our tax strategy is in keeping with our values, and with the strategic orientations determined by our management.

4.2. Detailed description of SEF issues and risks

Income taxes are described in detail in our consolidated financial statements, included at Item 18 of our 2020 Annual Report on Form 20-F, 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 audit.

4.2.10. Environment

Environmental protection at Sanofi comes within the overall scope of our Health, Safety and Environment (HSE) approach, as described in section 4.3.7, "Employee Health and Safety".

4.2.10.1. The Planet Mobilization roadmap

[GRI 305-5]

As a responsible business, we have embarked upon an ambitious policy to limit the direct and indirect impacts of our operations and products on the environment. Involved in environmental protection since 2010, we have updated our "Planet Mobilization" roadmap to reflect current and future issues, stakeholder concerns, and the risks and opportunities, in line with Sanofi's global strategy.

The Planet Mobilization roadmap sets out our environmental strategy, and the objectives set for our entire value chain for 2020 and 2025.

The program is piloted by a committee consisting of our Executive Vice President, Global Industrial Affairs (also a member of our Executive Committee); the heads of Environment, Corporate Affairs, Procurement, External Manufacturing, and R&D France; and senior representatives from our various operations. We also have separate operational committees for each key environmental issue (climate change, responsible water resource management, eco-design, biodiversity, waste management, pharmaceutical products in the environment), to make sure that the roadmap is properly implemented and that we achieve our objectives.

Planet Mobilization is built around five pledges:

- mitigate climate change and achieve carbon neutrality by 2050, and set Sanofi on a trajectory for limiting global warming to 1.5°C;
- limit our environmental footprint, and choose circular solutions that optimize the use and reuse of resources and reduce the impact of our emissions;
- improve the environmental profile of what we produce, by developing eco-innovative products that embody our eco-friendly ambitions and by favoring sustainable use of medicines;
- mobilize our people to support sustainable development, by promoting an eco-friendly culture in workplace routines and decision-making; and
- engage our suppliers in environmental initiatives, by practicing sustainable sourcing and leading by example.

4.2. Detailed description of SEFP issues and risks

The table below summarizes all our objectives for 2020 and 2025:

Environmental issue	Key Planet Mobilization commitments 2015 - 2025	2020 progress against:		Contribution to SDGs
		2019	2015 (baseline year)	
Climate change and carbon footprint (CO₂ emissions)	Industrial, R&D and tertiary sites for Scopes 1 & 2 (including medical rep fleet)			SDG 13: Take urgent action to combat climate change and its impacts
	50% reduction in greenhouse gas emissions (CO ₂ equivalent) by 2025 (relative to 2015)	-15%	-27%	
	Achieve carbon neutrality in 2050 for emissions caused by our operations			
Water (withdrawal)	Industrial, R&D and tertiary sites			SDG 6: Ensure availability and sustainable management of water and sanitation for all
	10% reduction in water consumption by 2020 (relative to 2015)	-5%	-22%	
	Management plan at all sites (priority to those in water stress zones)	Ongoing		
Pharmaceutical products in the environment	Industrial and R&D sites			SDG 12: Ensure sustainable consumption and production patterns SDG 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
	Emission management plan: At all priority sites by 2020 At all sites by 2025	Ongoing		
Waste	Industrial, R&D and tertiary sites Recycle/Reuse/Recover (3R) rate > 90% by 2025 (> 80% in 2020)	73% in 2020 vs 75% in 2019	56%	SDG 12.5: By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse
	Landfill disposal rate < 1% by 2025 (< 3% in 2020)	7% in 2020 vs 8% in 2019	6%	
Biodiversity	Biodiversity awareness plan at all sites	Local initiatives		SDG 15: Protect and restore terrestrial ecosystems, and halt biodiversity loss

During 2020, we carried out an update of our environmental objectives to 2025 and 2030, in line with our major Planet Mobilization commitments described above.

Because we want to play our part in combating climate change, we have pledged to achieve carbon neutrality by 2050. To help us achieve this, we are aiming to reduce greenhouse gas emissions related to our operations (Scopes 1 & 2) by more than half by 2030 (a 55% cut versus 2019). We are also aiming to reduce indirect emissions related to our value chain (Scope 3) by 14%. During 2020, our objectives were validated by the Science Based Target initiative (SBTi), giving them a scientific seal of approval as part of the planet-wide efforts needed to limit global warming to 1.5°C.

And we are going further: in 2020, we signed up to the RE100 initiative, reinforcing our ambition to use 100% renewably sourced electricity across the entire Sanofi scope by 2030.

We have also pledged to optimize our vehicle fleet (subject to availability of suitable models) in the regions where we operate, so as to reduce greenhouse gas emissions from our fleet. Our aim is that by 2030, our vehicle fleet should have a neutral carbon footprint.

We are fully aware of the environmental and public health issues around the use of water in our industrial operations. That is why we perform regular risk assessments at all of our industrial sites aimed at reducing their water footprint. This enables us to identify priority sites that call for particular attention, which are required to implement water management plans by 2025. Those plans will reflect the specific issues at each site, and will help us use water effectively, sustainably and responsibly. A program of this type will be rolled out to all our industrial sites by 2030.

Similarly, by 2025 all our production sites will have implemented a plan to manage pharmaceutical residues in the environment so as to reduce their potential impact on ecosystems.

Reducing our environmental footprint also involves local biodiversity management. So our sites that are located close to sensitive natural spaces will have to work with local stakeholders to develop a biodiversity protection program by 2025. Finally, we are committed to continuing

4.2. Detailed description of SEF issues and risks

our efforts in terms of waste management. Our objective is that by 2025, over 90% of our waste will be recycled, reused or recovered via waste-to-energy), and we will no longer use landfill.

Improving the environmental profile of our products is a priority for Sanofi. We are actioning this by extending the scope of the voluntary environmental impact assessments we carry out on our medicines. By 2025, we will have performed assessments on our top 100 medicines and on all newly launched medicines, regardless of whether there is any regulatory requirement to do so. We will also deploy pilot schemes to promote the responsible use of medicines, and the proper disposal of unused medicines, medical devices, and packaging. These pilot schemes will form the basis of a global program, to be rolled out by 2030.

All our people, from R&D through to marketing, are working to build eco-design into all new products launched between now and 2025 and improve the eco-profile of our currently marketed products, while retaining as our absolute priority the treatment of health conditions and patient access to healthcare.

4.2.10.2. Climate change: towards carbon neutrality

As a major player in the pharmaceutical industry and the world of healthcare we are committed to combatting and adapting to climate change, drawing on our expertise in prevention, research and treatment. 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 (see section 4.2.10.2.4, "Climate-related health issues").

At the 21st Conference of the Parties (COP 21) on climate change in 2015, we signed up to the appeal for business to mobilize against climate change. We reiterated that commitment at the One Planet Summit organized by the French government in December 2017. In 2019, Sanofi was one of the 99 major French companies to sign the MEDEF French Business Climate Pledge.

In June 2020, the Science Based Target initiative (SBTi) validated our objectives for reducing absolute emissions of greenhouse gas (GHG), both for our own operations (Scopes 1 & 2) and for indirect emissions associated with our value chain (Scope 3). Our objectives are based on the science and will contribute to limiting global warming to 1.5°C, in line with the 2012 Paris Agreement.

More broadly, Sanofi has embarked on a climate resilience strategy. That means that climate-related risks and opportunities are being evaluated in order to prepare our business for the changes brought about by climate disruption.

We apply the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD), an initiative that we have officially supported since December 2020. Detailed information is available in our public response to the CDP Climate Change Questionnaire. A summary of that information is provided below.

Governance of climate issues at senior management level

- Planet Mobilization is Sanofi's environmental and sustainable development program. That program is led by the Planet Mobilization Steering Committee, as described in the roadmap (see section 4.2.10.1, "The Planet Mobilization Roadmap"). As part of the Planet Mobilization governance structure, we have separate operational committees dedicated to each environmental issue, including a climate change committee that met four times during 2020.
- The Climate Change Operational Committee addresses issues around our pledge to limit global warming to 1.5°C across our entire value chain, and to achieve carbon neutrality by 2050. The Committee reports to the Planet Mobilization Steering Committee.
- We also have a Climate-Related Risk & Opportunities (TCFD) Committee, which works across all the pillars of our environmental strategy (in liaison with the Planet Mobilization Steering Committee) to drive the program around the TCFD recommendations. The committee consists of our heads of Environment, Risk Management and Insurance; the head of HSE for our R&D operations; senior representatives from Corporate Strategy, Finance and HSE; and a member of our Legal Affairs team.

Strategy

- Risks and opportunities
 - We have identified a number of specific climate-related risks and opportunities within our overall risk management process. These include transition risks and physical risks, but also business development opportunities.
 - Impacts on strategy, business and financial planning
 - Climate change is integral to the corporate strategy reflected in our Planet Mobilization roadmap.
 - Scenario analysis
 - Our Climate Committee has conducted in-depth case studies, classified by time horizon, to illustrate those risks and opportunities. Examples include a risk of production shutdown at a key site affected by a natural disaster, or our response to vector-borne or respiratory diseases. The Committee also assessed the materiality of scenarios with significant financial impacts.

Risk management

- Identification, evaluation and management of risks and opportunities integrated into our global risk management process
 - Identifying, evaluating and responding to climate risks is fully integrated into the risk management process applied across the whole of Sanofi. All risks are evaluated for their environmental impact.

- We have identified climate change, and its impact on health (including the impact of climate change on the Sanofi ecosystem and business model) as an emerging risk.

Objectives and indicators

- Objectives
 - We disclose our climate objectives, including on global warming, our carbon footprint, and water and waste management (see section 4.2.10.1., “The Planet Mobilization roadmap”).
 - We also disclose the timescale for our climate objectives, and the baseline year (see section 4.2.10.1., “The Planet Mobilization roadmap”).
- Key performance indicators
 - We disclose key performance indicators that measure progress towards our objectives in terms of energy, greenhouse gas emissions, water and waste (see section 4.2.10.1., “The Planet Mobilization roadmap”), as well as other environmental indicators.
 - Our greenhouse gas emissions are calculated in accordance with the GHG Protocol (see section 4.2.10.2.2., “Greenhouse gas emissions”).

Our performance is also being evaluated by the Carbon Disclosure Project (CDP) using their Climate Change questionnaire. In the 2020 CDP scores based on 2019 data, Sanofi was ranked A-.

4.2.10.2.1. Energy

[GRI 302-1, GRI 302-4]

4.2.10.2.1.1. Improve energy efficiency and encourage the use of renewables

To address the challenges of diminishing fossil fuel resources and climate change, we have adopted an approach that combines energy efficiency (consume less, consume smarter) with decarbonization of our energy supplies (consume differently).

Our energy efficiency approach extends to all our activities, buildings, processes and utilities. It takes in the architectural and functional design of new buildings, and our medical rep vehicle fleets. An energy saving program is in place at all of our sites. In 2020, 28 of our sites received ISO 50001 certification (Energy Management Systems). Various levers are being activated (depending on the activity carried on at the site), with a specific focus on air treatment systems that ensure high-quality environments in manufacturing and R&D buildings, which can account for up to 70% of energy consumption. However, these systems are important for the quality and safety of our medicines, and any alterations must be validated.

We have issued standards requiring energy efficiency to be built into the design and selection of plant and equipment that use energy. Our Sustainable Buildings Charter also helps promote energy-efficient buildings. At the end of 2020, over ten of our administrative buildings were certified LEED, BREEAM or HQE.

We also operate a low-carbon energy policy, favoring the use of lower-carbon energies for our projects and buying in electricity from certified renewable sources. In September 2020, we made a public pledge that by 2030, 100% of the electricity we consume will come from renewable sources, by signing up as a Gold Member of the RE100 initiative. In just two years, Sanofi has raised its use of renewables from 2%, first to 11% and then to 26% of its electricity consumption. The renewables we use are accredited under the Renewable Electricity Certificates (REC) program.

Finally, we have a renewable electricity Power Purchase Agreement with Enel in Mexico to supply energy to our three Mexican sites.

4.2.10.2.1.2. Energy consumption

Energy consumption (MWh)	2020	2019	2015 (baseline year)
Natural gas	2,103,912	2,098,930	2,110,964
Electricity ^(a)	1,175,594	1,413,230	1,621,486
Renewables ^(b) (electricity and biofuels)	437,015	169,804	24,462
Other energy sources (bought-in steam, waste-to-energy, etc.)	481,846	486,436	443,287
Total	4,198,367	4,168,400	4,200,199

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

(b) Includes renewable electricity sourced from Sanofi in-house projects.

Our energy consumption is virtually unchanged relative to 2015 (0.04% lower), despite a 6% increase in our activity levels over the same period.

4.2. Detailed description of SEF issues and risks

4.2.10.2.2. Greenhouse gas emissions**4.2.10.2.2.1. Direct and indirect emissions: Scopes 1 & 2**

[GRI 305-1, GRI 305-2]

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 vehicle fleet: we are targeting a 50% reduction by 2025 from the 2015 baseline. The ultimate goal is to be carbon neutral by 2050.

Alongside efforts to make our buildings and processes more energy efficient, we have introduced a policy for sales rep travel (including vehicle buying and eco-driving courses) that cut CO₂e emissions by 51% between 2015 and 2020.

We also have policies in place for managing our use of refrigerants. These include switching to substitute refrigerants with a lower global warming impact, improving leak prevention, and systematically analyzing accidental discharges so that we can learn the lessons and share them across all our sites. In five years, we have reduced the impact of refrigerant discharges by 47%, from 53,000 tonnes of CO₂ equivalent to 28,000 tonnes.

Greenhouse gases (Tonnes of CO ₂ e) ^(a)		2020	2019	2015 (baseline year)
Scope 1	Direct emissions	450,132	452,776	467,762
	Direct emissions from medical rep vehicle fleet	65,196	99,313	133,837
Scope 2	Indirect emissions	255,866	353,782	461,775
Total		771,194	905,871	1,063,374

(a) CO₂ e = CO₂ equivalent.

Direct and indirect CO₂e emissions were 15% lower in 2020 than in 2019.

Compared to 2015 (the baseline year for the Planet Mobilization program), direct and indirect emissions linked to energy consumption (Scopes 1 & 2) are down 27%.

In France, Scope 1 & 2 emissions represented 176,977 tonnes of CO₂e (including 4,234 tonnes for our medical rep vehicle fleet), down 5% on the 2019 level (186,413 tonnes of CO₂e, including 6,689 tonnes for our medical rep vehicle fleet).

4.2.10.2.2.2. Other indirect emissions: Scope 3

[GRI 305-3]

Including Scope 3 emissions gives a broad indication of total CO₂e emissions generated by Sanofi across the entire value chain. Scope 3 calculations are based on a wide range of data, so there is a high degree of uncertainty. We are keen to improve the quality of our Scope 3 data year by year.

Scope 3 was calculated for the 15 categories listed in the Greenhouse Gas (GHG) protocol. In 2020, we brought our methodology and calculations in-house, to improve the quality of the data collected and fine-tune certain assumptions. We view all categories as important and analyze them with the relevant players, which makes it possible to measure our Science Based Target initiative (SBTi) commitment.

Scope 3 (Tonnes of CO ₂ e) ^(a)	2020	2019
Calculated Scope 3 emissions (upstream)		
Category 1: Purchased goods and services	3,438,804	3,823,973
Category 2: Capital goods	634,505	652,794
Category 3: Fuel and energy-related activities	159,750	358,678
Category 4: Upstream transportation and distribution	196,664	216,483
Category 5: Waste generated in operations	351,145	372,442
Category 6: Business travel	57,829	154,990
Category 7: Employee commuting	162,756	150,766
Sub-total: calculated Scope 3 emissions (upstream)	5,001,453	5,730,126
Estimated Scope 3 emissions (downstream)		
Category 9: Downstream transport and distribution	769	874
Category 10: Processing of sold products	141,422	112,518
Category 11: Use of sold products	70,156	55,855
Category 12: End-of-life treatment of sold products	341,602	222,701
Sub-total: estimated Scope 3 emissions (downstream)	553,949	391,948
TOTAL ^(b)	5,555,402	6,122,074

(a) CO₂e = CO₂ equivalent.

(b) 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.

The reduction in 2020 compared with 2019 is mainly due to better-quality input data and assumptions, especially for Category 1 where the calculation is performed at product, raw material or finished goods level, reflecting the characteristics of each. Purchase volumes were stable year-on-year.

The variance in Category 3 reflects the use of new emission factors derived from the DEFRA/BEIS database. The calculation comprises upstream emissions from bought-in fuel and electricity, and losses through freight and logistics.

Business travel is separately monitored and is the focus of specific efforts. The COVID-19 pandemic was also a significant factor in reducing business travel.

The quantities of boxes and cardboard increased significantly in 2020 versus 2019, which had a knock-on effect on Category 12 emissions (end-of-life treatment of sold products).

4.2.10.2.3. Adapting to the consequences of climate change ⁽⁴⁾

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.

4.2.10.2.4. Climate-related health issues

Climate change is one of the greatest health challenges of our century. The World Health Organization (WHO) expects that between 2030 and 2050, climate change will lead to nearly 250,000 additional deaths each year. The direct effects of climate change include increased heat-related stress, floods, droughts, and extreme weather events, such as hurricanes. However, there are also indirect effects, such as atmospheric pollution; the propagation of diseases by vectors such as mosquitoes; an exponential rise in the allergenic potential of pollens; displacement of people; and post-traumatic stress caused by natural disasters.

⁴ 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.

4.2. Detailed description of SEF issues and risks

We are also working on several research and development 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.

At the same time, we are working on prevention and awareness programs for at-risk populations:

- promoting affordable treatment programs and prevention programs in the most malaria-prone regions;
- rolling out medical education programs for healthcare professionals in various regions, including India, Brazil, Mexico and the Middle East; and
- using the Sanofi Espoir Foundation to provide aid to communities suffering humanitarian crises caused by extreme weather events.

4.2.10.3. Water: a limited resource

4.2.10.3.1. Water resource management plan

[GRI 303-2]

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.

This year, Sanofi again completed the Water Security questionnaire of the Carbon Disclosure Project (CDP), obtaining the highest rating of A. This recognizes our achievement in consistently reducing the water footprint of our industrial operations over several years.

Utility services (steam, process water 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.

We seek to use this resource responsibly, by implementing water management plans at our sites, and pay particularly close attention to sites identified as priority in terms of water-related risks, especially in water stress zones.

In 2020, we launched a large-scale campaign to update water risk mapping across all our industrial sites, using a customized tool developed with the help of an external consultant. There are many water-related risks, but they can be classed in three main categories: physical, regulatory and reputational. An in-depth analysis, based on our own local data and a comprehensive independent review, has helped us fine-tune our list of priority sites potentially subject to water-related risks and those where additional investigation is needed at local level to confirm the situation. This list will be distributed internally during 2021. The four sites regarded as priority sites, as of the end of 2020, are Brindisi (Italy), Vertolaye (France), Karachi (Pakistan) and Jakarta (Indonesia).

4.2.10.3.2. Water consumption

[GRI 303-1]

Water used during manufacturing and heat exchange (heating or 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.

Nearly 42% of our sites cut their water withdrawal in 2020, resulting in a reduction in water withdrawal of 5% for the year and 22% versus 2015, well above our 10% objective.

Water consumption (millions of m ³ per year)	2020	2019	2015 (baseline year)
Withdrawal of surface water (lakes, rivers)	8	8.9	11.2
Withdrawal of groundwater	17.7	23.3	23.4
Withdrawal of water from public supply	7.5	8.3	8.2
Other sources	0.3	0.2	—
Total	33.5	42.8	42.7

Withdrawals at our four priority sites were just under 6.0 million m³ in 2020, 16% lower than in the previous year.

4.2.10.4. Waste: towards a circular economy

The key to our waste management policy is to reduce waste generation at source, followed by a systematic examination of reuse/recycle possibilities before waste is disposed of in any other manner (such as incineration with thermal recovery). Landfill is only used as a last resort and must be subject to audit.

We pay particular attention to on-site waste management, so that we can categorize and identify waste generated by each process and then collect, sort, store, transport and treat each type of waste appropriately.

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-specific 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).

Some of our waste is reprocessed on site so that it can be reused. For example, in 2020 we prevented 110,126 tonnes of solvent waste by regenerating solvents and feeding them back into our industrial processes.

4.2.10.4.1. Waste generated

[GRI 306-2]

We have set two 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 landfill disposal rate to 1%.

At the end of 2020, our 3R rate was 73% (excluding on-site recycling of solvents).

The landfill disposal rate in 2020 was 7%, one percentage point less than in 2019, and 67 of our sites no longer used landfill (versus 62 in 2019).

Waste (tonnes)	2020	2019	2015 (baseline year)
Hazardous waste			
Recycled hazardous waste	20,247	28,091	33,674
Hazardous waste incinerated with thermal recovery	55,701	58,280	39,417
Hazardous waste incinerated without thermal recovery	42,413	38,528	103,506
Hazardous waste sent to authorized landfills	2,630	2,067	1,698
Sub-total: hazardous waste	120,991	126,966	178,295
Non-hazardous waste			
Recycled non-hazardous waste	96,483	90,267	85,359
Non-hazardous waste incinerated with thermal recovery	26,018	23,195	18,094
Non-hazardous waste incinerated without thermal recovery	13,428	7,411	15,064
Non-hazardous waste sent to authorized landfills	15,873	18,040	18,488
Sub-total: non-hazardous waste	151,802	138,912	137,005
TOTAL hazardous and non-hazardous waste	272,793	265,878	315,300

Overall, total waste generated by Sanofi in 2020 was 14% lower than in 2015.

We reduced the quantity of hazardous waste in 2020 relative to 2019 by installing a new ammonia adsorption process at one of our chemistry plants in France, which saved over 5,000 tonnes of waste.

4.2.10.4.2. 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: 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 service management: matching quantities to needs and using just-in-time techniques for some outlets; charging users for bread so they do not automatically take it 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.
- Management of leftovers and waste: 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.

4.2. Detailed description of SEF issues and risks

We also conduct regular awareness campaigns at our French sites. These include weighing leftovers (especially bread), using sort bins instead of trash cans, and sharing good practice in preventing food waste.

4.2.10.4.3. Eco-design

Eco-design is a holistic approach that aims to reduce the environmental profile of a product across its entire life cycle by integrating environmental protection criteria at the design stage.

The eco-design pillar of our Planet Mobilization program applies this philosophy, with the aim of evaluating and optimizing the environmental profile of all new products launched on the market from 2025.

To reach that goal, we are drawing on our existing initiatives and programs, such as responsible and sustainable chemistry, rolling upgrade programs and eco-packaging.

Because we are keen to follow the science, we use the services of environmental experts. In 2020, for example, we worked with experts to analyze the life cycle of medical devices used in diabetes treatments and draw up an action plan to improve their environmental performance.

Packaging

For some years, many of our industrial sites have been simplifying, standardizing and optimizing both primary packaging (blister packs) and outer packaging for all our solid form products and pills. These initiatives should reduce our use of plastics, aluminum and cardboard, and also reduce our freight needs. We are now extending this approach to the rest of our product portfolio as part of our drive for continual improvement.

A good example of our eco-packaging approach is the Sanofi Pasteur Compact Box, which in 2017 won the Pharmapack Europe Eco-Design Award. This innovative design, developed with a business partner, halves the volume of vaccine packaging and eliminates the need for PVC blisters. The Compact Box is being accompanied by an upscaling of packaging, helping optimize cold chain distribution. Sanofi Pasteur is currently rolling out this packaging design across its entire range of vaccines.

4.2.10.5. Environmental releases

[GRI 413-2]

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 have implemented a range of action plans to limit these impacts, ensure that we comply with regulations and our own internal directives, and anticipate the impact of new and emerging regulations relating to the release of contaminants into the environment in every country where we operate. We are also working on impacts that occur after patients have used our products.

4.2.10.5.1. Organization

Our Environment department is part of our HSE department; for details about our organization in this area, see section 4.3.7., "Employee Health and Safety".

4.2.10.5.2. Policies and action plans**4.2.10.5.2.1. Managing pharmaceutical contamination and combatting bioresistance**

Pharmaceutical substances may be found in the environment as a result of medicines taken by patients and then excreted; inappropriate disposal of unused or date-expired medicines; and effluent from manufacturing sites. We strive to prevent and reduce the environmental impact of pharmaceutical substances (including antibiotics) by taking actions across the entire life cycle of our products, from development and manufacturing to end-of-life post patient use. Our key actions are:

- Evaluating and reducing the potential environmental impacts of our production sites, through a global program with a particular focus on the discharge of pharmaceutical substances in effluents.
- Obtaining new data to improve our understanding of how medicines impact on the environment, and assessing the environmental risks associated with patient use.
- Promoting proper use of our medicines. 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.
- Encouraging responsible disposal of unused or date-expired medicines, by raising patient awareness and supporting collection programs.

We also signed up to the Anti-Microbial Resistance (AMR) “Roadmap 2020” to help combat microbial resistance to antibiotics. This initiative initially brought 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 shared environmental limits.

4.2.10.5.2.2. 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:

- monitoring trends in the concentration of pollutants in the natural environment;
- reducing the quantities discharged at source; and
- installing state-of-the-art or innovative 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.

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);
- pollution management strategies (reduction at source, segregation, outsourcing, and dedicated or centralized treatment facilities); and
- monitoring discharges and auditing the performance of treatment facilities.

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

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 on site. 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:

- avoiding the use of solvents by substituting biological processes for chemical processes;
- encouraging the recycling of solvents;
- selecting the least toxic solvents;
- 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, activated carbon).

4.2.10.5.3. Performance indicators

Significant events with an environmental or regulatory impact are systematically reported at global level.

4.2.10.5.3.1. Managing releases of pharmaceuticals into the environment

Since 2016, we have been gradually rolling out a program to evaluate and reduce the environmental impact of potential releases of pharmaceutical substances from our manufacturing sites. 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. At the end of 2020, this program covered 50% of our chemical synthesis and dosage form sites, and 100% of our priority sites (which are identified on the basis of a risk analysis by substance and by site).

We are proactively assessing the environmental impact of the active ingredients in 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. We have drawn up an initial priority list of over 160 active ingredients. To date, our evaluation program has already covered 37% of these substances.

CHAPTER 4.

CORPORATE SOCIAL RESPONSIBILITY

4.2. Detailed description of SEF issues and risks

We also support unused medicine collection schemes (like the Cyclamed scheme in France) in many countries. Finally, we conduct awareness campaigns to help patients use medicines properly, especially antibiotics.

4.2.10.5.3.2. Managing other types of wastewater discharge

The data reported correspond to effluents reaching the environment (i.e., after internal and/or external treatment, depending on the site). 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.

Wastewater discharge (tonnes)	2020	2019
COD	1,982	2,243

Total COD discharges from our sites fell by around 12% in 2020. Decreases of varying degrees were recorded at 46 of our sites. This trend is consistent with the year-on-year trend in water withdrawal, which also fell slightly.

We work continually to improve the quality, relevance and accuracy of the metrics we use. For COD in particular, we are planning to report the annual quantity discharged by each site as measured within the site boundary, whether the site discharges directly to the environment (after onsite treatment) or indirectly via municipal drainage systems.

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

[GRI 305-7]

Solvents (tonnes)	2020	2019
Solvents used	178,381	184,472
Percentage of regenerated solvents	62%	62%

Volatile organic compounds (VOCs) (tonnes)	2020	2019
VOCs (estimated)	2,893	2,947
SOx - direct emissions	176	203

NOx (tonnes)	2020	2019
NOx - direct emissions	491	494

We adopt a proactive approach to monitoring and testing and have invested heavily in new techniques to improve thermal oxidation efficiency.

4.2.10.5.4. Remediation

4.2.10.5.4.1. 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.

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 2020 were immaterial.

4.2.10.5.4.2. 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 and Portland in the United States; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Beaucaire, Valernes, Limay, 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 2020 Annual Report on Form 20-F. In 2020, Sanofi spent €55 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 €713 million as of December 31, 2020, compared with €737 million in 2019. 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 2020 Annual Report on Form 20-F.

4.2.11. Animal protection

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 care, 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. Three new policies have been developed and approved by the Bioethics Committee since the end of 2019 relating to laboratory animal adoption, the reporting of undesirable events in the care and use of animals, and roles and responsibilities in the commissioning of third-party research and services. The policies on animal adoption and the commissioning of third-party research are supplemented by practical recommendations.

Our Chief Veterinary Officer is responsible for liaising with animal dealers, vets, and site-level Ethics Committees. In 2020, we instituted a global forum - scheduled to convene twice a year - to help members of our Ethics Committees develop their ethical competencies.

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 for research and the production process. An example of our proactive approach was our objective of obtaining certification for all our sites in 2020 from AAALAC International, an internationally-recognized body; we actually achieved this a year ahead of schedule. Use of animals represents only a small part of our R&D and manufacturing operations but is integral to our global research and analytical control strategy, which also includes non-animal methods and clinical research.

We are committed to developing alternative approaches. We 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 as established in regulations and international standards.

We promote a "culture of care", the core value of which is to adopt a responsible approach to animal testing among all professionals working at Sanofi sites.

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 policies.

4.3. Vigilance plan

At the end of 2020, 15 Sanofi sites in eight countries were using animals. All our sites have obtained AAALAC International accreditation except for the one located in Thailand, which has migrated towards a subcontracting model given a drop in activity levels. Three entities were due for a re-accreditation visit in 2020. In agreement with AAALAC International, only one was actually carried out, with the other two postponed until 2021. This delay was due solely to the public health context and does not call into question the quality of our sites.

Two new entities, Synthorx and Principia, joined the Sanofi group in 2020. The use of animals at these two entities was reviewed in order to bring them into compliance with our animal protection policies.

In 2020, 55 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 protection principles (there were no critical discrepancies).

During 2020, we continued with our efforts to reduce our use of animals. The total number of animals used at Sanofi sites in 2020 was 302,890 ⁽⁵⁾. Compared with a reported figure of 333,844 for 2019 (measured over an 11-month period, to fit in with the timescale for publication of our French-language *document d'enregistrement universel*), which represents a reduction of 9% (or 17% like-for-like). Since 2013, we have reduced the number of animals used by 45%.

4.3. Vigilance plan

4.3.1. Methodology for selecting risks for the duty of vigilance

[GRI 102-11, GRI 308-2]

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 the impacts on Sanofi and its stakeholders, while for the duty of vigilance only the impacts on people and the environment were assessed.

This means that although the risk mapping exercises are complementary, and to a very large extent overlap, there are some risks that are specific to just one of the two pieces of legislation. A list of these risks is presented in section 4.3.2., "Duty of vigilance risk table"; the related policies and action plans are described in section 4.2., "Detailed description of SEFP issues and risks" (for risks identified as common to both exercises) and in the present section (for risks specific to the duty of vigilance).

For risks specific to the duty of vigilance, we apply a three-step methodology:

- 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; and
- evaluate the level of control over these risks and prepare action plans to manage them.

In determining 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:

- the "Human Rights in Our Activities" guide, which identifies key human rights issues over the life cycle of our products; and
- our practice, 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, such as Together for Sustainability (TfS) and Pharma Supply Chain Initiative (PSCI), 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 issue 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.

⁽⁵⁾ Figures calculated in accordance with national legislation in each country where we use animals. For our European sites, refer to Commission Implementing Decision 2020/569, available at eur-lex.europa.eu.

The duty of vigilance risks identified in this section are those we regard as major; for a presentation of all the issues related to our duty of vigilance, refer to the *Plan de Vigilance* (Vigilance Plan) factsheet, available (in French only) via the Document Center on www.sanofi.com.

A cross-reference table showing all the information required by the duty of vigilance is provided in section 4.7, “Corporate social responsibility cross-reference tables”.

4.3.2. Duty of vigilance risk table

Category	Risk	Description	Section in this chapter
Health and safety	Employee health and safety*	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.	4.3.7. Employee health and safety
	Product safety for patients and consumers*	Risk of product safety breaches, from first administration in clinical trials on humans through to the end of the product's life cycle, that could have an adverse effect on patients or healthcare professionals.	4.2.4. Product safety for patients and consumers (SEFP risk)
Human rights and fundamental freedoms	Patient safety in clinical trials*	Risk that we will breach ethical standards (informed consent, transparency of results), which could have an adverse effect on patient safety.	4.2.5. Medical Ethics and Bioethics (SEFP risk)
	Biopiracy*	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.	4.3.13. Biopiracy
	Personal data protection*	Risk that we will fail to respect the privacy of customers, employees, patients or healthcare professionals by compromising the integrity, confidentiality or accessibility of their personal data.	4.3.10. Personal data protection
	Fundamental human rights at work*	Risk that the fundamental human rights of employees will be breached as a result of our operations, or those of our suppliers or subcontractors.	4.3.6. Fundamental human rights at work
Environment	Minimize water consumption	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.	4.2.10.3. Water: a limited resource (SEFP risk)
	Minimize environmental discharges*	Risk that discharges and emissions from our industrial and R&D operations will adversely affect the environment or human health or will not be appropriately managed by our own staff or by our suppliers or subcontractors.	4.2.10.5. Environmental releases (SEFP risk)

*Indicates risks that apply not only to our own operations, but also to those of our suppliers, subcontractors and partners. See section 4.2.15, “Procurement and subcontracting”, for measures taken to manage risks within our supply chain relating to employee health and safety, environmental releases and human rights.

4.3.3. Oversight

Our vigilance approach is under the joint control of our heads of CSR and HSE. Global coordination is provided by our 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; its remit includes global oversight of Vigilance Plan implementation. Monitoring of risk management policies and whistle-blowing systems is the responsibility of the specific departments concerned, such as HSE.

4.3.4. Dialogue with stakeholders

Sanofi makes regular presentations to trade unions about the rollout and monitoring of the Vigilance Plan, via a working group mandated by the Group Works Council. Meetings are held to discuss issues, such as risk mapping relating to human rights at work, sustainable procurement, whistle-blowing, and supplier assessments.

Two meetings were held in 2020, at which the issues presented included a follow-up on internal control points relating to policies on human rights at work; progress in procurement; and a status update on whistle-blowing reports under the duty of vigilance.

4.3.5. Grievance mechanism

A whistle-blowing system has been in operation at Sanofi since 2006, enabling any employee to report any breach of our Code of Ethics. It covers the issues identified in the Vigilance Plan, and is described in section 4.2.8.2.3., "Whistle-blowing".

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

4.3.6. Fundamental human rights at work

[GRI 102-12, GRI 407-1, GRI 409-1]

We employ nearly 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. In dealing with human rights, we refer to the following ILO conventions:

- freedom of association and recognition of the right to collective bargaining (ILO conventions 87 and 98);
- elimination of all forms of forced labor (ILO conventions 29 and 105);
- effective elimination of child labor (ILO conventions 138 and 182);
- elimination of discrimination in employment (ILO conventions 100 and 111);
- wages and employee benefits (ILO conventions 95, 131 and 135); and
- weekly rest (ILO conventions 14 and 106).

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.

4.3.6.1. Human rights risk mapping

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

- 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.
- 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 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.

4.3.6.2. 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.

4.3.6.3. 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 impacts on employees; and
- we classified risks relating to the fundamental rights of workers and ranked them by criticality (see section 4.3.6.1., “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.

4.3.6.4. Performance indicators

In 2019, we refined our human rights risk mapping so as to identify those countries where we need to focus our internal audit efforts. We identified 18 at-risk countries based on the following criteria: level of country risk, number of employees, and presence of production or distribution activities. These countries represent approximately one-third of the Sanofi workforce. Of these 18 countries, 7 (representing more than a quarter of the Sanofi workforce) have already been subject to audit.

In 2020, 16 countries (Algeria, Bangladesh, Brazil, China, Colombia, Egypt, India, Indonesia, Mexico, Pakistan, Russia, Saudi Arabia, South Africa, Thailand, Turkey, Vietnam) responded to the internal control questionnaire. The main findings are summarized below:

Issue	Findings
Child labor Principal control points:	
<ul style="list-style-type: none"> • No hiring of children aged under 15, or aged under 18 for dangerous work • Verification of age on hiring • Danger level assessment of jobs for young workers/compliance with ILO working hours 	No major compliance breaches reported
Forced labor Principal control points:	
<ul style="list-style-type: none"> • Existence of written, transparent employment contracts • Regularity of wage payments • Transparency and clarity of calculation methods, payslips, etc. • No need to work overtime to earn a decent wage • No withholding of wages or recruitment costs (including by recruitment agencies) • No retention of identity papers 	No major compliance breaches reported Difficulties reported by some countries relating to issues around decent wages and audit of recruitment agency practices
Working hours Principal control points:	
<ul style="list-style-type: none"> • Compliance with ILO working hours standards: weekly, daily, overtime, paid leave, maternity leave 	Reports of difficulties applying standards due to local legislation in certain countries
Freedom of association Principal control points:	
<ul style="list-style-type: none"> • No discrimination based on trade union membership, and no abusive practices against worker representatives • Respect for the right to collective bargaining 	Reports of difficulties applying standards due to local legislation in certain countries

Corrective action plans are being drawn up within the entities concerned. Group-wide initiatives will be rolled out in 2021 to help Sanofi subsidiaries address the difficulties identified in applying standards. We will draft a global policy on fundamental human rights at work, to collate and reinforce the requirements contained in our existing policies.

4.3.7. Employee health and safety

[GRI 403-1, GRI 416-1]

The health and safety of our employees is addressed as part of our global Health, Safety and Environment (HSE) strategy.

4.3.7.1. Sanofi HSE strategy

4.3.7.1.1. Sanofi HSE policy

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, validated by our senior management, and signed off by our CEO.

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

- We constantly strive to embed an HSE culture where each person takes responsibility for preventing accidents and harm to health, promoting wellness at work, and reducing environmental impacts. This message is shared with everyone in Sanofi.
- Development projects and product launches are assessed for potential risks to health, safety and the environment. These assessments draw on all our scientific and technical knowledge, use the best technologies available, and take account of the life cycle of the product in question.
- To protect the environment, we pay close attention to the impacts of our operations and products by conserving water and energy, and reducing the impact of emissions, effluent and waste across all our industrial, R&D and commercial activities. We are also actively engaged in fighting climate change.
- We encourage our suppliers, co-contractors and subcontractors to apply our HSE rules; when assessing and referencing them, we use application of our HSE rules as a criterion.

We adopt a constructive approach to transparency and dialogue with third parties on our HSE policy.

Sanofi drew upon the resources of its in-house HSE network to coordinate the response to the COVID-19 pandemic. A global crisis unit was set up at the onset of the crisis, along with similar units in each country, to coordinate the preparation and management of our response. Weekly meetings were held in each country throughout the crisis to ensure that procedures were being properly applied.

As a healthcare company, we set out strict safety measures to protect all our people against the pandemic, including barrier measures, temperature control and managing COVID cases. We established decision-making tools and criteria for tightening or easing lockdown, driven by the data in each country. Through a dedicated website and a range of other support measures, we helped our people adapt to new ways of working. These included tips on staying physically fit, on dealing with the mental health pressures of working from home over extended periods and being socially isolated, and on how to achieve good ergonomic conditions.

Around 70% of our workforce (mainly in production and R&D) continued to work on site, to ensure continuity of supply of our medicines and deliver on our public health mission.

HSE units at site level were called upon extensively as part of our COVID response, refocusing on the fundamentals and prioritizing business continuity. Our HSE network adapted to COVID-related restrictions by using online training, conducting virtual audits, developing ten onboarding modules, and creating a webinar on preventing accidents as people returned to work post-lockdown and during summer shutdown works. Nevertheless, our HSE teams remained fully mobilized to ensure continuity in production and in critical R&D activities.

4.3.7.1.2. Organization

In deploying the Sanofi HSE strategy, our global HSE organization is based on three pillars, all under the direction of our Global Head of HSE, who in turn reports to a member of our Executive Committee. Global HSE covers all business segments and geographies, and the entire life cycle of Sanofi products, and comprises:

- a global center of excellence, using scientific and technical expertise to develop global strategies across the whole of Sanofi, and providing support to our operations and partners;
- HSE Business Partners for our R&D and Industrial Affairs activities, subsidiaries and sales forces, tasked with cascading the global strategies down within their sphere of operations and monitoring performance; and
- regional HSE managers who 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.

Our HSE department heads up a number of expert committees that assess the impacts and hazards of substances and biological agents.

Sanofi also has in-house analytical laboratories, such as the Aramon facility in France. Staffed by a team of experts, the lab classifies the level of exposure of people to active substances; analyses environmental discharges from our sites; evaluates dangers associated with processes and classifies dust hazards and dust filtering equipment. The Aramon laboratory also develops specific analytical methods.

4.3.7.1.3. Managing HSE risks

Our HSE department has established a risk evaluation methodology that is applied to all our sites and is consistent with Sanofi's global risk evaluation methodology. The aim of this risk mapping process is to obtain a comprehensive overview, from site level upwards, of the criticality of the principal HSE risks to which Sanofi is exposed and the level of control over those risks.

Each site carries out a comprehensive risk evaluation program covering all its activities once a year or whenever a significant change occurs, which is signed off by management at site and activity level. The evaluation methodology identifies and quantifies hazards and assesses the level of risk in light of the extent to which the risk is controlled and the nature of the site:

- evaluation of regulatory compliance, including environmental permits, operating licenses, management of hazardous chemicals, transport of hazardous goods, and any regulated substances on the site;
- evaluation of the risk of exposure in occupational health terms, including potential exposure to chemicals, biosafety hazards and radiation, and physical stress factors;
- evaluation of major risks affecting business continuity, including process safety, risks of explosion or fire, and exposure to natural risks;
- evaluation of workplace risks, including solitary work, road safety, asphyxia, hazardous machinery, the risk of working at heights, handling and lifting equipment, electricity, and managing hazardous work sites; and
- evaluation of environmental risks, such as soil pollution, waste management, water and effluent management, atmospheric emissions and climate change.

A global HSE Risks Committee consolidates the site-level risk mapping and draws up a company-wide HSE risk map, which is then sent to Sanofi Risk Management.

All risk maps are translated into action plans which are periodically monitored at site 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 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.

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.

4.3.7.1.4. HSE management system

Sanofi distributes an HSE policy reference manual to all sites.

The manual sets out measures to be applied so that activities can be managed in a way that minimizes risks and impacts. It describes Sanofi's standards and methodological tools and builds in the results of risk/opportunity analysis and expectations on the part of stakeholders – including customers, NGOs, investors and civil society.

Seeking to improve at all times, the HSE department management has set out our HSE 2025 ambitions in a roadmap, backed by quantified objectives and action plans, that is shared across all levels of Sanofi.

Each site is subject to periodic monitoring to assess adherence to action plans and attainment of objectives.

The entire management system is reviewed regularly.

4.3. Vigilance plan

4.3.7.1.5. HSE compliance and internal audits

Wherever we do business, we are committed to complying with the HSE laws and regulations that apply to us and to implementing recommendations made by external audits conducted (for example) by our insurers, customers, or standards bodies.

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.

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

These audits are carried out by Sanofi Lead Auditors who are registered with the International Register of Certified Auditors (IRCA), supported by other staff members who have recognized HSE experience and have followed a dedicated training program accredited by IRCA. In advance of the periodic HSE audits, an independent expert conducts a compliance audit to check that local regulations are being applied. The HSE audit then checks that this was conducted properly and that an action plan is in place to deal with any non-compliance.

	2020	2019
Number of internal HSE audits, including Biosafety	38	54
Number of auditors with IRCA accreditation	22	23
Number of employees who have performed audits	80	81

By complying with Sanofi 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). Two sites have already been awarded ISO 39001 certification.

In 2020, 50 of our sites had one or more certifications: ISO 14001 (38 sites), OHSAS or ISO 45000 (21 sites), and ISO 50001 (28 sites). This represents 60% of our employees in Industrial Affairs, R&D, and corporate HQ premises.

In addition to internal verifications and audits, our sites are also subject to regular inspections by local authorities and to regulatory verifications by third parties on specific issues. For example, 139 visits were carried out by technical experts on behalf of Sanofi’s insurers during 2020, plus a further 45 remote diagnostic reviews during the period when travel was restricted because of the COVID-19 pandemic.

4.3.7.2. Workplace health and safety programs

[GRI 403-2]

4.3.7.2.1. Occupational injury prevention

Preventive measures are designed primarily to reduce the number and severity of occupational injuries and to minimize the exposure of permanent and temporary Sanofi employees, as well as our subcontractors.

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.

Analysis of occupational injuries includes a review of the root causes of serious and potentially serious accidents; identification of non-compliant situations and near misses; safety visits; and sharing of good practice. This helps guide the implementation of specific local or global preventive programs involving technical, organizational and people-based 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.

Learning from experience (incidents and good practices) is based on a dedicated reporting datasheet containing an analysis of significant incidents, 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 timeframe). 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 33 datasheets were distributed in 2020 to the whole global HSE network.

A campaign launched in 2018, focusing on preventing trip and slip hazards and other falls, significantly reduced accidents of this kind by 17% in 2019 (versus 2018), and by 47% in 2020 (versus 2019).

Preventive measures are also taken at site level, based on their risk analyses and actual incidents.

4.3.7.2.2. Road safety

During 2020, the travel restrictions imposed around the world due to the COVID-19 pandemic led to a reorganization of working practices and widespread use of remote communication. As a result, the distance covered by our medical reps on business trips fell by 32% relative to the previous year.

The practical training cycles originally scheduled were disrupted and replaced by online training and awareness sessions.

As each lockdown ended and field visits resumed, specific safety refresher courses were organized before employees took to the road again. Our road safety committees continued to be mobilized everywhere in the world, pursuing the actions that we have been taking over several years. Consequently, road accident injuries fell by 68% (16, versus 50 in 2019), even though the distance travelled fell by only one-third.

4.3.7.2.3. Occupational health

Based on an evaluation of health risks, each site implements risk prevention programs and occupational health practices in accordance with Sanofi's HSE rules. This mainly involves individual and collective containment and protection measures to prevent exposure at all workstations where chemical substances or biological agents are handled.

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. These assessments form part of the work of two committees, covering chemical risks (COVALIS) and biological risks (TRIBIO), which determine adequate preventive and protective measures for our people. These committees pool the resources of our network of international experts and draw upon Sanofi standards and policies.

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).

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.

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

In line with European statistics, the principal type of occupational disease recognized within Sanofi during 2020 was the musculoskeletal disorder category.

The number of occupational diseases is decreasing following the rollout of an ergonomics program to prevent such disorders.

4.3.7.2.4. Health and safety training

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

Each new employee receives initial health and safety 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.

Founded in 2012, the Sanofi HSE Academy enables all employees to access the training programs developed and approved by our HSE department, supplementing the training provided directly by local sites.

Highlights of 2020 include:

- Training delivery was adapted to meet the challenges of the COVID-19 pandemic, with face-to-face sessions replaced by remote learning, including modules on auditor training; leadership and safety culture; managerial safety visits; trainer training; and basic and intermediate ATEX (explosive atmosphere).
- The rollout of the Safety Culture program ("Rules that Save Lives"), which was launched in 2019, continued through 2020; 84,408 people have received training, or more than 95% of our global workforce. Our local trainers continued to roll out the Managerial Safety Visits program at all sites.
- Training modules to support employees resuming onsite work were developed and translated into several languages for our commercial operations; 11,188 people received training.
- An onboarding program for HSE managers was developed and rolled out remotely worldwide from October 2020. Around thirty HSE employees have started or completed the program to date.
- For technical and regulatory training, we developed basic-level e-learning modules (one theory, ten practical) on risk prevention in explosive atmospheres, and delivered them in 15 languages. 1,225 people received training worldwide.
- The machine safety program was disrupted by COVID-19, with only 39 people receiving training worldwide.

4.3.7.3 Occupational injury/disease indicators

Topic	Ambition	Progress		Contribution to SDGs
		2020	2019	
Health and safety in the workplace				
Decent work	Reduce the total occupational injury frequency rate (any employee) below 2 by 2020	1.7	2.2	SDG 8: Decent work and economic growth
	Reduce the lost time injury frequency rate – any employee below 1.4 by 2020	1.1	1.5	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.
Safety indicators		2020	2019	
Lost time injury frequency rate ^(a) – Sanofi personnel		0.9	1.3	
Lost time injury frequency rate ^(a) – any employee ^(b)		1.1	1.5	
Total occupational injury frequency rate – Sanofi personnel		1.3	1.8	
Total occupational injury frequency rate – any employee ^(b)		1.7	2.2	
Number of deaths		0	2	
Number of occupational diseases reported		34	28	

(a) For definitions, see section 4.5.2.2., “Safety indicators”.
 (b) “Any employee” includes Sanofi employees, temporary workers and subcontractors.

Our safety performance was better than in previous years, mainly due to fewer falls and vehicle accidents. Another factor was an increase in teleworking among administrative and sales staff due to the COVID-19 pandemic.

A total of 34 occupational diseases were reported to local authorities in 2020: 26 in France, 6 in Germany and 2 in the United States, all countries with well-established recognition and reporting systems. Most of the occupational diseases related to musculoskeletal disorders. Nine cases from 2019 were reported late and have been added to the 2020 data.

4.3.8. Product safety for patients and consumers

See section 4.2.4., “Product safety for patients and consumers”.

4.3.9. Patient safety in clinical trials

See section 4.2.5., “Medical ethics and bioethics”.

4.3.10. 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.

4.3.10.1. Organization

Our Data Protection Officer is responsible for implementing a Privacy and Personal Data Protection program within Sanofi. In this, he is supported by our corporate privacy team (the Global Privacy Office), and an international network of Local Privacy Officers (LPOs) in each country where we have subsidiaries. He is also supported by a network of Functional Privacy Officers (FPOs), representing global functions, such as Research & Development, Human Resources, Information Technology & Solutions, Finance, Commercial Services, Industrial Affairs, and our Global Business Units.

4.3.10.2. Policies and action plans

Our global approach to the processing of personal data is set out in two documents: the Sanofi Global External Privacy and Data Protection Policy and the Sanofi Global Internal Privacy and Data Protection Policy. Both policies are worldwide in scope and apply to all Sanofi employees processing personal data. The commitments set out in the policies are without prejudice to the application of and compliance with the privacy laws and/or local culture of each country where we process personal data.

We also apply our policy requirements contractually to third parties processing personal data on behalf of Sanofi (such as consultants, service providers, vendors or other partners), for example by asking them to sign data transfer agreements.

The very nature of our business requires the processing of data of individuals who receive our treatments. Such data may be collected in clinical trials or genetic and epidemiological studies, during the monitoring of pharmacovigilance information, and under Patient Support

Programs. No consent is required for the reporting of adverse events for pharmacovigilance purposes, but the person reporting the signal – usually a healthcare professional – will inform the patient that their health data is being transferred but that it will not be directly identifiable. Such data transfers are for pharmacovigilance purposes only and are restricted to the holder of the marketing approval and to health authorities responsible for pharmacovigilance.

Our Global Privacy Office uses the PRIMA (PRivacy IMPact Assessment) tool, which is made available to any Sanofi employee who needs to process personal data. PRIMA enables users to check their project for compliance with data protection regulations and Sanofi policy, determine any corrective action required, and update the Sanofi data processing register. This guarantees an audit trail for all projects involving the processing of personal data. We have also developed awareness-raising videos and training modules (updated in 2019) so that all our employees know the importance of issues around the protection and transfer of data within Sanofi.

The Global Privacy Office is now rolling out a new application, OneTrust, to replace PRIMA. Like PRIMA, OneTrust helps users to check that projects involving the processing of personal data comply with regulations and Sanofi policy, to determine any corrective action required, and to update the Sanofi data processing register. This ensures there is an audit trail for all such projects. OneTrust offers additional functionalities, including managing security incidents affecting personal data; bringing websites that use cookies into compliance; managing requests from people whose data are held and who wish to exercise their rights; and mapping IT systems and service providers involved in the processing of personal data.

The Global Privacy Office also continues to develop and distribute awareness-raising videos and training modules so that all our employees know the importance of issues around the protection and transfer of data within Sanofi. Finally, the Global Privacy Office has issued a set of position papers and a Privacy Checklist to support project managers as they implement a Privacy-By-Design culture.

4.3.11. Water resource management

See section 4.2.10.3., “Water: a limited resource”.

4.3.12. Environmental releases

See section 4.2.10.5., “Environmental Releases”.

4.3.13. Biopiracy

Sanofi is committed to complying with conventions on the protection of biodiversity and combatting biopiracy. Compliance with local regulations derived from the Nagoya Protocol requires coordinated efforts across all Sanofi entities. In 2015, we set up a project team to track worldwide implementation of the Nagoya Protocol and analyze its implications for our operations. At that stage, the focus was on identifying the biological materials we use to discover, develop, manufacture and package our products, and on documenting the country of origin and date of acquisition, in accordance with our own guidelines. During 2016 and 2017, the project team drafted documents and policies relating to the Nagoya Protocol. We also created a dedicated intranet site, accessible to all our employees, to raise awareness of the Nagoya Protocol. Staff in key departments were provided with specific training and awareness programs in 2017. To continue the internal rollout and ensure compliance, we set up a Nagoya expert group who report to our Bioethics Committee. The Nagoya expert group continues to work on issues arising from implementation of the protocol in the signatory states. The aim is to monitor how practices are changing in light of the reaction from stakeholders. For example, the use of digital sequence information on genetic resources is an issue still under review. The actions taken by Sanofi relate to the use of natural substances to develop new medicines.

These include abiding by the principle that when we commercialize products derived from natural substances, we share our profits with countries that allow access to their natural resources and with local populations who have specific know-how. So whenever we investigate the use for R&D purposes of a new product isolated from a natural source, we will carry out due diligence to ensure we comply with international conventions.

Other risks of adverse impacts on local communities include the environmental impact of our operations, and in particular risks relating to environmental releases (section 4.2.10.5.) and to the use of water resources (section 4.2.10.3.).

4.3.14. Procurement and subcontracting

[GRI 102-9, GRI 407-1, GRI 414-2]

We buy raw materials, goods and services all round the world, and use a diversified panel of suppliers reflecting the diversity of our activities. Our Procurement function is centralized and acts in the name of all Sanofi entities (including our Global Business Units and support functions). This structure delivers synergies in terms of both expertise and procurement costs. Our 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	2020	2019	2018
Procurement spend (€ billion)	14.8	14.5	15.6
<i>in OECD countries</i>	13.3	12.2	13.3
<i>in non-OECD countries</i>	1.5	2.3	2.3
Number of suppliers	54,507	68,000	86,000
Number of countries where we have suppliers	138	152	157

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.

In September 2020, PSCI held virtual training courses for Indian and Chinese suppliers on: pharmaceutical residues in the environment and antimicrobial resistance; business ethics and human rights; safety and the environment; safe processes; and occupational health. In total, 95 of our suppliers of active ingredients took part (49 from India, and 46 from China).

Under the auspices of PSCI, we worked with our peers to develop the first-ever environmental and social risk mapping exercise for a dozen natural or mineral commodities that are used and shared by our industry, such as palm oil and fish oil.

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, with which all our suppliers must acquaint themselves. The Code of Conduct was updated in 2020 to include data protection and a requirement for our suppliers to secure commitments from their own suppliers. In addition, we conduct anti-corruption due diligence before doing business with at-risk suppliers.

A supplier onboarding application is currently being rolled out, which by the end of 2020 covered around 60 countries. The procurement risk mapping exercise described below has been integrated into this new application, allowing for upfront evaluation of new suppliers on health and safety, environmental and human rights criteria. All new suppliers have to complete a self-assessment questionnaire so that we can be sure they meet our requirements.

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) for 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 around forty were classified as inherently high-risk in terms of environmental protection, health and safety, and human rights. These 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 risk mapping was updated in 2020, enabling 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, 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 the PSCI or TfS industry-wide initiatives), risk assessments, prevention plans or targeted awareness campaigns.

Suppliers identified as being in the highest risk categories have their CSR performance assessed by an external service-provider. The results of those assessments 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 2022.

We assessed 212 suppliers in 2020. Of these, 180 were undergoing a reassessment, and 54% of those had improved their rating after following an action plan.

Despite COVID-19, we were able to continue our supplier evaluation program in compliance with lockdown restrictions by conducting remote virtual audits, retaining the services of accredited local firms, or retrieving shared audits from industry initiatives to which we belong (PSCI and Tfs).

We also aim to have completed audits of all our suppliers of high-risk critical active pharmaceutical ingredients (APIs) and all our contract manufacturing organizations (CMOs) by the end of 2021.

	2020	2019	2018
Number of Sanofi CMO audits	42	72	64
Number of audits of active pharmaceutical ingredient (API) suppliers	44	87	90
Number of shared audits (PSCI) of miscellaneous suppliers: packaging and CRO categories ^(a)	35	-	-

(a) Data available from 2020.

Results from these audits for the 2016-2020 period showed that one-quarter of the suppliers failed to meet the required standard, mainly suppliers based in India and China. All of these suppliers are required to follow a corrective action plan. During the 2016-2020 period, 83 API suppliers and 172 CMOs were reassessed, and nearly half of these had improved their performance.

4.4. Sanofi's contribution to Sustainable Development Goals

Today we are confronted by societal challenges like a growing and ageing population, income disparities and climate change. At the same time, technological advances (such as the rise of digitization) present significant opportunities as well as challenges. Given these profound upheavals, companies are not only required to perform well financially, but must also explain what they are doing to respond to these 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 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. Details about our programs on access to healthcare are provided in section 4.2.2.

4.4 Sanofi's contributions to Sustainable Development Goals

In addition to SDG 3, Sanofi initiatives that contribute to SDGs are shown in the table below:

Topic	Ambition	Progress		Contribution to SDGs
		2020	2019	
Access to Healthcare for the Underserved				
Infectious diseases	To help eradicate sleeping sickness by 2020. To help eradicate polio by 2023.	See section 4.2.2., Access to healthcare	See section 4.2.3.2., "Infectious diseases".	SDG 3: Good health and well-being SDG 3.3: By 2030, end the Aids epidemic, tuberculosis, malaria and neglected tropical diseases, and combat hepatitis, water-borne diseases and other communicable diseases.
Non-communicable diseases	To help reduce the burden on low and intermediate income countries of non-communicable diseases like childhood cancer, diabetes and mental health disorders.	See section 4.2.2., "Access to healthcare".	See section 4.2.3.3., "Non-communicable diseases".	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.
Human Capital				
Gender balance	Achieve gender balance in Sanofi Senior Leaders by 2025. Achieve 40% of women in executive posts by 2025.	38.8% 31.3%	37.2% 29.9%	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.
Corporate citizenship				
Decent work	Reduce the total occupational injury frequency rate (FR) – any employee to below 2 by 2020 Reduce the lost time injury frequency rate – any employee to below 1.4 by 2020	Total occupational injury FR – any employee: 1.7 Lost time injury FR – any employee: 1.1	Total occupational injury FR – any employee: 2.1 Lost time injury FR – any employee: 1.5	SDG 8: Decent work and economic growth 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.
Communities	In France, have 10% of work/study placements occupied by young people from deprived urban areas	5.3% ^(a)	6.4%	SDG 4: Quality education SDG 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all.
Healthy planet				
Climate change - Carbon footprint (CO ₂ emissions)	Reduce greenhouse gas emissions (Scopes 1 & 2) by 50% by 2025, versus 2015 Achieve carbon neutrality by 2050 for emissions caused by our operations	-27%	-12%	SDG 13: Climate action SDG 13: Take urgent action to combat climate change and its impacts
Water	10% reduction in water consumption by 2020 (relative to 2015) Implement a management plan at all sites by 2025 (priority to those in water stress zones)	-22% See section 4.2.10.3.1., "Water resource management plan".	-19% See section 4.2.14.3.1., "Water resource management plan".	SDG 6: Clean water and sanitation SDG 6: Ensure availability and sustainable management of water and sanitation for all.
Waste	Reuse/recycle/recover at least 90% of our waste by 2025 Achieve landfill disposal rate of below 1% of total waste by 2025	73% 7%	75% 8%	SDG 12: Responsible production and consumption SDG 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.
Pharmaceutical products in the environment	Implement a life cycle management plan at all priority production sites by 2025	100%	75%	SDG 12.5: By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse
Biodiversity	Promote biodiversity on all our sites by 2025	Local initiatives ^(b)	127 sites in 58 countries	SDG 15: Life on land SDG 15: Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss

(a) The fall in the number of young people from deprived urban areas is due to the pandemic, which meant that (unlike in previous years) we were unable to meet them (for example, there were fewer face-to-face careers events). As part of our inclusivity policy, we are reiterating our commitment to have 10% of work/study placements occupied by young people from deprived urban areas by 2023 and will adopt a more proactive policy to reach that target.

(b) Because of COVID-19, we were unable to hold our "Environment Day" event in 2020.

4.5. Methodological note on data reporting

[GRI 102-46, GRI 102-48, GRI 102-49]

4.5.1. General comments

4.5.1.1. Scope of consolidation

Unless otherwise specified:

Social data:

- HR data are consolidated for all Sanofi companies worldwide that are fully consolidated for financial reporting purposes, regardless of their activity (industrial, research, commercial or administrative). Workforce data are derived from Sanofi's payroll system, and other HR data from the Workday Global HR system.
- 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;
 - in the case of an acquisition, the new site must start reporting in the month when it joins the Sanofi scope of consolidation (official date of first-time consolidation for financial reporting purposes), or in the case of a site under construction, from the commencement of works; and
 - if a site is divested, it ceases to be reported from the official date on which the divestment is recognized for consolidated financial reporting purposes.

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.
- The environmental impact of CO₂ emissions from our vehicle fleet covers all Pharmaceutical Operations subsidiaries (field sales forces, but excluding management).
- First-time consolidations:
 - If a site is acquired, it must start reporting in the month when it joins the Sanofi scope of consolidation. To ensure year-on-year comparability, data from the year of first-time consolidation are also added back for prior years.
 - If a new facility is installed, data reporting must start in the month when it comes into service. The data are not added back to prior years because it is a new activity.
- Deconsolidations:
 - If a site is divested without its activities being transferred to another Sanofi site: reporting for the site ends on the official date on which the divestment is consolidated for financial reporting purposes. The historical data are retained but are no longer consolidated.
 - If a site is divested and its activities are transferred to another Sanofi site: reporting for the site ends on the official date on which the divestment is consolidated for financial reporting purposes. The historical data are retained and consolidated by the transferee site.

Environmental data other than Scope 3 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 2020 Annual Report on Form 20-F.

4.5.1.2. Changes in scope of consolidation

See Item 4.D., "Property, Plant and Equipment", of our 2020 Annual Report on Form 20-F.

Synthorx and Principia were acquired in 2020.

4.5.1.3. 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 have used the SHERPA system to collect and consolidate safety data across our entire reporting scope since 2017.
- 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. Environmental indicators are collected during an annual campaign, except for indicators relating to energy/water consumption and waste, which are collected quarterly.

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 2020 is included in the baseline year (2015) and the intervening years (2016 to 2019) on the basis of its 2020 data, so as to report data on a constant scope basis.

4.5.1.4. 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; and
- practical arrangements for the collection and input of data, as described below:
 - Our change in HR platform from Convergence to Workday: in terms of movements, the reasons for staff departures (“layoffs”, “resignations” and “by mutual agreement”) are more comprehensive in Workday than they were in Convergence. In calculating the resignation rate on permanent contracts, the 2018 figures include resignations only, whereas the 2019 figures also include departures by mutual agreement at the employee’s request. It was not possible to recalculate the 2018 figures to align on this new calculation method. Like-for-like comparisons for individual definitions can be made between 2019 and 2020 data.
 - The 2018 figures for layoffs comprised the following categories: “layoffs”, “death”, “incapacity”, and all “departures by mutual agreement” (whether at the request of the employee or the employer). By contrast, the 2019 figures for layoffs comprise “layoffs” and “departures by mutual agreement at the employer’s request”. A new “Other” category has been created to separate out death and incapacity. Like-for-like comparisons for individual definitions can be made between 2019 and 2020 data. This is why, to the extent possible, we specify the definitions and methodologies used for each of the indicators described below, and any margin of uncertainty.

4.5.1.5. 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.

4.5.2. Detailed indicators

4.5.2.1. Social indicators

4.5.2.1.1. 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.

4.5.2.1.2. Regions

The “Europe” region shown in the workforce data tables is defined as follows:

- Europe: Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom.

4.5.2.1.3. 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.

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.

4.5.2.1.4. 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 2020, 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; and
 - Business Development, Management and Leadership.
- le@rn, a system dedicated to training in good pharmaceutical practices at Sanofi, which is deployed worldwide; and
- Peps, a training system for our German employees.

Difference between the number of employees receiving training via iLearn in 2020 (107,183) and our total workforce as of December 31, 2020 (99,412):

This difference arises because:

- employees receiving training via iLearn during 2020 who left Sanofi during the year are included in the training data but not in the year-end workforce data; and
- iLearn data include all employees (permanent, fixed-term, apprentices, interns, etc.) other than external contract staff; by contrast, workforce data include only employees on permanent and fixed-term contracts and apprentices.

4.5.2.1.5. 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 posts (other than Executive Committee members) 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.

Managers: Employees who manage direct subordinates.

4.5.2.2. Safety indicators

4.5.2.2.1. 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 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.

4.5.2.2.2. 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.

4.5.2.2.3. 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.

4.5.2.3. Environmental indicators

4.5.2.3.1. 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, those emission factors are applied to data for the baseline year (2015), current year and previous year;
- 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.

4.5. Methodological note on data reporting**Scope 3 calculation:**

- 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; for sub-categories not included in that database, we have used other standard calculation methods.
- Emissions relating to purchased goods and services (category 1) are based on our actual volumes for the previous year, and full-year projected volumes for the current year. This approach was adopted because it allows for optimal modelling of this category (which is our biggest Scope 3 emitter).
- Category 9 (downstream transport and distribution): excludes the impacts of travel by doctors and nurses.
- Category 11 (use of sold products): excludes travel by patients to pharmacies.

The calculation of our CO₂ 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.

4.5.2.3.2. 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.

4.5.2.3.3. 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 plus solvents recycled on site. Waste includes both hazardous and non-hazardous waste.

A site is considered to be no longer using landfill when its landfill disposal rate is less than 1%.

4.6. Report of the Independent Third Party

[GRI 102-50, GRI 102-56]

Year ended December 31, 2020

Report of the independent third party on the consolidated statement of extra-financial performance

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

To the Annual General Meeting of Sanofi shareholders,

In our capacity as (i) an independent third party accredited by COFRAC under no. 3-1681 (for the scope of our accreditation, go to www.cofrac.fr) and (ii) a member of the network of one of the statutory auditors of your company (the "entity"), we hereby report to you on the consolidated statement of extra-financial performance for the year ended December 31, 2020 (the "Statement"), included in the management report pursuant to Articles L. 225-102-1, R. 225-105 and R. 225-105-1 of the French Commercial Code.

Responsibility of the entity

It is the responsibility of the Board of Directors to establish a Statement in compliance with 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 in respect of those risks; and the outcomes of those policies, including key performance indicators.

The Statement has been prepared in accordance with the entity's procedures (the "Reporting Framework"), the significant 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 reference to 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 applicable laws and regulations, ethical standards and professional standards.

Responsibility of the independent third party

It is our responsibility, based on our procedures, to express a limited assurance conclusion (Part 1, "Report on the compliance and fairness of the Statement") on:

- the compliance of the Statement with article R. 225-105 of the French Commercial Code; and
- the fairness of the information provided pursuant to paragraph 3 of I and II of Article R. 225-105 of the French Commercial Code, i.e. the outcomes of the policies, including key performance indicators, and actions related to the principal risks (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 on whether the information selected by the entity (the "Selected Information") and identified by the symbol * in Appendix 1 has been prepared, in all material respects, in accordance with the Reporting Framework (Part 2, "Limited assurance report on the Selected Information").
- to express, at the entity's request and outside the scope of our accreditation, a reasonable assurance conclusion on whether the information selected by the entity (the "Selected Information") and identified by the symbol α in Appendix 1 has been prepared, in all material respects, in accordance with the Reporting Framework (Part 3, "Reasonable assurance report on the Selected Information").

However, it is not our responsibility to express an opinion on the entity's compliance with other applicable legal and regulatory provisions, in particular as regards the Vigilance Plan and the fight against corruption and tax evasion, or on the compliance of the entity's products or services with applicable regulations.

1. Report on the compliance and fairness of the Statement

Nature and scope of our procedures

Our procedures as described below were performed in accordance with Articles A. 225-1 *et seq* of the French Commercial Code, the applicable professional standards of the *Compagnie nationale des commissaires aux comptes*, and ISAE 3000⁽¹⁾:

- we obtained an understanding of the operations of all the entities included in the scope of consolidation, and of the summary of principal risks;

¹ ISAE 3000 – Assurance engagements other than audits or reviews of historical financial information.

4.6. Report of the Independent Third Party

- we assessed the appropriateness of the Reporting Framework in terms of its relevance, completeness, reliability, impartiality and clarity, with due consideration of industry best practices where applicable;
- 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 the information regarding human rights and the fight against corruption and tax evasion as specified in the second paragraph of Article L. 22-10-36 of the French Commercial Code;
- we verified that the Statement presents the information specified in Article R. 225-105 II of the French Commercial Code where such information is relevant to the principal risks, and includes an explanation of the non-disclosure of any information required by the second paragraph of Article L. 225-102-1 III of the French Commercial Code;
- we verified that the Statement presents the business model and a description of the principal risks associated with the operations of all the entities included in the scope of consolidation, including where relevant and proportionate risks associated with their business relationships, their products or services, and their policies, actions and outcomes, including key performance indicators relating to the principal risks;
- we consulted documentary sources and conducted interviews to:
 - assess the process for selecting and validating the principal risks, and the consistency of outcomes (including key performance indicators) with the principal risks and policies presented; and
 - corroborate the qualitative information (actions and outcomes) that we regarded as the most important, as presented in Appendix 1. For some risks (Product Quality, Product Safety for Patients and Consumers, Patient Safety in Clinical Trials, Ethics and Business Integrity, and Supply Chain Continuity), we performed our procedures at consolidating entity level. For the other risks, we performed our procedures at consolidating entity level and in a selection of other entities: Sanofi US, Sanofi Germany, Frankfurt Chemistry, Frankfurt Injectables H600, Singapore Chemistry, Tongji Pharma, Aramon Chemistry, Vitry Specialty Care Operations, Marcy Immuno-Oncology, Elbeuf Chemistry, Sisteron Chemistry;
- we verified that the Statement covers the consolidated scope, i.e. all the entities included in the scope of consolidation in accordance with article L. 233-16 of the French Commercial Code, subject to the limitations set out in the Statement;
- we obtained an understanding of the internal control and risk management procedures applied by the entity, and assessed the data collection process intended to ensure the completeness and fairness of the Information;
- for the key performance indicators and other quantitative outcomes that we regarded as the most important (as presented in Appendix 1), we carried out
 - analytical procedures to verify that the data collected had been correctly consolidated, and to check the consistency of data trends;
 - substantive tests using sampling techniques, in order to verify that the definitions and procedures had been properly applied and to reconcile the data with the supporting documents. Those procedures were conducted at a selection of contributing entities as listed above, and cover between 15% and 31% of the consolidated data selected for such tests (22.1% of the workforce, 31% of hazardous waste, 15% of VOC emissions, and 29% of COD emissions);
- we assessed the overall consistency of the Statement based on our knowledge of all the entities included in the scope of consolidation.

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

Resources

Our procedures involved eleven professional staff and took place between September 2020 and February 2021, over a total engagement period of twelve weeks.

We conducted about thirty interviews with the persons responsible for preparing the Statement, including representatives from Corporate Social Responsibility, Human Resources, Product Quality and Safety, Bioethics, Ethics and Business Integrity, HSE and Procurement.

Conclusion

Based on our procedures, we have not identified any material misstatement that causes us not to believe that the consolidated statement of extra-financial performance complies with the applicable regulatory provisions and that the Information, taken together, is fairly presented, in accordance with the Reporting Framework.

2. Limited assurance report on the Selected Information

Nature and scope of our procedures

For the Selected Information identified by the symbol * in appendix 1, we performed procedures of the same nature as described in part 1 of this report. We performed those procedures in accordance with ISAE 3000² and with professional standards applicable in France.

The sample selected represents between 17% (water consumption) and 22% (energy consumption) of the quantitative environmental information presented.

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

Conclusion

Based on our procedures, we have not identified any material misstatement that causes us to believe that the Selected Information has not been fairly prepared, in all material respects, in compliance with the Reporting Framework.

3. Reasonable assurance report on the Selected Information

Nature and scope of our procedures

For the Selected Information identified by the symbol ▣ in appendix 1, we performed procedures of the same nature as described in section 1 of this report for those key performance indicators and other quantitative outcomes that we regarded as the most important, but in greater depth, especially as regards the scope of the tests. We performed those procedures in accordance with ISAE 3000² and with professional standards applicable in France.

The sample selected represents 50% (for direct and indirect greenhouse gas emissions) of the quantitative environmental information presented for France.

We believe that our procedures were sufficient for us to express reasonable assurance about the Selected Information.

Conclusion

In our opinion, the Selected Information has been fairly prepared in compliance with the Reporting Framework in all material respects.

Paris-La Défense, March 4, 2021

The Independent Third Party
EY & Associés

Jean-François Bélorgey
Partner

Caroline Delérable
Partner, Sustainable Development

² ISAE 3000 - Assurance engagements other than audits or reviews of historical financial information.

CHAPTER 4.

CORPORATE SOCIAL RESPONSIBILITY

4.6. Report of the Independent Third Party

Appendix 1: Information regarded as the most important

Social information	
Quantitative information (including key performance indicators)	Qualitative information (actions and outcomes)
Lost time injury frequency rate – Sanofi personnel* Lost time injury frequency rate – any employee* Total occupational injury frequency rate – Sanofi personnel* Total occupational injury frequency rate – any employee* Number of occupational diseases reported* Number of employees under contract at December 31, 2020, split by region, activity, gender, age, and type of contract Number of new hires and departures (all reasons) Turnover – permanent contracts Resignation rate – permanent contracts Internal transfer rate for all employees, executive and Grade 5 posts Number of people trained via the iLearn system Number of training hours delivered via the iLearn system Number of training modules via the iLearn system Percentage of women in Senior Leader roles* Percentage of women in executive roles*	Health and safety in the workplace* Measures taken to attract and retain talent (Employee Value Proposition, Strategic Workforce Planning, diversity policy)
Environmental information	
Quantitative information (including key performance indicators)	Qualitative information (actions and outcomes)
Total quantity of hazardous waste Quantity of hazardous waste reused/recycled/recovered Quantity of hazardous waste recycled Quantity of hazardous waste incinerated with thermal recovery Quantity of hazardous waste incinerated without thermal recovery Quantity of hazardous waste sent to authorized landfills Total quantity of non-hazardous waste* Quantity of non-hazardous waste reused/recycled/recovered* Quantity of non-hazardous waste recycled* Quantity of non-hazardous waste incinerated with thermal recovery* Quantity of non-hazardous waste incinerated without thermal recovery* Quantity of non-hazardous waste sent to authorized landfills* Landfill disposal rate of hazardous and non-hazardous waste Total reuse/recycle/recover rate of hazardous and non-hazardous waste Number of sites not sending hazardous and non-hazardous waste to landfills Wastewater discharge (Chemical Oxygen Demand) Airborne emissions (total consumption of solvents, percentage of solvents recycled, emissions of Volatile Organic Compounds) Total water consumption, and split by source of supply (worldwide)* Total water consumption, and split by source of supply (in water stress zones)* Total energy consumption, and split by energy source* Renewable energy consumption* Direct and indirect greenhouse gas emissions (Scopes 1 & 2) – worldwide* Direct and indirect greenhouse gas emissions (Scopes 1 & 2) – France* Greenhouse gas emissions generated as a result of the company's operations, including Scope 3* categories	Measures to prevent, recycle and eliminate hazardous waste Measures to prevent, reduce or remediate releases into the air (management of Volatile Organic Compounds), water (management of environmental releases of pharmaceutical substances) and the soil Water consumption and supply in light of local constraints*, percentage reduction in water consumption versus the 2015 baseline year* Measures to improve energy efficiency and the use of renewables* Percentage reduction in direct and indirect emissions (Scopes 1 & 2) versus the 2015 baseline year* Proportion of production sites subject to pharmaceutical contamination assessments (cumulative, since 2016)

Appendix 1: Information regarded as the most important

Social information	
Quantitative information (including key performance indicators)	Qualitative information (actions and outcomes)
Number of whistle-blowing reports received by Ethics & Business Integrity, and number of related dismissals or resignations for misconduct	Measures taken in ethics and business integrity
Number of whistle-blowing reports to Ethics & Business Integrity substantiated	Measures taken in product pricing
Number of GQA internal audits	
Number of regulatory inspections, and split by authority	Measures taken in product quality
Number of recalls, including Class 1 recalls	
Number of internal audits and inspections relating to pharmacovigilance	Measures taken in product safety (pharmacovigilance)
Percentage of individual pharmacovigilance cases submitted to European health authorities within the regulatory deadline	
Number of signals	Measures taken in medical ethics and bioethics
Number of clinical trials with information-sharing	
Number of inspections conducted on activities relating to clinical trials	Measures taken in animal protection
Number of scientific papers published	
Number of evaluations of compliance with animal protection principles conducted on suppliers and contracted research organizations	Measures taken in supply chain continuity
Number of animals used by Sanofi sites	Actions in support of human rights, especially compliance with ILO fundamental conventions*
Overall service level	
Rate of dependency on India and China for active ingredients	
Percentage of active ingredients produced within the Sanofi in-house network	Consideration of corporate social responsibility in relations with suppliers and subcontractors*
Number of audits of suppliers and subcontractors (Sanofi Contract Manufacturing Organizations, suppliers of Active Pharmaceutical Ingredients)*	
Number of countries that responded to the internal control questionnaire on compliance with human rights policies*	Actions on access to healthcare*
Number of doses of injectable polio vaccine supplied to UNICEF*	
Number of doses of injectable polio vaccine supplied to Brazil, India, Indonesia and the Philippines*	

* Information which the entity has voluntarily elected to produce and disclose in its management report

4.7. 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.

4.7.1. Statement of Extra-Financial Performance (SEFP)

SEFP topic	Cross-reference to the present document (Chapter 4) or to the 2020 Annual Report on Form 20-F	Page(s)
Business model		
Business environment		
a) Customers		
Distributors/wholesalers, pharmacies, hospitals, clinics, public bodies	• 20-F: Item 4, B.6.1., "Marketing and distribution"	31
Marketing practices: direct sales, tenders	• 20-F: Item 18, Note B.13., "Revenue recognition"	F-24
b) Prescribers		
	• 20-F: Item 4, B.6.1., "Marketing and distribution"	31
c) Competition		
	• 20-F: Item 4, B.6.2., "Competition"	32
d) Regulatory framework		
	• 20-F: Item 4, B.6.3., "Regulatory framework"	32
e) Payers		
Government health insurance systems	• 20-F: Item 4, B.6.4., "Pricing and reimbursement"	34
Private insurers (e.g. in the United States)		
f) Number of countries in which Sanofi products are sold		
	• 20-F: Item 4, B.6.1., "Marketing and distribution"	31
g) Net sales		
3-year trend in net sales	• 20-F: Item 18, "Consolidated income statements"	F-4
Net sales by segment and geographical region	• 20-F: Item 5, A.2.1, "Net Sales"	63
Organization and structure		
Sanofi		
a) Number of employees		
Total, and split by segment, geographical region, gender, and type of contract	• Chapter 4: 4.2.1.7., "Additional workforce information"	16
Split by function	• Chapter 4: 4.2.1.2., "Workforce"	5
b) Sanofi sites		
Number of countries in which Sanofi operates	• 20-F: Item 4, B.6.1., "Marketing and distribution"	31
Location and number of production/R&D/tertiary sites	• 20-F: Item 4, B.8., "Production and raw materials" • 20-F: Item 4, D.1., "Overview" • 20-F: Item 4, D.2., "Description of our sites"	39 44 45
c) Operations and product life cycle		
Research and development	• 20-F: Item 4, B.5., "Global Research & Development"	25
Production: biological, chemical, pharmaceutical, vaccines	• 20-F: Item 4, B.8., "Production and raw materials" • 20-F: Item 4, D.1., "Overview" • 20-F: Item 4, D.2., "Description of our sites"	39 44 45
Sales and distribution	• 20-F: Item 4, B.6.1., "Marketing and distribution"	31
End of life cycle management	• Chapter 4: 4.2.10.5., "Environmental releases"	43
d) Therapeutic areas and associated products		
Pharmaceuticals	• 20-F: Item 4, B.2., "Main pharmaceutical products"	15
Consumer Healthcare	• 20-F: Item 4, B.3., "Consumer Healthcare"	22
Vaccines	• 20-F: Item 4, B.4., "Vaccine products"	23
Number of products	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Consumer Healthcare" • 20-F: Item 4, B.4., "Vaccine products"	15 22 23
Product types (vaccines, biologics, pills, injectables)	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Consumer Healthcare" • 20-F: Item 4, B.4., "Vaccine products"	15 22 23
e) Global Business Unit (GBU) structure		
Overview of GBUs	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Consumer Healthcare" • 20-F: Item 4, B.4., "Vaccine products"	15 22 23
Net sales by GBU	• 20-F: Item 5, A.2.1, 1/ "Net sales by operating segment and Global Business Unit"	63
Suppliers/Subcontractors		
Total amount of purchases Number and type of suppliers Geographical location	• Chapter 4: 4.3.14., "Procurement and Subcontracting"	58
Partnerships/alliances		
Regeneron and Bristol-Myers Squibb agreements Alliance with Alnylam	• 20-F: Item 18, Note C, "Principal alliances"	F-29

CHAPTER 4.

CORPORATE SOCIAL RESPONSIBILITY

4.7. Corporate social responsibility cross-reference table

SEFP topic	Cross-reference to the present document (Chapter 4) or to the 2020 Annual Report on Form 20-F	Page(s)
Financial performance		
Management report	<ul style="list-style-type: none"> 20-F: Item 5, "Operating and Financial Review and Prospects" 	48
Trends, objectives and strategies		
a) Trends	<ul style="list-style-type: none"> 20-F: Item 4, B.1., "Strategy" 20-F: Item 4, B.6., "Markets" 	13 31
b) Objectives and Strategy	<ul style="list-style-type: none"> 20-F: Item 4, B.1., "Strategy" 	13
Principal extra-financial risks		
<ul style="list-style-type: none"> Information about how the reporting entity takes account of the social and environmental consequences of its operations, and the effects of those operations on human rights and the fight against corruption and tax evasion 	<ul style="list-style-type: none"> Chapter 4, "Corporate Social Responsibility" 	1
Other topics cited in Article L. 225-102-1 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	<ul style="list-style-type: none"> Chapter 4: 4.2.10., "Environment" 	36
Societal commitments in support of sustainable development	<ul style="list-style-type: none"> Chapter 4: 4.2.2., "Access to healthcare" 	18
Circular economy	<ul style="list-style-type: none"> Chapter 4: 4.2.10.4., "Waste: towards a circular economy" 	43
Reducing food waste	<ul style="list-style-type: none"> Chapter 4: 4.2.10.4.2., "Initiatives to reduce food waste" 	43
Combating food insecurity and promoting responsible, fair and sustainable food	<ul style="list-style-type: none"> N/A 	
Respect for animal welfare	<ul style="list-style-type: none"> Chapter 4: 4.2.11., "Animal protection" 	47
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	<ul style="list-style-type: none"> Chapter 4: 4.2.1.3.1.1., "Promoting social dialogue" 	6
Initiatives to combat discrimination and promote diversity, and measures to support people with disabilities	<ul style="list-style-type: none"> Chapter 4: 4.2.1.6., "Diversity that sets us apart" 	12

4.7.2. Duty of vigilance

Duty of vigilance topic	Cross-reference to the present document (Chapter 4)	Page(s)
Identification and evaluation of risks generated by operations		
	<ul style="list-style-type: none"> 4.3.2., Duty of vigilance risk table 	49
Regular evaluation procedures		
Product safety for patients and consumers	<ul style="list-style-type: none"> 4.2.4.1., "Organization" 4.2.5.1.1., "Organization" 	27 29
Biopiracy	<ul style="list-style-type: none"> 4.3.13., "Biopiracy" 	57
Personal data protection	<ul style="list-style-type: none"> 4.3.10., "Personal data protection" 	56
Employee health and safety	<ul style="list-style-type: none"> 4.3.7., "Employee health and safety" 	52
Environmental releases	<ul style="list-style-type: none"> 4.2.10.5.2., "Policies and action plans" 	44
Water resource management	<ul style="list-style-type: none"> 4.2.10.3.1., "Water resource management plan" 	42
Human rights	<ul style="list-style-type: none"> 4.3.6.1., "Human rights risk mapping" 	50
Procurement and subcontracting	<ul style="list-style-type: none"> 4.3.14., "Procurement and subcontracting" 	58
Appropriate actions to mitigate risk or prevent serious harm		
Product safety for patients and consumers	<ul style="list-style-type: none"> 4.2.4.2., "Policy and action plans" 4.2.5.1.2., "Policy and action plans" 	27 29
Biopiracy	<ul style="list-style-type: none"> 4.3.13., "Biopiracy" 	57
Personal data protection	<ul style="list-style-type: none"> 4.3.10., "Personal data protection" 	56
Employee health and safety	<ul style="list-style-type: none"> 4.3.7.2., "Workplace health and safety programs" 	54
Environmental releases	<ul style="list-style-type: none"> 4.2.10.5.2., "Policies and action plans" 	44
Water resource management	<ul style="list-style-type: none"> 4.2.10.3.1., "Water resource management plan" 	42
Human rights	<ul style="list-style-type: none"> 4.3.6.3., "Policies and action plans" 	50
Procurement and subcontracting	<ul style="list-style-type: none"> 4.3.14., "Procurement and subcontracting" 	58
Whistle-blowing systems and report-handling		
	<ul style="list-style-type: none"> 4.3.5., "Grievance mechanism" 	50
Arrangements for monitoring actions taken and assessing their effectiveness		

4.7. Corporate social responsibility cross-reference table

Product safety for patients and consumers	• 4.2.4.3., "Performance indicators"	28
	• 4.2.5.1.3., "Performance indicators"	30
Biopiracy	• 4.3.13., "Biopiracy"	57
Personal data protection	• 4.3.10., "Personal data protection"	56
Employee health and safety	• 4.3.7.3., "Occupational injury and disease indicators"	56
Environmental releases	• 4.2.10.5.3., "Performance indicators"	44
Minimizing the use of water resources	• 4.2.10.3.2., "Water consumption"	41
Human rights	• 4.3.6.4., "Performance indicators"	51
Procurement and subcontracting	• 4.3.14., "Procurement and subcontracting"	58

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