Corporate Social Responsibility

Chapter 4 of 2021 Document d'enregistrement universel

2021

sanofi

Forward-Looking Statements

This document 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, 2021. 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 2021 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 2021 Document d'enregistrement universel issued in French. It is provided solely for the convenience of English-speaking readers.*

This chapter sets out for 2021 [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 European Directive 2014/95/EU on the publication of non-financial information;
- law no. 2017-399 of March 27, 2017 on the duty of vigilance of parent companies and companies acting as principals; and
- the European Regulation 2020/852 of June 18, 2020 (the so-called "Taxonomy" Regulation) on the establishment of a framework to promote sustainable investments within the EU.

Tables cross-referencing the contents of this chapter to those legal disclosure requirements are provided in section "4.8., Corporate social responsibility cross-reference tables".

Our extra-financial reporting principles are based, among others, on the guidelines of the Global Reporting Initiative (GRI). 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.

This report also follows the guidelines of the SASB (Sustainability Accounting Standards Board) and the TCFD (Task Force on Climate-related Financial Disclosures). The relevant cross-reference tables are available in section "4.8., Corporate social responsibility cross-reference tables" and "4.3.10.2., Resilience to climate change", respectively.

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 "4.6., Methodological note on data reporting".

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 "4.7., Report of the Independent Third Party".

4.1. New CSR strategy and governance

[GRI 102-14]

4.1.1. Sanofi's commitment to society

Sanofi's integrated social impact strategy aims to build a healthier, more resilient world by ensuring access to healthcare for the world's poorest people and bringing focus to addressing broader unmet needs. Integrated within the company's "Play to Win" business strategy, Sanofi's commitment to society will continue the fight against infectious diseases such as sleeping sickness and polio, while accelerating our goal of reducing the environmental impact of our products and of our worldwide operations. Key to tackling the global challenges that face our company are our people, who each have a role to play in building a diverse and inclusive workplace.

Sanofi's social impact strategy focuses on four building blocks aligned with our "Play to Win" core business strategy:

- ensuring affordable access to healthcare;
- innovating for vulnerable communities;
- protecting the planet; and
- building an inclusive workplace.

Sanofi's commitment to society:

Affordable Access	Vulnerable Communities	Healthy Planet	Inclusive Workplace
• Non-profit Business Unit **Sanofi Global Health** to provide 30 essential medicines to 40 of the world's poorest countries • **100,000 vials** to be donated to patients with rare diseases • **Global Access Plan** for all new products two years post-launch	• Eliminate **sleeping sickness** by 2030 • Eradicate **polio** • Develop treatments for **childhood cancers**	• **Eco-design** for all new products by 2025 • **Blister free** vaccine packs by 2027 • **Carbon neutrality all scopes** by 2030 including 100% renewable electricity and carbon neutral fleet	• A **senior leadership community representative** of society by 2025 • **Social & economic engagement in all communities** where we operate (e.g. volunteering) • Social impact integrated in **leaders' career development**

4.1.1.1. Ensuring Affordable Access

A staggering two billion people worldwide still lacked access to quality medicine and healthcare in 2021. Sanofi aims to change this by ensuring affordable access to medicines for underserved communities, while helping to build sustainable healthcare systems.

Key objectives:

- we aim to use our expertise to reinforce affordable access and quality care, to ensure underserved populations receive the treatments they need. We have created Sanofi Global Health (SGH), a non-profit Business Unit that operates in some of the least developed regions of the world, offering at the onset 30 of our essential medicines including treatments for cardiovascular diseases, diabetes, cancer, malaria and tuberculosis;
- we are also committed to helping 1,000 patients living with rare diseases who have no access to treatments, and will donate 100,000 vials of medicine for their treatments each year. This continues our 30-year commitment to patients suffering from rare diseases, such as Fabry, Gaucher or Pompe diseases, for whom access to treatment is often limited; and
- the affordability of our medicines is not the only barrier to access for many people, availability is also key. Our goal is to develop a global access plan for all new products, making them available in selected relevant markets within two years post-launch. This bold ambition will ensure that millions more people receive timely treatment and thousands of lives are saved.

4.1.1.2. Innovating for Vulnerable Communities

As part of our commitment to society, we consider it essential to identify how our science can bring the greatest benefit, especially for vulnerable communities.

Key objectives:

- we will continue our contribution to the efforts led by the World Health Organization (WHO) to eradicate polio and eliminate sleeping sickness, two diseases that afflict marginalized and vulnerable communities, with vaccines and new therapeutics; and
- we have also reflected more broadly about vulnerable communities, and have identified a huge gap in treatment for children who suffer from cancer. Our R&D teams include world-class scientists who have deep knowledge of the specific challenges of pediatric oncology and understand the crucial need to find treatment.

4.1.1.3. Protecting the Planet

We are also mindful of our obligation to do all we can to ensure a healthy planet. Through our "Planet Mobilization" environmental sustainability program, we are working to minimize the direct and indirect impacts of our activities and products on the environment. The program covers the entire life cycle of our products, from raw materials to potential end-of-life impact.

Key objectives:

Regarding environment, Sanofi is committed to:

- achieve carbon neutrality by 2030 for Scopes 1, 2 and 3 (SBTi – Science Based Target initiative – approved targets): (i) Reduce GHG emissions from Sanofi activities (Scopes 1 and 2) by 55% and from Scope 3 by 14% by 2030 (base year 2019); (ii) reach 100% renewable electricity across all global operations by 2030; and (iii) achieve a carbon neutral car fleet by 2030; and
- improve the environmental profile of our products: (i) eco-design approach for all new products by 2025; (ii) assess impacts of our top-selling medicines on ecosystems by 2025; and (iii) develop and operate a global program by 2030 to promote responsible use and proper disposal of unused medicines, medical devices, and packaging. In particular, we will end the use of plastic in blister packs for all our vaccines by 2027. This is a truly complex industrial endeavor that will address the problem of plastic waste in the environment.

4.1.1.4. Building an Inclusive Workplace

With more than 95,000 employees comprised of 142 nationalities, we work constantly to make our workplace inclusive and diverse.

Key objectives:

- gender diversity: To enhance gender equality, we have pledged to reach equal representation of women and men among its senior leaders by 2025 and achieve 40% representation of women in our Executives population by 2025;
- we are fostering inclusion and sustainability in the local ecosystems in which we operate, serving communities through volunteering; and
- we are embedding our commitment to society in our leaders' career development paths to strengthen the social impact of their decisions.

4.1.2. CSR governance

[GRI 102-26]

Our Board of Directors has a commitment to promoting long-term value creation while taking account of the social and environmental impacts of our activities. A review of our CSR strategy and performance is conducted by the Board at least once a year.

The Appointments, Governance and CSR Committee of the Board ensures that CSR issues are given due consideration in developing and implementing our corporate strategy. In particular, the Committee ensures that our commitments and policy orientations are consistent with what our stakeholders expect from us.

Our Head of CSR reports to our Head of Corporate Affairs, who in turn reports to our Chief Executive Officer (CEO).

The compensation policy of our CEO is designed to motivate and reward performance, and to ensure that a significant portion of his compensation is contingent on the attainment of financial, operational and social criteria that are aligned with our corporate interest and with creating shareholder value. Since 2020, a specific individual CSR performance criterion has represented 15% of his annual variable compensation package.

4.2. Statement of Extra-Financial Performance

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

[GRI 102-46]

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 the 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 "4.2.2., Table of SEFP risks and issues".

Policies and action plans for each of those risks are described in section "4.3., Detailed description of SEFP risks and issues".

A cross-reference table showing all the information required in the SEFP, including the presentation of the business model, is provided in section "4.8., Corporate social responsibility cross-reference tables".

4.2.2. Table of SEFP risks and issues

[GRI 102-15, GRI 102-47]

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.		4.3.1. 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 our ability to implement our strategy and attain our objectives.	x	4.3.1. 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.		4.3.2. 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	4.3.2. 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	4.3.3. 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 consumers.	x	4.3.4. 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.		4.3.11. 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	4.3.6. 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.		4.3.7. Local communities
	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 combating and preventing corruption and fraud; and also of non-compliance with pharmaceutical industry codes of conduct or our own values and ethical policies.	x	4.3.8. Ethics and business integrity
Environment	**Climate change and carbon footprint**	Issue	We must limit the impact of our operations on climate change, and take account of the consequences of climate change (impact of extreme weather events on our infrastructure and supply chain; scarcity of resources; carbon taxes; financial impacts; and the direct or indirect repercussions for human health).		4.3.10.2. Resilience to climate change
	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	4.3.10.5. Environmental releases

* *Indicates risks that apply not only to our own operations, but also to those of our suppliers, subcontractors and partners. See section "4.4.14., Procurement and subcontracting", for measures taken to manage risks within our supply chain relating to employee health and safety, environmental releases and human rights.*

4.3. Detailed description of SEFP risks and issues

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

4.3.1. Human capital

Our ambition to 2025 is to reinforce our position as an innovative global biopharmaceutical leader focused on human health with the support of digital solutions. We aspire to generate growth for our three Global Business Units (Specialty Care, Vaccines, and General Medicine) and our standalone Consumer Healthcare entity.

The “Play to Win” strategic roadmap consists of four key objectives:

- focus on growth;
- lead with innovation;
- accelerate efficiency; and
- reinvent how we work.

To achieve this ambition, we must provide a supportive environment to attract and retain a skilled and engaged workforce in a stretched and competitive talent market. That is why Sanofi has defined a People strategy – fully aligned with our business goals – which fuels the passion of our people to bring their whole and best selves, offering an inclusive workplace and innovative ways of working. Our People strategy combines a strategic people-centric design and solid end-to-end human resources delivery services in a fast-changing environment.

4.3.1.1. A solid framework to guide our people actions

4.3.1.1.1. Our people strategy

In our industry, people from both healthcare and non-healthcare backgrounds are a key asset to help us grow and make an impact on the world. Candidates and employees must understand our purpose and believe they will strive and get endless opportunities to learn and progress in various sectors around the globe.

Our Human Resources (HR) function acts as a strategic partner, a business enabler, and a catalyst for change. It owns our People strategy, which sets a clear ambition and frames our yearly roadmap, anchored in four pillars:

- healthy organization: an agile and competitive organization meeting the needs of patients and the market we serve, with a robust talent pool and the right capabilities;
- purposeful experience: our employees own their career journey, we expect them to stretch themselves through compelling work experiences;
- winning culture: our culture allows our people to thrive and enables business success; and
- diversity edge: our business outperforms through our ability to fully leverage the diversity of our people and our partners.

Although owned by the HR function, this People strategy is a responsibility shared with business leaders, which is translated into action by linking 20% of the variable portion of compensation awarded to members of our Executive Committee to achieving a set of key people-related performance indicators: 10% related to gender balance, and 10% related to individual career development plans and our progression on the “Play to Win” culture indicators.

4.3.1.1.2. Our governance and organization

HR at Sanofi is led by a Chief People Officer, who is a member of the Executive Committee and reports directly to our Chief Executive Officer.

Progress on our people agenda is discussed on a regular basis with the Executive Committee and the Board, with a deep dive on focused topics when co-creation, reviews, or decisions are important to our progress.

Our general governance and HR policies are people-centric and business-relevant.

Our HR function operates on global lines, with harmonized processes and shared tools deployed across all of Sanofi.

HR Business Partners, supporting each GBU and function, are aligned with the business organizational structure to ensure total relevance in the way we drive our strategic people agenda and manage senior talent:

- Global Business Units (GBUs): General Medicines, Vaccines, Specialty Care, and the standalone Consumer Healthcare business;
- global functions: Research & Development, Industrial Affairs and corporate functions, with Digital as a standalone given the importance of our digital transformation ambitions; and
- across five regions: North America, Europe (including France), International, Japan & Pacific, and China.

Four Centers of Expertise lead the development of global HR solutions, which are then translated and deployed by the local HR teams: Talent Management, Rewards & Performance, Organizational Development & Learning, and Diversity, Culture & Experience.

Our HR Services organization is centered on a global core model, with both local and centralized teams serving the various geographies. It is responsible worldwide for providing streamlined, harmonized and automated processes that make up the entire employee lifecycle, from hiring and onboarding, through the various roles an employee occupies in the organization, to leaving.

Overall, our HR function is staffed by about 1,100 people, approximately half of them HR Business Partners, plus around 480 people under the HR Services organization.

The Business Partner role is crucial to anticipating and delivering the evolution of our workforce in terms of shape, size, and skills in a fast-changing environment. In 2021, significant business transformations were conducted; HR was instrumental to their success, demonstrating our ability to attract and retain talent while seamlessly restructuring significant parts of our organization. We streamlined our organizational structures and processes thanks to new technologies, more agile project management, better prioritization, and new business models. Examples of these transformations are:

Making Sanofi CHC a leading Consumer Healthcare organization

To deliver on this ambitious goal, we will make Sanofi Consumer Healthcare (CHC) more agile and responsive, so that it can operate effectively in the specific pharmaceutical industry market. We have made significant progress on the creation of our standalone CHC entity, which is now about half-way complete. The new operating model is taking root: around 94% of the organization has been staffed.

Creating EUROAPI, a new independent active pharmaceutical ingredient company, based in France and serving the European market

We expect EUROAPI, a specialist company developing, manufacturing, and selling active pharmaceutical ingredients (API), to become Europe's leading API producer and the world no.2 in what is currently a fragmented market.

EUROAPI became an autonomous entity as of October 1, 2021 and is en route to becoming a complete standalone company.

Focusing General Medicines on Key Markets

We reorganized around key assets/key markets while moving to new business models in Europe and internationally.

Investing at scale in mRNA

We are creating a Center of Excellence (COE) with representation in both Lyon (France) and Cambridge (United States), comprised of about 400 people. This is a significant scientific and technical upskilling effort and also a cultural shift, towards operating as a ‘Biotech like’ entity with lean processes and an agile operating model.

Enabling “Play to Win” with digital transformation

We are handling a massive digital transformation in alignment with the four pillars of our People strategy. Our Digital organization is evolving to drive this transformation, working closely with our GBUs, support functions and HR to progress the priority projects. In 2021, the HR digital environment evolved as we rolled out a number of solutions to help deliver our People strategy. Examples include:

- a single Learning Management System across the world;
- a tool for advanced analytics supporting Strategic Workforce Planning;
- preparing an executive scouting candidate relation management (CRM) system;
- piloting an innovative Talent Marketplace;
- revamped feedback in our career management tool; and
- a new engagement survey platform.

More examples are provided in the corresponding sections.

4.3.1.1.3. A new culture to “Play to Win”

Progress in executing the “Play to Win” priority “Reinvent How We Work” means not only restructuring our organization to make sure we are fit for purpose to “Play to Win”, but also first and foremost changing our culture.

We aim to create a place where employees can bring their best selves to work and are able to contribute to our “Play to Win” strategy. That means changing the way we behave, how we interact with each other, the systems, tools and processes we use, the way we make decisions, and how we spend our time. This plays a key role in attracting and retaining talent.

Given the importance of culture to deliver on our “Play to Win” strategy, significant effort and attention has been dedicated to accelerating the shift. Through the People strategy, Sanofi ensures that culture, mindset, and behaviors are aligned with:

- our employee value proposition, to attract and retain people in a competitive talent market and meet the aspirations of diverse generations and cultures;
- our core values and compliance rules across the company, to achieve execution of the strategy and deliver on the far-reaching goals of our transformation; and
- our “Play to Win” strategy by enforcing the expected behaviors and providing a coherent framework to improve talent attraction, retention, and loyalty, and securing the commitment of current and future generations.

Changing an organizational culture is a marathon. 2020 was about putting in the grassroots groundwork around clear expected behaviors: Stretch, Take Action, Act for Patients and Customers, and Think Sanofi First [(1)]. The rollout started organically, in a bottom-up and country-driven model, through a network of informal in-country influencers, and employee-driven, evidence-based storytelling.

2021 has been about a more all-round embedding of the culture to create high levels of awareness and understanding among all Sanofi employees, using a hybrid approach – sustaining the bottom-up effort, while adding top-down activities:

- awareness: an online employee space providing a holistic resource on “Play to Win” from strategy to culture, an online toolkit in seven key languages with concrete tools, tips, and tricks on how to activate the behaviors, and culture workshops in countries and for global teams;
- education: an eLearning module in seven key languages;
- storytelling: roundtable discussions between Executive Committee members and employees called "Candid Chats" and testimonials on real-life examples of living the behaviors; and
- dedicated support: coaching provided to Executive Committee members and the senior leadership team.

In addition, a broader “Leading by Example” program was launched in 2020 to support leaders and teams who face many different business challenges and obstacles related to teamwork. In 2021, more than 120 fit-for-purpose workshops and interventions were facilitated, including coaching and team building.

As a result, when we conducted our follow-up Culture Barometer in June 2021, followed by our “Your Voice” survey at the end of 2021, we saw a 10% uplift in awareness and a significant 15% uplift in employees seeing their managers demonstrate the “Play to Win” behaviors compared to 2020 results. We will continue to measure progress through specific questions embedded into our regular people engagement surveys and adapt our efforts accordingly.

Going forward, we will be moving from understanding to activation, particularly among our senior leader and manager populations. We are driving this change against a backdrop of the COVID-19 pandemic, which radically modified the way our employees work, as well as deep organizational change. Early 2022, we will have a revamped Employee Value Proposition (EVP), outlining what employees can expect from Sanofi as an employer; this will be set within a new corporate purpose and overall narrative, all aligned with “Play to Win”. This will help us to continue to embed our new culture in a coherent and engaging way.

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

4.3.1.2. Building a clear vision of the workforce to support long term business success

4.3.1.2.1. A glance at our global workforce

[GRI 102-8]

Sanofi had 95,442 employees under contract at the end of 2021, including apprentices, which is 4% fewer than at the end of 2020.

External staff represented a total of 6,565 full-time equivalents in 2021 (7,742 in 2020), comprising 5,593 temporary staff (6,193 in 2020), and 972 third-party sales forces staff (1,549 in 2020).

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

	Worldwide		Europe [(a)]		United States		Rest of the world	
Employees under contract as of December 31	2021	2020	2021	2020	2021	2020	2021	2020
Distribution by region								
Employees under contract	95,442	99,412	47,039	46,761	13,030	12,972	35,373	39,679
%	100.0%	100.0%	49.3%	47.0%	13.7%	13.0%	37.1%	39.9%
Distribution by gender								
% women	47.7%	46.8%	48.8%	48.6%	51.4%	50.5%	44.9%	43.4%
% men	52.3%	53.2%	51.2%	51.4%	48.6%	49.5%	55.1%	56.6%
Distribution by type of contract, work time and gender								
Permanent contracts	88.4%	88.9%	92.7%	93.6%	99.8%	99.8%	78.6%	79.9%
% women	47.2%	46.2%	48.7%	48.5%	51.4%	50.4%	42.9%	41.3%
Fixed-term contracts	11.6%	11.1%	7.3%	6.4%	0.2%	0.2%	21.4%	20.1%
% women	51.4%	51.2%	49.6%	50.4%	52.2%	67.9%	52.2%	51.5%
Part-time employees	3,450	3,719	3,294	3,533	115	136	41	50
Full-time equivalents	2,653	2,891	2,529	2,739	93	113	31	38
% women (full-time equivalents)	85.5%	86.2%	86.5%	87.4%	55.9%	59.6%	90.6%	83.1%

(a) For a list of countries included in the Europe region, refer to section "4.6.2.1.2., Regions".

Distribution of employees under contract by activity

Employees under contract as of December 31	Worldwide		Pharmaceuticals		Vaccines		Consumer Healthcare		Other [(a)]	
	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020
Employees under contract	95,442	99,412	60,964	64,604	15,672	15,676	8,857	9,127	9,949	10,005
%	100.0%	100.0%	63.9%	65.0%	16.4%	15.8%	9.3%	9.2%	10.4%	10.1%

(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	2021	2020	2019	2018
Production	37,431	37,935	37,873	38,790
Research and development	16,223	15,446	15,538	15,140
Sales force	21,113	25,203	26,178	28,914
Marketing and support functions	20,675	20,828	20,820	21,382
Total	**95,442**	**99,412**	**100,409**	**104,226**

Workforce in main countries where Sanofi operates

Employees under contract as of Dec. 31	Worldwide		France		United States		Germany		China		India		Brazil	
	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020
Employees under contract	95,442	99,412	25,245	25,337	13,030	12,972	8,862	8,979	7,201	7,777	4,060	4,805	2 917	3,152
% of total employees under contract	100.0%	100.0%	26.5%	25.5%	13.7%	13.0%	9.3%	9.0%	7.5%	7.8%	4.3%	4.8%	3.1%	3.2%

Distribution of employees under contract by age bracket

	Worldwide	
Workforce as of December 31	**2021**	**2020**
Under 21 years	0.2%	0.3%
21 to 25 years	4.4%	4.5%
26 to 30 years	10%	10.8%
31 to 40 years	29.8%	30.4%
41 to 50 years	29.8%	29.4%
51 to 60 years	22.4%	21.5%
Over 60 years	3.5%	3.2%

The average age of our employees in 2021 was 42.5 years (versus 42.1 years in 2020).

New hires and departures by region[a] **Workforce as of December 31**	**Worldwide**		**Europe[b]**		**United States**		**Rest of the world**	
	2021	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**
Employees under contract	**95,442**	**99,412**	**47,039**	**46,761**	**13,030**	**12,972**	**35,373**	**39,679**
Permanent staff[c]	88.4%	88.9%	92.7%	93.6%	99.8%	99.8%	78.6%	79.9%
Total number of new hires	12,865	11,873	4,636	4 229	2,097	1 997	6,132	5 647
of which permanent contracts	*6,056*	*5,965*	*1,975*	*1,771*	*2,082*	*1,976*	*1,999*	*2,218*
of which permanent contracts %	*47.1%*	*50.2%*	*42.6%*	*41.9%*	*99.3%*	*98.9%*	*32.6%*	*39.3%*
Total number of departures	16,850	12,710	4,382	3,787	2,168	1,589	10,300	7,334
of which permanent contracts	*11,078*	*7,839*	*2,610*	*2,136*	*2,160*	*1,578*	*6,308*	*4,125*
of which permanent contracts %	*65.7%*	*61.7%*	*59.6%*	*56.4%*	*99.6%*	*99.3%*	*61.2%*	*56.2%*
Resignation rate on permanent contracts[d]	6.7%	4.2%	2.2%	1.7%	11.3%	7.7%	11.8%	6.0%
Turnover – permanent contracts[e]	10.2%	7.8%	5.2%	4.5%	16.5%	13.7%	15.0%	10.0%

(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 "4.6.2.1.2., 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

Number of departures **Based on employees under contract as of December 31**	**Worldwide**	
	2021	**2020**
Total number of departures	16,850	12,710
Resignations:	48.1%	47.5%
of which voluntary departures: fixed-term contract employees[a]	*29.9%*	*39.1%*
of which voluntary departures: permanent contract employees	*70.1%*	*60.9%*
Layoffs	34.5%	31.8%
Expiration of fixed-term contracts	12.3%	15.4%
Retirement	4.4%	4.3%
Other (death and incapacity)	0.7%	1%

(a) 78.6% of these were in China, where all new hires are generally on fixed-term renewable contracts.

4.3.1.2.2. Strategic workforce planning

In the context of our “Play to Win” strategy, we are adapting our organizational structure to align on our strategic objectives and to meet the operational challenges that go with transformation and product launches. The aim: to develop a structure and working practices that enable us to continue meeting patients' needs fully across all our markets, while developing the capabilities required for the future and encouraging the emergence of a new generation of leaders.

To execute this strategy, Sanofi identifies and forecasts critical resourcing issues, risks, and trends in the areas of demographics, skills, and profitability. This helps to holistically address the risks and opportunities related to Human Capital Readiness, as identified through the yearly global risk assessment. These dimensions are mapped to Strategic Workforce Planning (SWP), which is articulated around four imperatives:

- right shape: the headcount pipeline and mix are consistent with growth objectives;
- right size/growth: workforce allocation is optimized and balanced between higher productivity and operating expense constraints;
- right skills: we source and develop critical skills and attract the right talents to prepare for the future; and
- right culture: we demonstrate “Play to Win” behaviors, embed new ways of working, and evolve our operating models.

Mitigating the risks requires focus on several areas:

- connect workforce planning and business planning to match our workforce capabilities with the ambition: for example, in the Dupixent® ramp-up, we ensured staffing was fully in line with the product launch strategy in each country;
- build effective governance to ensure better connection and execution between global and local levels;
- attract and retain talent by designing career management and offering customized people development solutions; and
- promote an attractive working environment in a context of transformation to maintain engagement and foster diversity.

Our SWP efforts started in 2016, and since then we have grown the practice to help the business identify workforce needs, assess existing competencies, and develop relevant learning solutions based on critical gaps at every level of our organization.

Since 2020, we have embedded the SWP approach in our Business Strategic Planning exercises through specific analysis, highlighting the most critical areas in terms of competency development needs, with a pattern of delivery adjusted to priority business needs:

- Specialty Care: Dupixent®, Rare Blood Disorders and Oncology;
- major global support functions in ten countries, representing approximately 80% of the workforce in those functions; and
- sales teams, with the General Medicines GBU as a priority.

In 2021, the focus was on Dupixent® and global support functions, using deep competency analysis to assess gaps and source the organization accordingly.

4.3.1.3. How we attract and retain talent to deliver on our strategy

4.3.1.3.1. Efficient hiring and fostering internal mobility

Insights from Strategic Workforce Planning (SWP), supplemented by external benchmarking, bring the necessary understanding of our internal strengths and overall challenges to focus our efforts on what matters most when it comes to attracting and retaining the talents we need to succeed. This leads to a sourcing strategy which combines external talent attraction (for selected hard-to-upskill/reskill jobs and emerging new jobs) with internal transfers and promotions, while fostering diversity.

As an overarching framework for a holistic approach, our Employee Value Proposition (EVP) will set the scene when launched in early 2022. We will continue to measure our overall success and progress by combining external indices – such as S&P, Glassdoor, and Top Employers – with internal talent metrics.

Upstream, our strong Executive Recruitment and Scouting team enables us to access the best talent in the market, and supports our effort to secure solid succession plans, with reliance on headhunters limited to specific cases.

Downstream, our recruitment model fully supports our transformation by delivering high permanent recruitment volumes (17% increase), with spikes in the United States and China. Overall, our internal hiring rate continues to progress (42% of permanent positions), enriching the pipeline of our next generation of leaders and offering diversified career opportunities. This is done in conjunction with a robust and inclusive approach to talent management, as a key success factor for individual and organizational performance.

In 2021, we were able to attract key skills to deliver our strategy, specifically in Dupixent®, Oncology, R&D, mRNA, and Digital. We also appointed several key executives through internal promotion, including Executive Committee members and the level below.

More importantly, the vast majority of the 150+ senior leaders recruited externally since 2020 are assessed as delivering high impact: a proof point of the efficacy of our hiring process.

Beyond traditional ways to fill positions, we are giving managers rapid access to skilled resources by launching our global Talent Marketplace in our career management tool. Successfully piloted in 2021, this will be extended in 2022 so that all our managers can use automated skills matching to staff projects with talents from across the company. We expect this digital initiative to accelerate cross-functional moves, improve career experiences, and give Sanofi a competitive advantage in attracting talent.

As a result:

- 89% of our high potential talents are in the succession pipeline;
- 1,155 of our employees moved to a new position in another function in 2021; and
- in 2021, the turnover rate of our high potential talents in senior and executive positions was 5.2%.

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

	2021 targets	2021	2020
Internal recruitment rate[(a)(b)] *(Senior Leaders population)*			
Executive posts[(c)]	90%	76%	87%
Grade 5 posts[(c)]	80%	81%	75%
Total workforce excluding executive posts (in %)		*42%*	*40%*
Succession planning *Executive posts*		45%	43%
Inter-entity job transfers[(d)] ***(cross-GBU/GSF)*** *Employees eligible for variable compensation (STI)*		4,300	2,932
Promotion rate[(e)] *Employees eligible for variable compensation (STI)*		16.0%	26.0%
Staff turnover			
Permanent contracts[(f)]		10.2%	7.8%
Employees eligible for variable compensation (STI)			
Voluntary[(g)]		8.9%	6.0%
Total[(h)]		13.8%	9.5%
High Potential employees eligible for variable compensation (STI)			
Voluntary[(g)]		8.3%	6.9%
Total[(h)]		10.0%	8.1%

(a) Requisition filled internally in period / Total requisitions filled in the period

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

(c) See section "4.6.2.1.5., Employee grades".

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

(e) Promotion rate = Number of promotions of employees eligible for STI/ Average total number of employees eligible for STI.
For 2021, promotions were calculated on the basis of job changes due to promotion. In 2020, job change metrics were in the process of being standardized, and promotions were calculated on the basis of pay upgrades; this explains the variation compared to 2020.

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

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

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

4.3.1.1.3.2. Investing to develop our employees and be fit for purpose

[GRI 404-1, 404-2, 404-3]

Our new Leadership Framework for all employees defines four skills and four behaviors that are important if we are to excel and execute our strategy, and that will help employees role model the "Play to Win" behaviors that underpin our corporate culture. This framework is now embedded in our talent acquisition and development processes, driven by our People strategy principles: people-centric, inclusive, efficient, and simple, enabling brilliant people management.

This framework is a major symbolic step forward in our "Play to Win" culture transformation because it gives all our employees an open and transparent view of how they can develop their leadership skills. It encourages everyone to be a leader no matter where they are in the organization, inspiring and delivering results with and through others, and leveraging their diverse backgrounds and their blend of experiences.

Talent development is embedded in our strategic business agenda. Our Executive Committee conducts substantial talent discussion and reviews quarterly, focusing on specific areas in line with SWP, as well as digging into selected senior roles to ensure that talents are given the right attention and that Individual Development Plans (IDPs) and succession plans are managed with the right discipline.

We also continue to execute a yearly Talent Management cycle throughout the entire organization. HR is partnering with managers to support them with talent reviews and succession planning. Many local talent events are conducted in the various countries to encourage talent discovery, discussion of succession plans, and the development needed to support identified successors.

Our Talent Management playbook has been updated with the overall approach and focus for 2021 while also providing managers with guidance and resources to support development discussions.

As part of the Talent Management playbook, we have focused our collective efforts on:

- pivotal roles: present across the organization, these roles call for the creation of 'Talent Pools' for succession, supporting greater transversality. A number of pools are being developed over time (starting in 2021 with General Managers), using a common framework for requirements and potential development pathways;

- Next Generation of Female Executives: to reinforce our pipeline, we have begun to identify the next generation of female executives. They will be given specific attention so that a solid comprehensive development plan is drawn up and executed, covering networking, exposure, and training; and
- Rising Stars: we are also paying specific attention to the next generation of leaders further along the pipeline by deploying fast-track programs for accelerated development; this is currently being piloted in China and the International region.

4.3.1.3.2.1. Our career hub: enabling employees to drive their career journey

We are framing our career management approach to best adapt to our company's needs and to evolving employee expectations, empowering everyone to drive their career by offering tools and support to encourage learning, experimentation, and transversal moves. Every employee owns the creation and execution of an impactful Individual Development Plan (IDP) based on the 70-20-10 model[(1)], with support from their manager and HR, as a key approach for development and growth.

Many global and local campaigns are regularly deployed to promote the IDP. Employees and their managers can easily access and identify the learning resources at their disposal. As a result, an IDP has been completed or is in progress for 69% of all employees in scope, and more than 90% for high potential employees.

To facilitate this and take full advantage of emerging digital solutions, we started in 2021 to deploy our Career Hub, a centralized platform which enables employees to identify and access various career development opportunities, using different tools and resources such as:

- Talent Marketplace: a talent mobility platform using smart technology to match employees' skills with opportunities across Sanofi, within or outside their own organization. This will provide all employees access to short term projects (gigs) to develop their skills, as well as personalized recommendations for full time roles based on their skills. In 2021, we started deployment in our China, global R&D, Digital and HR organizations, and are preparing to extend the platform to the entire employee community in early 2022;
- job shadowing: employees can connect and interview co-workers to learn more about different positions or work areas; and
- mentoring: employees can identify an available mentor and start a mentorship to develop a skill, gain exposure, or explore possible career journeys.

4.3.1.3.2.2. Our competency frameworks: enabling focused, relevant development

IDPs are drawn up and then reviewed as needed (at least annually) in accordance with the Talent Management framework. In 2020, significant effort was deployed to equip managers and employees for constructive discussions on development needs and leveraging solutions. To further support this, in 2021 we centralized a set of competencies related to each job, defined in accordance with our internal Job Catalog. We now have more than 70% of Sanofi's workforce mapped to our competency framework, enabling them to voluntarily self-assess against the target proficiency levels. Progress has also been made through competency survey campaigns covering more than 13,000 employees. This will continue to grow into 2022, and facilitate:

- assessment of team competency gaps, to shape learning strategies for various job segments, and hence the deployment of relevant training offers;
- dialogue between employees and managers to deliver focused IDPs; and
- engagement of a broad capability-building community to support the entire organization in identifying company-wide competency gaps and proposed remedial actions.

4.3.1.3.2.3. A broad learning offer through Sanofi university

Sanofi has invested substantially in offering multiple learning opportunities that are critical for our competitive advantage and success in tomorrow's world and are aligned with our "Play to Win" strategy. Launched in March 2020, Sanofi University is a key resource for Sanofi employees to own their skills for today and tomorrow. It empowers everyone to drive their own development, helping to unleash their potential and equip them to "Play to Win".

Sanofi University is made up of eight Learning Institutes, each focused on core capabilities: People Development, Research & Development, Medical & Market Access, Digital, Industrial Development & Manufacturing, Sales Transformation, Corporate Expertise, and Global Marketing Excellence.

The corresponding world-class learning and development resources are easily accessible to all our people across the world through our iLearn shared platform. These include learning opportunities from prestigious academic institutions, carefully curated short duration learning, TED talks, playlists specially compiled by learning experts and thought leaders, and much more. Open 24/7 and mobile, it encourages employees to learn when and where they want, fostering a culture of continuous learning to support employees' career evolution and prepare them for their next roles.

(1) The 70-20-10 model is based on the fact that learning comes 70% from job-related experiences, 20% from interactions with others, and 10% from more formal training.

Training performance indicators[a] (based on the iLearn[b] system)	2021	2020
Number of employees receiving training	105,959	107,183
Number of training modules[c]	118,723	47,118
Number of training hours	2,628,618	2,582,027

(a) These figures do not include training programs followed by subcontractors.
(b) iLearn delivers all compulsory and support function training.
(c) The significant increase in the number of training modules between 2020 and 2021 is due to the integration of all our former training systems into our single iLearn platform.

In 2021, the number of training hours per employee receiving training increased by approximately 3% (24.1h/employee receiving training in 2020 and 24.8h/employee receiving training in 2021). At the same time, the portfolio of available training courses has increased by more than 150%, and has been optimized and streamlined, in particular by making available shorter formats that are better adapted to the needs of employees. 100% employees completed at least one training module.

The following examples demonstrate Sanofi's actions in 2021 and their impact on developing our employees:

- Digital — 52% knowledge uplift on the topic of digital transformation:

  In June 2021, we launched DiscoverDigital 2.0 online learning, an enterprise-wide foundational digital upskilling program, available to all Sanofi employees. The objective is to connect and align the organization across common, high priority digital and data topics (including Agile, Customer and User Experience), supporting Sanofi's employees to achieve the right level of proficiency in digital skills and a mindset for the future. The program has already reached approximately 17,900 employees who have actively learned compared with the initial goal of 20,000 in 2021. Some countries are exceptionally engaged, such as India and Mexico where over 45% of employees have completed learning. As a result, learners have achieved a 52% knowledge uplift on the topic of digital transformation, with over 90% of the 773 learners surveyed stating they are more aligned on the meaning of digital transformation and are better prepared to embrace the practical changes that digital transformation will bring.

- Research & Development — 700 R&D people engaged in Data Science upskilling:

  Digital transformation in R&D requires new skillsets, especially in data processing and analysis. The R&D Data Science upskilling program, launched in 2021, is a large scale, multi-year initiative, targeting data scientists and the people they interact with. The goal is to build a strong digital culture across R&D and to develop 11 data science core competencies at four proficiency levels through professional learning paths. 700 employees (7%) have already committed to one or more learning paths within the past few months.

- People Development — investing in people, management, and leadership skills:

  As part of our effort to democratize learning and to support our colleagues around the world, new online learning solutions are available, with over 2,400 digital resources from prestigious authors and thought leaders. More than 30,000 (30%) employees have completed one or more courses on people development (online and/or in virtual classes), spending nearly six hours (average) on acquiring or reinforcing their knowledge and skills.

4.3.1.4. An engaging work environment

[GRI 102-41]

4.3.1.4.1. Compensation and employee benefits

4.3.1.4.1.1. A thoroughly thought-out compensation policy

Our compensation policy is designed to reward employee performance by 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. Directors, Senior Management and Employees — B., Compensation" of our 2021 Annual Report on Form 20-F.

The key components of our compensation policy are:

- fixed reward is in the form of base salary established according to the employee's skills, level of contribution to the organization, and market practices;
- 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; and
- equity-based programs:

– Long Term Incentive (LTI) compensation is delivered using performance shares, designed to build loyalty and motivate critical employees and key talents towards achieving Sanofi's long-term goals. Along with the 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 upon Sanofi attaining performance criteria over three financial years; and

– Employee Stock Purchase Plan (ESPP) is a company-run program in which employees can become Sanofi shareholders by acquiring our shares on preferential terms.

(€ million)	2021	2020	2019
Net sales	37,761	36,041	36,126
Personnel costs	9,340	9,079	9,188
Ratio of personnel costs to net sales	24.7%	25.2%	25.4%

4.3.1.4.1.2. High quality employee benefits

Employee benefits are primarily plans providing for retirement benefits, reimbursement of medical expenses, and death and disability 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 (and, in general, their spouses and children) receive a fair level of reimbursement of medical expenses as well as death benefits.

In the 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.

Following best market practice, 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).

Regarding "insured" plans, Sanofi seeks to optimize funding and reduce administrative costs by using a captive insurance company. This program not only offers economies of scale for Sanofi subsidiaries, but is also designed to ensure financial oversight and optimal governance. Sanofi has had a dedicated Steering Committee since 2010. The remit of the Committee, which is chaired by our Chief Financial Officer and our Chief People Officer, is to:

- review and approve Sanofi's overall employee benefits strategy; and
- review and approve the implementation or amendment of any defined-benefit pension plan.

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, US, UK, and Ireland, for example.

In some countries, medical benefits also include programs focusing on prevention, vaccination, screening (e.g. diabetes and skin cancer), nutritional advice, wellbeing, etc.

4.3.1.4.2. Fostering dialogue to pursue progress

4.3.1.4.2.1. 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, develop or update specific agreements, and to organize their implementation. 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 the 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, helping to create a stimulating work environment and encourage participation in decisions aimed at improving the way we work.

These efforts reflect one of the principles of our Social Charter: that improvements in working conditions and the need to adapt to our environment go hand-in-hand.

Since 2015, Sanofi has applied a worldwide policy on freedom of association that applies to all employees; see the Vigilance Plan, section "4.4.6., Fundamental human rights at work".

Approximately 51% of Sanofi employees are covered by a collective agreement. In countries where no collective agreement exists, there are other approaches through a specific employee relations Center of Expertise, focus groups, Speak-Up events, or similar opportunities which are in place to ensure ongoing involvement of employees at all levels.

Focus on France

As part of the organizational change to serve the new "Play to Win" strategy, collective redundancy agreements were signed in November 2020 within the Sanofi-Aventis Groupe, Sanofi-Aventis France, Sanofi Chimie and Sanofi Winthrop Industrie entities. Voluntary departures are under way, supporting employees who wish to pursue a personal project or take early retirement.

R&D in France is moving forward with its transformation by strengthening its global expertise in Centers of Excellence (COEs), mainly focusing on research in oncology, immuno-oncology, immuno-inflammation, and vaccinology.

This refocusing of our R&D activities requires the transfer of our neuroscience research activities to the global COE based in the United States, and the transfer of operations from our Strasbourg site to the global Oncology and Immuno-Oncology COE based in Vitry-sur-Seine near Paris. Sanofi has initiated a process of reindustrialization of the Strasbourg R&D site and has launched a search for a potential acquirer for the site in the same sphere of operations, so as to provide redeployment opportunities for Strasbourg employees who do not wish to relocate to the Vitry-sur-Seine site. In early January 2022 NovAliX, a Contract Research Organization (CRO) specializing in drug research and development, acquired the Sanofi site in Strasbourg.

To support this development, an agreement related to employee support measures was signed in May 2021 with representative unions. It was announced that a budget of €1 million would be devoted to retraining the affected employees, with "tailor-made" internal training courses. In addition, 130 external hires are planned by end 2023 to strengthen expertise in the COEs and rebalance the age pyramid.

The Consumer Healthcare (CHC) GBU has been transformed into a standalone entity and has been operational since July 1, 2021.

Implementation of the EUROAPI project started in October 2021, when all the employees involved were transferred to the dedicated standalone legal entity within which they continued in their existing roles (head office teams, sales teams based in Paris, and the industrial sites at Vertolaye and Elbeuf).

Sanofi in France continues to support the internal or external repositioning of employees who are in at-risk positions. In 2021, around 100 people signed up for this initiative, which is supplemented by negotiations on job and career management.

Focus on Germany

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

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

During 2021, negotiations were conducted with these bodies on a range of issues:

- reorganization projects affecting Corporate Functions, R&D, and Industrial Affairs: negotiations were started in 2020 with local and central Works Councils around the loss of up to 800 positions and the related impacts; those negotiations were successfully completed, and balances of interest were agreed upon between the social partners;
- ongoing enhancements to our new systems (Workday, iLearn), with the Central Works Council agreeing to the rollout of new functionalities;
- consultation with the Central Works Council on the creation of job and development profiles for Marketing, Public Affairs, and Medical Functions at all of our Global Business Units;
- implementation of all components of the Tariff Agreement for the chemical industry, which was agreed upon in 2020; and
- negotiations (from the second quarter of 2021) on a new mobile office policy based on Sanofi's new Global Flexible Work guidelines.

4.3.1.4.2.2. Continuous feedback

Feedback is another important lever in enabling our employees to try out and start living the "Play to Win" behaviors. Employees need to feel supported and safe to take action with calculated risks and share their mistakes to extract learning. To cite a few examples.

- Individual and team feedback:

  Having more feedback (informal and formal), and check-ins between managers and teams (as well as between employees and their direct reports, peers, colleagues, and stakeholders), helps everyone to grow and develop. In 2021, we made a start with embedding continuous feedback. More feedback tools, including tools linked to the streamlined formal performance management process, will follow in early 2022, as well as peer-to-peer ways to recognize living the "Play to Win" behaviors.

- All-employee feedback:

  Sanofi conducts regular employee engagement surveys to ensure we listen comprehensively to what our people think.

  In June and November 2020 and in June 2021, our "Culture Barometer" survey focused on observations about living the "Play to Win" behaviors in our organization. The results indicated that awareness, understanding and modelling of the behaviors is high among employees and continues to grow. It also shows that complexity remains high, and we need to accelerate our efforts to simplify our business processes.

  At the end of 2021, Sanofi launched "Your Voice", a survey approach using an intuitive platform to listen to our employees, identify any gaps in how we are progressing in our "Play to Win" transformation, and engage managers in driving actions that result in positive change for a purposeful employee experience, a winning culture, and delivering our "Play to Win" strategy.

"Your Voice" uses a confidential external platform. It operates in real time, meaning that aggregated and anonymized results were available to managers directly after the survey closed. Managers were then empowered to share themes and take action with their teams by agreeing on a 12-month plan that will directly improve their employee experience. The questions from previous "Culture Barometers" were included in the "Your Voice" survey, giving another measuring point on our progress.

With a response rate of 81%, initial analysis shows that our employees are most positive about aligning goals, knowing what they are expected to deliver and how to support team objectives. They also value relationships with their peers, and can count on co-workers for support. And finally, they feel encouraged and supported in their development by their managers. Areas for further improvement include making the "Play to Win" strategy even more tangible at every level; tackling complexity to make things easier, quicker, and simpler; and improving people's wellbeing.

Looking forward, this platform will enable managers to have regular check-ins with their teams and ask for feedback.

4.3.1.5. Creating our Diversity Edge

[GRI 405-1, GRI 405-2]

4.3.1.5.1. Our new "All In" strategy

Diversity & Inclusion (D&I) is part of our larger "Play to Win" strategy and our Corporate Social Responsibility strategy, helping us reinvent how we work and enabling our cultural transformation. In this new strategic context, we co-created and launched a new global D&I strategy in June 2021 called "All In", focused on delivering strong outcomes across three key pillars by 2025:

Building representative leadership (focused on our workforce)	Creating a work environment where we can bring our best selves (focused on our workplace)	Engaging with our diverse communities (focused on our marketplace)
• Gender balance: 50:50 for senior leaders and 60:40 men:women for executives • Year on Year (YoY) % increase of local workforce diversity representation for hiring and career progression • Recognized as a Top 10 Employer for different strands of diversity	• 100% of employees will have access to flexible working arrangements, subject to job activity • 80%+ score in our Diversity & Inclusion Index • 100% of people with disabilities have workplace accessibility	• Year on Year (YoY) % increase of clinical trials achieving diversity targets • 100% senior leaders are active in CSR programs • 450 suppliers signed up to our Solidarity Sourcing program (about €6 billions spending)

We know that the best way to deliver impact is by doing it together as an organization with our people, our suppliers, our stakeholders, and society. Together we will deepen our understanding by having constant conversations and putting in place more deliberate actions to drive greater equity across five key strands of diversity: Gender, Race/Ethnicity/Faith, Disability, Age and LGBTQIA+[(1)]. We will also ensure that anti-racism is a systemic part of our organization and is reflected in everything we do, making sure we maintain local relevance.

In 2021, the main focus was on establishing the strategy and governance arrangements, which include:

- a dedicated global team of four employees and a regional/function D&I Leadership Team of 25 members;
- setting up a new Global Employee Resources Group (ERG) tasked with defining structure, vision, roles, and goals and representing each of our five diversity strands, with Executive Committee sponsors for each of these strands. The ERG will provide leadership at the most senior level, and support voluntary Global ERGs with allyship and advocacy. During the discovery phase in 2021, we identified approximately 50 local ERGs / Affinity groups to feed into future new global ERGs to go live in 2022; and
- a Diversity, Equity, & Inclusion Board, including Executive Committee members and external Key Opinion Leaders.

Examples of actions already delivered include:

- concrete D&I action plans in our Top 10 markets (France, United States, United Kingdom, Brazil, Italy, Germany, Spain, China, Japan, Russia);
- a dedicated knowledge-sharing SharePoint accessible to all employees for communicating strategy, tools, dashboards, ERG connections, learning modules, events. etc.; and
- a comprehensive "All In" D&I learning experience, with many initiatives geared toward employees and managers, starting with an overview of the D&I eLearning module for all Sanofi employees. Examples include:
  - "Challenge Your Bias": completed by 3,120 employees in 2021, this highly interactive, instructor-led workshop helps employees develop further awareness of their own unconscious bias and learn strategies for mitigating behaviors that are not aligned with our inclusive work culture;
  - a curated collection of eLearning, videos, articles, guides, and assessment tools from a variety of internal and external sources to provide a foundational understating of D&I, addressing self-awareness of D&I fundamentals and how to behave more inclusively; and
  - an instructor-led, thought-provoking workshop on Inclusive Leadership targeted at all Sanofi people managers, where participants will share experiences, insights, and best practices with management peers.

(1) *Lesbian, gay, bisexual, transgender, queer, intersex, asexual and others.*

4.3.1.5.2. Building representative leadership

Sanofi demonstrates an intentional focus on diversity and inclusion in:

- talent acquisition, through inclusive recruitment processes and diversification of talent sourcing;
- talent development, ensuring equal learning and development opportunities for all; and
- talent retention, with specific attention to diversity in our succession plans.

Our hiring managers are being trained in effective and inclusive recruitment, and we are equipping our eight search firms with our D&I strategy and expectations.

Wherever possible, relevant country targets and ambitions have been put in place, with a few examples below:

- US: 37% people of color representation by 2025;
- UK: 25% representation of people from a minority and/or ethnic background at final interview stage for senior positions; and
- France and other countries: targets set to increase representation of people with a disability (organizational relationship with Valuable 500 initiated).

In France, Sanofi has for many years been working with young people to support their training and improve their employability (through internships, apprenticeships, or "VIE" – the French international internship program). This investment is accelerating from year to year, reflecting our responsibility as a large French company to help young people integrate with the world of work.

The national "1 jeune, 1 solution" plan is fully implemented by Sanofi through recruitment and support programs.

In France, Sanofi continues to demonstrate its commitment around three key areas:

- recruitment/placement: toward greater diversity:

  In 2021, more than 1,600 apprentices joined our staff, with an increased focus on inclusive hiring. Of those apprentices, 8.5% come from deprived neighborhoods and were recruited through the "*Place d'Avenir"* program, which supports efforts to combat self-censorship in employment and improve job opportunities.

  We are also organizing a Career Forum in conjunction with our healthcare ecosystem, bringing together 40 partners to offer employment opportunities to all young people at Sanofi.

- training: beyond the professional training that we offer, we innovated in 2021 with the "*Passeport Formation*", to better prepare young employees by developing their soft skills and know-how. 200 young people have started a certified training program around three topics: personal development/efficient working, project management, and engaging and motivating employees; and
- commitment: we work closely with the schools and universities ecosystem to develop specific partnerships in line with our business needs. And in close collaboration with our French CSR team, we offer comprehensive support – including mentoring and working with non-profits – to allow everyone to discover the world of work and the healthcare ecosystem.

To mention a few global initiatives within diversity strands:

For LGBTQIA+ talents, we have partnered with MyGwork to attract more diverse profiles beyond gender balance (building a safe and rewarding space for employees with diverse sexual orientations and gender identities), as well as supporting and connecting with the community (through networking and career events).

For Generations: we have partnered with OneYoungWorld to identify and develop Young Talents of Sanofi to advocate change and lead on the Sustainable Development Goals. Five talents have been nominated to participate in the next Summit in Tokyo.

Population of millennials	2021	2020
New hires of people aged 30 or under as a % of total new hires	51%	53%

Number of interns and apprentices hired (excludes apprentices in Germany):	2021	2020
Apprentices	1,451	1,302
Interns	3,037	2,845

4.3.1.5.2.1. Focus on gender balance

In terms of governance, our Gender Balance Board consists of eight senior executives (four women and four men) and five Executive Committee members. They support nine regional Gender Balance networks around the globe, and sponsor initiatives to promote gender balance within Sanofi. 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. We have committed to achieving gender balance of 50% in senior leadership and 40% of women in our executive teams by 2025. Those KPIs are included in the performance objectives for the annual variable compensation of all our executive teams.

To achieve this commitment, we are combining several actions covering Talent Management, Talent Acquisition, and Talent Development. In 2021 specifically:

- "ELEVATE" is our nine-month global female talent accelerator program to prepare a future generation of female senior leaders and executives. The program was created in 2018, and 135 women have now completed it, of whom over 73% have been promoted. In 2021 the ELEVATE Booster PLUS program selected ELEVATE alumni to be sponsored by executives who partner closely with Talent Management and leverage their Sanofi contacts in the business to advocate, sponsor, and mentor participants;
- identification of the "Next 100" female executives is complete and their development journeys have been designed – including 360°, networking, creating visibility, and follow-up on progress; and
- we have global partnerships in place with Catalyst, the Healthcare Businesswomen's Association (150 members), and the Women's Forum (22 delegates for the Global Meeting).

In addition, we are embedding gender balance in our hiring, mobility, and succession planning processes, and are monitoring progress through several meaningful indicators to ensure we meet our global 2025 ambition. Our 2021 data show that we are on track.

	Performance indicators			
Gender balance[(a)]	**2021**		**2020**	
Our ambition is to achieve gender balance in Sanofi Senior Leaders[(a)] (approximately 2,340 positions) by 2025.	40.1%	women	38.8%	women
Our ambition is to achieve 40% women in our Executive population (approximately 500 positions) by 2025.	34.2%	women	31.3%	women

(a) Both indicators are included in the collective qualitative criteria for variable compensation of the Executive Committee (counts for 10%).

Gender balance by grade

Employees under contract as of December 31	Worldwide		Non-manager		Manager [(a)]		Senior leader [(a)]		Executive posts [(a)]		Executive Committee	
	2021	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**	**2021**	**2020**
Employees	95,442	99,412	77,210	80,419	18,232	18,993	2,346	2,219	530	514	13	12
% women	47.7%	46.8%	48.6%	47.9%	44.1%	42.2%	40.1%	38.8%	34.2%	31.3%	23.1%	25.0%
% men	52.3%	53.2%	51.4%	52.1%	55.9%	57.8%	59.9%	61.2%	65.8%	68.7%	76.9%	75.0%

(a) See section "4.6.2.1.5., Employee grades".

A gender pay gap is driven primarily by higher representation of one gender in traditionally higher and/or lower paid skill sectors/jobs. As of December 2021, Sanofi has an average global pay gap of 4.3% in favor of women, mainly driven by our gender distribution in job families and geographic footprint. The nature of the calculation means the pay gap may fluctuate year on year, influenced by our business model and strategy.

4.3.1.5.2.2. Ensuring pay equity

At Sanofi we believe that all employees irrespective of their gender should be paid equitably for similar work. This does not necessarily mean that everyone doing the same job has identical pay. Any difference in pay should be explained with objective reasons, in line with Sanofi's Reward and Performance policy and practice.

In 2021 we launched a Global Pay Equity Action Plan to track and reinforce practices to ensure and promote pay equity. This action plan includes three core global commitments:

- making dashboards available that allow countries to monitor gender pay gaps by job level on a regular basis and to develop action plans to remediate any unjustified pay gaps;
- raising Pay Equity Awareness by strengthening managers' skills in identifying and addressing factors that may impact pay gaps at critical pay steps (hiring, pay reviews etc.); and
- implementing reviews of base salary for employees returning from parental/family leave.

We aim to avoid any discrimination (e.g. based on gender) in the compensation paid in respect to a given position at equivalent levels of individual performance. Where disparities exist, we seek opportunities to allocate specific budgets to address pay gaps in one or multiple steps. For example, in France, 0.1% of total payroll is allocated to adjustments, such as reducing the pay gap between women and men. Similarly, many other countries also kept a dedicated budget to address pay equity related adjustments during 2021.

Sanofi once again ranks in the top third of companies in the official French gender equality index, achieving scores ranging from 75 to 97 out of 100 in the latest index (published March 2021) and a headcount-weighted average of 89/100 (the average for all companies with more than 1,000 employees was 88/100). The index awards scores out of 100 on five key gender equality criteria: pay gap (basic and variable pay plus bonuses); gap in distribution of individual pay raises; gap in distribution of promotions; percentage of female employees receiving a pay raise on return from maternity leave; and number of women in the ten highest-paid employees.

4.3.1.5.3. Creating a work environment where everyone can bring their best selves

4.3.1.5.3.1. Establishing a global wellbeing program

Sanofi has implemented a global approach to wellbeing for all employees worldwide. As a company with high performance ambitions, we need to support our colleagues to thrive and be successful by energizing them and creating a collaborative working environment where they feel optimistic, hopeful about the future, and passionate about what they do.

Sanofi's Global Wellbeing Program is based upon four pillars, providing tools and resources to help in and outside of work with:

- **Healthy Minds:** supporting emotional and mental wellbeing

  Employees and managers are encouraged to be aware of early warning signs of mental health struggles. There are ongoing campaigns to destigmatize mental health, one example being a campaign in the US called "It's OK To Not Be OK".

- **Healthy Bodies:** supporting good physical health, focusing on prevention and on quality healthcare

  As a global healthcare company, Sanofi believes an employee's physical health is key to their long-term wellbeing.

  Sanofi also has a minimum level of death and disability benefits mandated globally to provide peace of mind when an employee's health or life is threatened.

- **Healthy Working Culture:** building a "Play to Win" culture that is respectful, supportive, and inclusive at all levels

  Sanofi believes in a healthy culture which is supportive and where managers and employees can thrive in their work and feel empowered to innovate and grow. Sanofi's "Play to Win" strategy describes a culture and behaviors that are a pre-requisite for continuing to build this supportive environment. This is embedded in into Sanofi's leadership and performance management framework with managers and employees regularly receiving relevant feedback.

- **Healthy Finances:** helping people feel comfortable, confident, and in control managing their finances

  Financial security is key to the wellbeing of employees. Through our new global hotline, all our employees worldwide can access financial advice to help them plan better for specific events (e.g. home purchase, retirement planning) or deal with difficult situations (e.g. debt).

  In addition to the suite of financial savings and pension vehicles provided by Sanofi to its employees around the world in line with market practices, Sanofi is globally committed to support employees to save money through its Employee Share Purchase Plan, which provides an attractive way for employees to purchase Sanofi shares at a discounted rate.

Concretely, the Global Wellbeing Program includes:

- an externally hosted, global employee assistance program called "Be Well Guidance Resources", which offers confidential, free support for all employees and their direct dependents. Be Well Guidance Resources offers a free, multilingual 24/7 hotline that colleagues can contact to ask for advice and support on a wide range of topics, from psychological support to financial and legal guidance. Be Well Guidance Resources are due to go live from January 2022;
- a broad multilingual Learning & Development offering, which is already in place to help with Healthy Minds and Healthy Working Culture; and
- a way to build support and transparency into our culture so that employees all feel comfortable to speak up if they observe or are faced with behaviors not in line with our "Play to Win" behaviors. We call this "Speak Up!" It relies on clear and confidential processes and channels to seek advice on things employees observe that are not acceptable.

During 2020 and 2021, 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 increased the distribution of online newsletters and advice to reach as many of our people as possible, with extra support for teleworkers, sales force, and shift workers.

4.3.1.5.3.2. A global framework for flexible work

Our “Play to Win” priorities (Growth, Innovation, and Efficiencies) can only be successful with the fourth priority: Reinvent How We Work. Only by changing how we work can we transform the practice of medicine and create a place where everyone can bring their best selves to work. Working flexibly is an important part of this: it builds inclusion, helps all of us to unleash our full creative potential, and fosters our new culture by helping us live the “Play to Win” behaviors.

A well-balanced, flexible workplace helps everyone feel more included because it shows that Sanofi acknowledges and caters to individual needs and working styles.

As part of the new D&I strategy, Sanofi‘s “Global Flexible Work guidelines” have been updated based on a consistent global framework launched in May 2021. The global guidelines are applied locally through country-wide policies defined and implemented by Sanofi’s local country teams in full compliance with local labor law and practices.

By 2025, Sanofi is committed to offering access to flexible working arrangements to 100% of employees, subject to their job profile.

4.3.1.5.3.3. At the forefront of societal change: our global gender-neutral paid parental leave policy

In line with our D&I strategy, we are rolling out a global standard for inclusive and equal parental leave. From January 1, 2022, Sanofi will grant 14 weeks paid parental leave to any Sanofi employee welcoming a new child through childbirth or adoption, no matter which country they are working in and irrespective of gender or sexual orientation, as long as the employee is recognized as the child’s parent as per local legislation or practice.

Since pioneering this policy in Latin America in 2020, we have seen first-hand the concrete and positive impact it can have for employees becoming parents. It will give our employees the freedom to determine the childcare arrangements that work best for them as a family and provide quality time to better bond together: a step forward for driving equality in the workplace and greater choices beyond.

4.3.1.5.3.4. Attention to disability

Locally, Sanofi subsidiaries define specific programs.

For example, Sanofi in France is continuing to demonstrate commitment with the fifth renewal of its Group Agreement on disability for the period 2021-2023, built on five pillars:

- priority monitoring of employees with disabilities to ensure they can remain in their job;
- ongoing integration of employees with disabilities, whatever the nature of the disability;
- strengthening communication and information through awareness initiatives;
- constantly improving the accessibility of workstations and information (for example, making Tadeo – a computer-assisted solution which facilitates communication with deaf or hard of hearing people – available to all employees); and
- maintaining strong, ongoing relationships with organizations such as the protected and adapted work sector.

A network of 32 disability delegates in the workplace provides local focus and attention.

Sanofi is committed to achieving a direct employment rate of 6% for disabled workers by the end of the agreement in 2023.

In France, Sanofi had 1,498 employees with disabilities in 2021.

As another illustration, Spain has implemented the “*Aflora”* plan. Since 2018, “*Talento sin Etiquetas*”/“Talent with no tags” has helped inclusion for disabled people, creating a culture of normalizing and raising awareness around disability. Employees with a disability, or who have a child with a disability, are given a monthly allowance. In 2021, 29 employees benefited from these allowances.

4.3.1.5.4. Engaging with our diverse communities

Finally, our commitment to external communities has several components which all progressed in 2021, and contribute to positioning Sanofi as an employer of choice:

- **A global volunteering framework:**

Sanofi has a history of engagement with communities through volunteering. Thousands of employees have contributed and many continue to do so. Run by Sanofi and our partners, our volunteering activities support our Corporate Social Responsibility (CSR) goals, which are all about social and economic engagement in all communities where we operate.

To facilitate and encourage employees to be actively involved in volunteering activities, at the end of 2021, Sanofi launched a global volunteering program. Set up with clear guidelines and a common platform expanding on our existing French "*Je m'engage*"/"We volunteer" program, it provides all employees with one paid day off per year to support volunteering activities for good causes selected by Sanofi. Countries will progressively deploy the program throughout 2022.

A number of initiatives were taken in various countries during 2021, reflecting a significant level of commitment. Examples include:

- establishing a dedicated D&I leader for clinical trials to ensure we increase the number of clinical trials achieving our diversity target;
- defining Global CSR projects for our senior leaders, with a clear governance approach;
- a global supplier diversity framework to increase the inclusion of historically disadvantaged or under-represented groups in our sourcing processes is under way. In 2021, we became a global member of WEConnect International, a global network that connects female-owned businesses to qualified buyers around the world. WEConnect International is a certifying body (certification available in more than 50 countries) to help ensure that businesses are at least 51% owned, managed, and controlled by one or more women;
- a Solidarity Sourcing program that ensures our large corporate supplier base reflects our behaviors. In 2021, we launched the program with 30 of our top global suppliers. Our goal is to engage 450 suppliers by 2025, representing over €6 billion (40% of our global expenditure); and
- a local footprint assessment, to engage sites and countries in evaluating their social and environmental impacts on their locality and increase interaction with local stakeholders.

As another illustration, in France specifically, we are continuing with our "*Cancer & Travail - Agir ensemble*", program, to better support people and teams facing cancer. This initiative supports and improves the lives of employees directly and indirectly affected by cancer, and their teams, in all Sanofi sites in France. It started with Sanofi France's May 2017 signature of the French National Cancer Institute (INCa) charter, when Sanofi pledged 11 commitments to help support employees affected by cancer and promote health. This is delivered through a network of 30 support and counseling centers where people can talk freely about cancer-related issues. These are staffed by multidisciplinary teams with complementary skills: occupational health, social care and human resources professionals, plus an employee with experience of being a patient, a caregiver and a manager who has provided cancer-related support. These support and counseling centers (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. The network has over 150 volunteers, who have helped over 250 employees; survey respondents indicated a satisfaction rate of 98%, with 100% saying they would recommend it to a colleague. This program also advocates to change perceptions and representations of living and working with cancer.

We have also contributed to and funded a thesis on "Cancer: Vulnerability and Performance" to help identify levers and brakes. Finally, Sanofi is part of an open innovation project to try out in real life situations new tools and approaches that may deliver better support.

4.3.2. Access to healthcare

[GRI 203-1]

4.3.2.1. 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, as well as in specific entities like Sanofi Global Health and the *Sanofi Espoir* Foundation. The ten-year mandate of the latter came to an end on December 31, 2021. Sanofi has decided not to renew this mandate and has created an endowment fund in order to redefine its philanthropic commitments for the years to come.

As part of the 2021 update to our corporate social responsibility roadmap, signed off by our Board of Directors, we have refocused our access to healthcare approach around two key priorities, and a number of key programs:

- we are stepping up research and development so that we can help vulnerable communities by contributing to the control, elimination and eradication of certain infectious diseases through our vaccines portfolio, targeting our efforts on diseases where we can make a tangible contribution such as polio and sleeping sickness. At the same time, we are committed to developing novel medicines to eliminate childhood deaths from cancer; and
- we will secure access to medicines in the poorest nations by helping to set up sustainable healthcare systems via the creation of our dedicated Sanofi Global Health entity, while making sure people with rare diseases can access treatment and developing worldwide access plans for our new products so that they can be available on all the selected markets within two years of first launch.

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 "4.3.2.2., Innovation and patent management"); availability (section "4.3.2.3., Availability"); product pricing (section "4.3.2.4., Product pricing"); and quality care and patient support (section "4.3.2.5., Patient care and support").

Those programs must:

- meet public health needs in the target country, in a field where Sanofi has expertise;
- target 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, people with disabilities, etc);
- be 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);
- build in a long-term future for the program, and allow for an exit strategy; and
- include clear, achievable public health objectives, along with appropriate metrics, targets and indicators for monitoring delivery against those 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).

4.3.2.2. Innovation and patent management

4.3.2.2.1. 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 2021
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 663 in 2020, dropping below 1,000 for the third consecutive year.	To help eradicate sleeping sickness by 2030. Sanofi has made this one of its societal commitments.	Since 2009, we have been working with the Drugs for Neglected Diseases Initiative (DNDi) NGO 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 ten days, and is effective in both the first and second phases of the disease in adults and children aged six years and over and weighing 20 kg and over. Fexinidazole received WHO pre-qualification in 2019, and has been submitted for approval by the Ugandan health authorities. It has been added to the WHO essential medicines list and to WHO guidelines for the treatment of sleeping sickness, as a first-line treatment for first-stage sleeping sickness and non-severe second-stage cases. Sanofi has partnered with the WHO since 2001 to support the program against neglected tropical diseases, especially sleeping sickness. At the end of 2020, our total contribution to this WHO program was $100 million. Since then, we have renewed our collaboration agreement with the WHO for a further five years, to the tune of $25 million ($5 million a year). 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).	The first objective – eliminating sleeping sickness as a public health issue seems to have been reached. In parallel, we have committed to supporting the WHO in its objective of sustainably eliminating sleeping sickness by 2030, as stated in the WHO roadmap for neglected tropical diseases. Following the first successful treatment of a patient with fexinidazole in DRC in January 2020, the drug was approved in Uganda and by the US Federal Drug Administration (FDA) in 2021, becoming the only all-oral treatment for sleeping sickness to be licensed in the United States. In September 2020, Sanofi and DNDi announced that they are jointly developing acoziborole. Results from pivotal Phase II/III clinical trials will be published in 2022. If those results are positive, 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.
Malaria			
In 2020, 241 million cases of malaria and 627,000 deaths were recorded.	Continue research into the technical life cycle for the pediatric indication of primaquine.	We are working to make primaquine more accessible for children. Primaquine, which is widely used to prevent relapses in people with Plasmodium vivax malaria, is also recommended as a transmission blocker in the elimination of Plasmodium falciparum malaria.	In 2021, a generics company filed a prequalification dossier with the WHO for a pediatric dose, reducing the criticality of Sanofi's development program.
Tuberculosis (TB)			
There was a significant fall in the number of recorded cases of tuberculosis in 2020 to 5.8 million, an 18% drop compared with 2019. Excluding people with HIV, 1.3 million people died with TB, along with a further 21,400 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 FDA approved rifapentine for the treatment of latent TB infection (LTBI), in combination with isoniazide. This paved the way for WHO prequalification in 2017. In 2020, the CDC published initial 12-month results from a 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[(a)].	At the end of 2020, Sanofi informed the healthcare authorities of the presence of nitrosamine impurities in certain batches of rifampicin-family antibiotics. The position adopted by the authorities, including the FDA, is that the risk of interrupting tuberculosis treatment outweighs the potential risk from the presence of nitrosamines. The healthcare authorities have temporarily raised the upper limit for nitrosamine, so that all the drug companies involved can release their products. During 2021, we focused our efforts on developing a remediation plan to reduce or eliminate the impurities. In parallel, the ongoing clinical trial in children has been temporarily suspended while the situation is assessed with the authorities.

(a) N Engl J Med 2021; 384:1705-1718. DOI: 10.1056/NEJMoa2033400.

4.3.2.2.2. 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. Since December 2019, we have publicly disclosed the patent status of our essential medicines and vaccines in developing countries. We have also confirmed that we will 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.

4.3.2.3. 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 participate in WHO pre-qualification programs, such as the tuberculosis and sleeping sickness programs.

Disease & global context	Target	Sanofi action	Progress in 2021
Polio			
Polio mainly affects children under the age of five. One infection in 200 causes irreversible paralysis. Polio has been classified by the WHO as an absolute priority since it launched the Global Polio Eradication Initiative (GPEI) in 1988. GPEI estimates that without its eradication efforts, 200,000 to 250,000 cases of polio would have been diagnosed each year, causing paralysis in four million children over the last 20 years. If polio is not eradicated, significant financial and operational resources will be required to continue monitoring and controlling the disease.	Eradicate polio, in line with the objectives of the Global Polio Eradication Initiative. We have made this one of our commitments to society.	Sanofi Pasteur has partnered the Global Polio Eradication Initiative (GPEI) for more than 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. The polio eradication program is a remarkable success story: the number of countries where polio caused by wild poliovirus is endemic has fallen from 125 in 1988 to just two in 2021. The COVID-19 pandemic had negative repercussions for polio eradication programs during 2020. However, vaccination programs have now resumed, and the number of cases caused by wild polovirus in 2021 gives grounds for optimism. Since the start of 2021, there have only been five cases of polio caused by wild poliovirus, compared with 140 in the same period of 2020. 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. 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 inactivated polio vaccine (IPV) doses required by UNICEF. 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. To permanently interrupt transmission of polio virus and lock in the historic gains achieved worldwide once eradication is complete, Sanofi has developed a new hexavalent vaccine containing IPV that has been specifically developed for GAVI countries. A prequalification application for this vaccine has been filed with the WHO.	In 2021, Sanofi supplied 50.5 million inactivated polio vaccine (IPV) doses to UNICEF for countries eligible for GAVI funding. Sanofi Pasteur also supplied 31 million doses to Brazil, India, Indonesia and the Philippines for their national polio vaccination campaigns.

Disease & global context	Target	Sanofi action	Progress in 2021
COVID-19			
COVID-19 is a disease caused by the SARS-CoV-2 coronavirus. Most symptomatic patients recover, but 8%-10% of patients in the US and EU require hospital treatment, and a significant proportion need intensive care and/or mechanical ventilation.	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, GAVI and the Coalition for Epidemic Preparedness Innovations (CEPI) alongside UNICEF - aims to ensure fair and equitable access to COVID-19 vaccines in every country in the world. Given the progress on our development program, and on the vaccinations that fall within the scope of COVAX, we are in ongoing dialogue with GAVI/COVAX.	In response to the current pandemic, Sanofi has partnered with GSK to develop an adjuvanted recombinant 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 COVID-19 vaccine affordable to the public, using mechanisms that offer fair access to people in all countries. Pending the arrival of our own vaccine candidate, we have entered into three agreements to carry out vaccine pre-production for three other manufacturers, each of whom needed extra industrial capacity: Moderna (in the United States), BioNTech (in Germany) and Johnson & Johnson (in France).	In February 2021, we launched a Phase II study as planned. The results have been published[(a)]. Based on the study, we were able to launch a Phase III effectiveness study in May 2021. The study, which includes many countries, aims to demonstrate protection against severe effects of COVID-19. Enrollment was completed in 2021, and the first results are expected in the first quarter of 2022. If the vaccine meets clinical standards of safety, effectiveness and immunogenicity, regulatory steps will be taken so that the vaccine can be approved for use as soon as possible. In parallel with the effectiveness study, a study evaluating the vaccine's capability as a booster began in July 2021. This aimed to generate immunogenicity data that would allow appropriate use of the vaccine in 2022 vaccination programs. The data obtained to end 2021 are positive, showing that neutralizing antibodies increased across all primary vaccines administered (mRNA or adenovirus) in a nine- to forty-three-fold range and for all age groups tested, with a good safety and tolerability profile. The three technology transfers have been completed; manufacturing is ongoing, and by end 2021 had already enabled 90 million doses to be delivered.

(a) https://www.medrxiv.org/content/10.1101/2021.10.08.21264302v1

4.3.2.4. 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 2021
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 540 million cases of malaria, from its launch in 2007 to the end of 2021.	In 2021, more than 8 million ASAQ Winthrop® malaria treatments were sold at preferential prices, despite a marked slowing of demand due to the global prioritization of major programs, itself caused by the COVID-19 crisis.
Tuberculosis (TB)			
	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.	In 2019, Sanofi, Unitaid 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.	During 2021, Sanofi continued, in the spirit of that agreement, to maintain access in low-to-middle income countries. In addition to the impact of COVID-19 on TB programs, delivery capacity was impaired by the discovery of nitrosamine impurities and the introduction of corrective measures (see section "4.3.2.2.1., Innovation").

Disease & global context	Target	Sanofi action	Progress in 2021
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.	Donate 100,000 vials a year to treat people with rare diseases. We have made this one of our commitments to society.	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. The first Charitable Access Program was launched in the United States in 1991, the year in which the treatment was approved. Over the last 30 years, the program has been expanded to support more than 3,300 people with five types of lysosomal storage disorders in over 100 countries.	In 2021, 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 across six continents. It has been extended to new countries, following the first approvals in Mozambique and Senegal.

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.

4.3.2.4.1. 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 2021, we set up Sanofi Global Health, a new entity dedicated to selling affordable medicines in some of the world's poorest regions. The non-profit entity will use its revenue, derived from sales at low prices, to fund capacity-building and training/education programs in countries where the entity operates. In the first instance, Sanofi Global Health is operating in some of the world's poorest 40 countries, offering 30 of our essential medicines to treat cardiovascular diseases, diabetes, tuberculosis, malaria, certain neglected tropical diseases, and cancer. Sanofi Global Health also works with local healthcare authorities and health professionals to help establish and enhance sustainable healthcare systems for people with chronic diseases that require long term care.

4.3.2.4.2. 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 38.1% 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.

4.3.2.4.3. 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.

4.3.2.4.4. 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.

The CMS issued a projected US healthcare cost growth rate for 2021 of 5.1%[(1)].

During 2021, we increased the price of 50 of our 81 prescription medicines. All those price increases were in line with our pricing principles.

4.3.2.4.5. 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)]
2018	+4.6%	-8.0%
2019	+2.9%	-11.1%
2020	+0.2%	-8.0%
2021 [(b)]	NA	NA

(a) For the entire portfolio of Sanofi prescription medicines.
(b) 2021 data will be published in our Prescription Medicine Pricing Principles factsheet by April 2022, and made available in the CSR document center on our website Sanofi.com.

(1) *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected*

4.3.2.5. 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 2021
Oncology			
Worldwide, nearly 400,000 cases of cancer are diagnosed in children under 19. Nearly 80% of them live in countries with limited resources where cure rates are only 20%-30%, compared with 80% in developed countries[(a)].	By 2021, provide care to 100,000 children with cancer and train 30,000 healthcare professionals through the My Child Matters program.	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. The program provides improved access to early diagnosis and care. 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.	All the initiatives supported by the My Child Matters program continued during 2021. A total of 80 projects have been implemented under the auspices of the program, in around 60 countries. To date, this *Sanofi Espoir* Foundation program has treated more than 127,000 children with cancer globally, beating its target for combating childhood cancer. The Foundation also contributes to increasing the number of trained healthcare professionals; to date, nearly 50,000 have benefited, ahead of the initial target. In its roadmap for the 2019-2021 period, the Foundation intensified its support for initiatives in low-to-middle income countries; these now account for two-thirds of the projects supported, helping us to achieve the objectives set by the WHO[(b)].
Diabetes			
In 2021, the International Diabetes Federation estimated that 537 million adults and 1.2 million children were living with diabetes. Rising rates of obesity and reduced physical exercise mean that type 2 diabetes is affecting people at ever-younger ages, making it a global public health issue with serious consequences. In 2021, the new WHO Global Compact to speed up action to tackle diabetes called on nation states to expand education at community level to improve understanding of diabetes, and of how it can be prevented and treated.	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. Encourage local and national decision-makers to take action or adopt public health policies so that education about diabetes can be provided in schools.	The KiDS project was born of a partnership between the International Diabetes Federation (IDF) and the International Society for Pediatric and Adolescent Diabetes (ISPAD). It is a schools-based educational program designed to improve the treatment and integration of children with type 1 diabetes, and to increase awareness of the benefits of a balanced diet and physical activity in preventing the development of type 2 diabetes. The KiDS project operates in each country through partnerships with various agencies (governmental authorities, patient groups, learned societies, NGOs, etc). 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; these include a guide to nutrition and diabetes, and the NutriQuiz online game. This material is culturally adapted and translated, so that the target audience can buy into the key messages. From its inception in 2013 through the end of 2021, the program has reached more than 340,000 children and nearly 19,800 teachers, in over 2,100 schools across ten countries.	During 2021, the program continued to be adversely affected by school closures due to the COVID-19 pandemic. However in Colombia – the eleventh country to launch the program – the first awareness sessions have just begun. To encourage decision-makers to implement systemic actions and policies, the IDF and ISPAD - along with their local partners - have called on ministers of Health and Education in 20 countries to embed education about diabetes in schools, and an awareness toolbox has been developed and explained through open-access webinars. New partnerships have been struck with the Qatari and Algerian health ministries, and with stakeholders in Spain, to roll out the KiDS program in 2022.

Disease & global context	Target	Sanofi action	Progress in 2021
Mental health			
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.	Improve healthcare access for people with mental disorders or epilepsy in low-income or middle-income countries through the Fight Against STigma (FAST) program. 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.	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 to 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.	Cumulatively, by the end of 2021, over 11,500 healthcare staff had received training, awareness and education campaigns had reached nearly 3.9 million people, and more than 134,500 people with mental disorders or epilepsy had been diagnosed and/or treated. For example, the program in Mali that began in 2018[c] has already enabled over 3,900 new patients to be diagnosed and treated by trained general practitioners; it is still ongoing, and has trained more than 50 general practitioners via an eLearning platform. Our initiative with the Senegalese Ministry of Health has already provided training to 130 primary healthcare professionals, using a combination of an eLearning course and interactive webinars hosted by local psychiatrists. And in South Africa, 613 front-line healthcare staff received training in 2021, on top of the 1,120 trained in the first phase during 2019/2020[d].

(a) https://www.who.int/fr/news-room/fact-sheets/detail/cancer-in-children

(b) https://www.who.int/docs/default-source/documents/health-topics/cancer/who-childhood-cancer-overview-booklet.pdf

(c) Poudiougou O et al., 'Mental health capacity building in Mali by training rural general practitioners and raising community awareness', Pan African Medical Journal, 2021; 38(389).

(d) Slaven F et al., "Can a brief training intervention help improve Mental health service delivery in South Africa?", Afr J Prim Health Care Fam Med. 2021 Oct 26;13(1):e1-e6.doi: 10.4102/phcfm.v13i1.2909.

4.3.3. Product quality

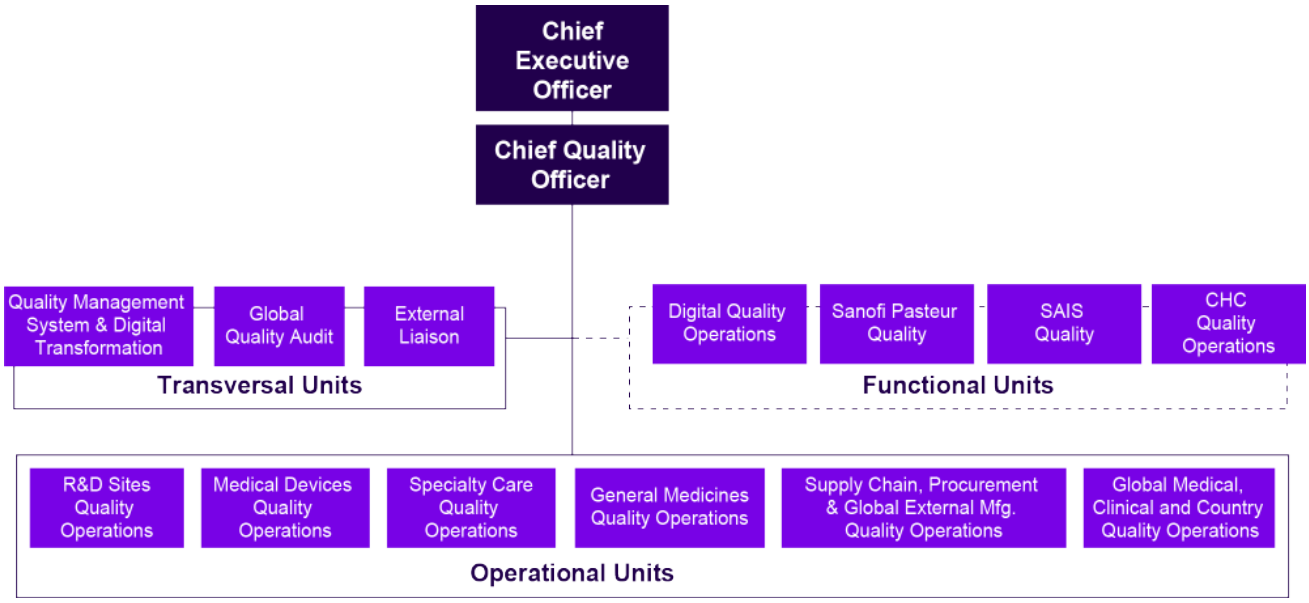
4.3.3.1. Organization

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.

Our CQO represents Sanofi's senior management on all matters related to quality. 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 manufacture, distribution and commercialization), for all the product families in the Sanofi portfolio: active pharmaceutical ingredients, prescription and over-the-counter medicines, vaccines, medical devices (including apps and hybrid products), nutraceuticals 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.

4.3.3.2. 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 system 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), 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, global 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. 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; and
- 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 by practice communities, which share and discuss quality-related issues and processes.

Highlights of 2021 were:

- Global Quality Strategy

  During 2021, we took a series of actions to start implementing the Global Quality Strategy, following its update in 2020:

  – we selected a supplier to deliver the new tool to support our quality systems. The solution will be deployed in the first quarter of 2022. It will be fully integrated from R&D through commercial operations, with enhanced digital solutions based on artificial intelligence;

  – a quality culture development tool was developed, and embedded into our Quality Maturity Index (QMI). Operational deployment of the QMI is ongoing across all our Global Business Units; and

  – employee buy-in to Good Manufacturing Practices was extended beyond the Quality sphere with the rollout of an awareness program across all Industrial Affairs staff. The completion rate as of end October 2021 was 93%, with industrial operations and quality functions covered. This approach is being reinforced by annual Good Practice refresher courses, developed by the global support functions and provided to the whole Quality network.

- Nitrosamine risk assessment

  Since 2019, Sanofi has been working intensively to respond to regulatory concerns about the risk of the presence of nitrosamines (carcinogenic impurities) in medicines[(1)]. We have set up a dedicated in-house task force on the control of nitrosamines, in collaboration with external technical working groups, in particular with the European Federation of Pharmaceutical Industries and Associations (EFPIA).

  – in 2021, we completed the nitrosamine risk assessment for our portfolio of commercialized products (chemical, biological and vaccines) in compliance with global regulatory requirements, and informed the healthcare authorities within the required timeframe;

  – for example, around 4,000 notifications have been sent to the competent European regulatory authorities on chemical entities alone, covering both risk-free and at-risk products;

  – at present, a vast program of analytical tests is ongoing to confirm or refute any theoretical risk identified during the initial assessment; and

  – this approach is enabling us to implement actions to reduce risks, and as the case may be to take all necessary steps in close collaboration with the competent healthcare authorities to protect patient health and safety.

(1) References: EMA advises companies on steps to take to avoid nitrosamines in human medicines / US FDA Guidance on Control of Nitrosamine Impurities in Human Drugs.

4.3.3.3. Performance indicators

	2021	2020	2019
Internal quality audits Note : includes audits of Sanofi entities and third-party audits	210	161	204
Regulatory inspections	190	177	309
of which European inspections	55	55	70
of which US FDA inspections	13	22	44
Number of regulatory actions taken[(a)]			
Note : in 2021, as in 2020, there was a significant reduction in inspections 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.	0	0	1
Recalls	38	39	45
of which Class 1 recalls[(b)]	3	2	4

(a) US FDA Warning Letter, US FDA Consent Decree, suspension/withdrawal of GMP certificate.
(b) Definition as per EMA SOP/INSP/2018 and US 21CFR part 7.

4.3.4. 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 aim to:

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

4.3.4.1. Pharmacovigilance

4.3.4.1.1. 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 safety specialists convey sound communication messages that are perceived as transparent, data robust, audience focused and ethical. 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.

4.3.4.1.2. 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.

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

GPV holds memberships in well-established 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 this evolving landscape and that GPV is able to meet the Sanofi's new objectives as a responsible pharmaceutical company, GPV has been constantly improving the robustness of its governance safety operating model. 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. In 2021, this program grew significantly following the deployment of a competency framework; and
- delivering an ambitious technological development plan to automate and apply artificial intelligence to the processing of our pharmacovigilance data. This was seen as a pre-requisite not only for managing the growing volume of data but also for addressing the diversity of safety information, including social media and patient support programs.

During 2021, the ramp-up of our new technological platform showed evidence of delivering business value and quality, with highly satisfactory key performance indicators in line with initial expectations. From 2022 onwards, our goal is to further expand the scope of use of our technology platform in full transparency with regulators at key milestones. Our platform will leverage AI/automation where it performs best to supporting our safety experts in their assessments by:

- accelerating the rollout of a structured approach to benefit/risk profile evaluations, relying if necessary on population-based epidemiological statistics ; and
- increasing the efficiency of the epi-methodologies used, so we can detect and evaluate potential signals associated with the use of our products faster.

In parallel with these pharmacovigilance-oriented improvements, from an organizational perspective, GPV has continued on the Sanofi Transformation Journey:

- extending its scope of expertise and onboarding new competencies:
  - in the growing field of acquisitions and divestments, and portfolio management (e.g. the CHC carve-in, Principia, Translate Bio, Kiadis, Kadmon, etc.); and
  - creating a center of excellence in translational safety science (this refers to nonclinical and clinical safety assessment used to support drug discovery and development and is an overarching term encompassing the steps that must be taken to move nonclinical safety findings into predicting adverse outcomes in humans);
- creating the conditions to simplify our PV organization in selected geographies and countries by identifying partners capable of ensuring sustainable distribution of our portfolio of medicines and vaccines for patients.

4.3.4.1.3. Performance indicators

Signals assessed	2021	2020	2019
Total signals	375	344	395
of which PRAC/HA signals[(a)(b)]	188	125	204

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

Pharmacovigilance audits and inspections	2021	2020	2019
Number of audits	41	33	39
Number of inspections	4	5	4

These audits and inspections are included in the figures reported in the Product quality section (“4.3.3.3., Performance indicators”).

Our performance indicator of submissions of individual pharmacovigilance cases to the European healthcare authorities by the regulatory deadline reached 98,6% in 2021.

4.3.4.2. Fight against falsified medicine and illicit trafficking

4.3.4.2.1. Organization and governance

Under the auspices of Sanofi Global Security, Sanofi has established a transversal, centralized organization to design a dedicated strategy, coordinate action plans, and respond quickly to incidents or crises reported by our Global Business Units, and our Legal, Industrial Affairs, Quality, Regulatory, Pharmacovigilance, Medical, and Corporate Affairs departments.

Seasoned intelligence and investigation experts identify illicit sales of falsified products in the field and on the internet.

Our dedicated Central Anti-Counterfeiting Laboratory (LCAC) based in Tours (France) analyzes suspicious samples and provides scientific information useful for the public health authorities and for potential prosecutions.

The Sanofi Global Security network supports the implementation of actions to combat falsified medicine and illicit trafficking in liaison with the industry, law enforcement, and health authorities. This provides a capacity to detects medicine trafficking globally and to deploy a consistent level of security measures to prevent risks to products and patients.

4.3.4.2.2. Policy and action plans

The fight against falsified medicine and illicit trafficking strategy includes the following actions:

- monitoring online sales offers (marketplaces, social media, online pharmacies) to request the takedown of illicit offers and investigate sellers;
- analyzing suspicious Sanofi products in our dedicated LCAC Laboratory;
- securing the supply chain to ensure integrity and thus avoid infiltration;
- authenticating products via Simple Authentication and Security Layer (SASL) labels and an innovative digital solution (eSASL);
- conducting awareness programs for 40 of the world's poorest countries in the world with the Sanofi Global Health entity;
- actively working within and partnering a wide variety of institutions, professional organizations, and international, regional, and national associations, both public and private (WHO, Europol, *G5 Santé*, PSI, OCLAESP, Unifab, Leem, EFPIA, etc.) to help design and implement joint programs and initiatives such as:
  - compliance with WHO recommendations by reporting all confirmed cases to national health authorities (Access to Medicine index - ATM - being a key benchmark); and
  - supporting the implementation of specific legislation on the danger of counterfeit or falsified medicines for public health to be integrated into specific laws such as the Digital Service Act; and
  - supporting law enforcement bodies and customs in their effort to dismantle criminal networks, by providing key information and specialized training;
- supporting efforts by public authorities to maintain the highest standards of drug quality and safety and to combat pharmaceutical crime (e.g. serialisation) by:
  - working closely with local authorities and professional organizations to deliver information and design educational programs to create awareness and fight against falsified medical products and their potential damage to patient health; and
  - raising internal and external awareness about the risks associated with falsified medicines and vaccines.

This comprehensive strategy shows Sanofi's strong commitment from the market to remove dangerous medical products and thus protect the patients.

4.3.4.2.3. Performance indicators

Since the first quarter of 2020, the COVID-19 pandemic and the successive lockdowns imposed in countries have led to a drastic decrease in field investigations and law enforcement operations. These factors explain the reduction in the number of seizures and dismantling of illicit manufacturing sites since 2020, compared to 2019 (a situation faced by all pharmaceutical companies).

Fight falsified medical products and illicit trafficking as of December 31, 2021	2021	2020	2019
Number of seizures (doses)	706,477	2,859,054	5,278,814
Number of illicit falsified medicine manufacturing facilities	1	3	23
Number of suspect product analyses conducted by LCAC since 2008	45,955	44,022	41,885
Sanofi legal actions against falsified medicines (including pre-litigation)	42	46	37
Web monitoring[a]:			
Number of fraudulent offers detected	2,062	1,230	ND
Number of takedowns (offer removed)	1,548	ND	ND
Number of illicit online pharmacies detected	1,800	ND	ND
Number of takedowns (offline sites)	1,109	ND	ND

(a) Reduce illicit offers and mitigate risks on patient's health, a proactive web monitoring and takedown process (since 2021) on life savings products in key markets (North America, Europe, Asia) have been accelerated. All actionable evidence is systematically shared with local authorities to leverage results against criminal networks involved in pharmaceutical fraud.

4.3.5. Medical ethics and bioethics

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

4.3.5.1.1. 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), 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 accessible to the public[(1)]. 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 though 2021. 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 those recommendations are being implemented (or if not, of the reasons why).

During 2021, the ABC and the Bioethics Committee were involved in strategic thinking within Sanofi about clinical trials versus placebo, including with specific reference to the COVID-19 pandemic.

4.3.5.1.2. Policy and action plans

Recommendations from our Bioethics Committee may lead us to implement policies and good practice guidelines, responsibility for applying which rests with the relevant Global Business Units. During 2021, we reviewed our policies on the use of laboratory animals, the use of stem cells, and use of genetic materials, to which we made no major changes.

4.3.5.1.2.1. 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.

(1) https://www.sanofi.com/en/our-responsibility/documents-center/ethics-and-transparency

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

We conduct clinical trials in low-to-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 “4.3.2., 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 participated in the Clinical Research in Resource-Limited Settings working group of the Council for International Organizations of Medical Sciences (CIOMS), which issued its final report in June 2021.

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

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

4.3.5.1.2.3. 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 “4.3.5.1.2.2., 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[(1)]. In addition to those 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.

4.3.5.1.3. Performance indicators

4.3.5.1.3.1. Medical ethics and clinical trials

None of the 35 inspections conducted on our clinical research activities in 2021 resulted in regulatory action.

The decrease in regulatory inspections of approximately 50% from 2020 onwards is related to the COVID-19 pandemic. Measures associated with the pandemic, including lockdowns and travel restrictions, required adaptations to allow for fully electronic sharing of data and documents, in accordance with applicable data privacy and security provisions.

4.3.5.1.3.2. Transparency of medical and clinical data

- Sharing of clinical data: Between January 1, 2014 and December 31, 2021, Sanofi received 184 requests from 18 countries to share data relating to 486 clinical trials.

  Data sharing was approved for 166 clinical trials:

  – data from 98 clinical trials were released under a data sharing agreement (the research projects involved are ongoing or completed), 16 of which led to publication;

  – data from a further 36 clinical trials will be shared once the data sharing agreement has been signed off; and

  – for the other 32 clinical trials, data sharing agreements are still being negotiated, or have been rejected or abandoned by the researchers making the request.

(1) *https://www.phrma.org/Codes-and-guidelines/PhRMA-Principles-on-Conduct-of-Clinical-Trials*

In addition, 19 clinical trials are under evaluation, and 301 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 2021: 812 scientific and medical papers sponsored or signed by Sanofi were included in the PubMed database, which references over 5,200 journals.

4.3.6. 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, because some of our products require long and complex production processes, interruptions may occur 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[(1)] 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 98.7%.

4.3.6.1. Organization and policy

Industrial Affairs at Sanofi has a governance structure that establishes the sourcing policy for our products; its 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. That 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.

4.3.6.1.1. 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.

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

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.

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 five-ten years) to inform our investment decisions by giving us visibility on sales for a product, a region or a specific technology.

4.3.6.1.2. 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 ten 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.

4.3.6.1.3. 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;
- 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).

4.3.7. 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.

A Sanofi-specific methodology was defined in 2018, and subsequently 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).

During 2021, the methodology was rolled out at four more sites in the Lyon region of France: the vaccines R&D and manufacturing facilities at Marcy-l'Étoile and Neuville-sur-Saône; the Lyon Genzyme Polyclonals bioproduction facility; and the Sanofi Lyon Campus tertiary site.

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.

4.3.8. 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.

4.3.8.1. Organization

4.3.8.1.1. 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; Health, Safety & Environment (HSE); and Corporate Social Responsibility (CSR).

4.3.8.1.2. 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.

4.3.8.1.3. 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: • 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 fraud prevention, and 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 1,300 "E&BI Champion (EBICs)" 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.

4.3.8.2. Policy and action plans

4.3.8.2.1. 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 35 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
- business integrity.

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.

4.3.8.2.2. 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 eLearning 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.

4.3.8.2.3. 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.

4.3.8.3. Performance indicators

2021 Training

- 110,607 employees followed at least one Ethics & Business Integrity training module; and
- a total of 161,186 Ethics & Business Integrity training modules were followed in the year.

2021 Whistle-blowing hotline

- In 2021 the E&BI department received 596 alerts. A total of 238 cases were substantiated and resulted in 70 dismissals or resignations related to misconduct. Other corrective actions were also implemented as per Sanofi's disciplinary and corrective actions policy, for example: additional training, process improvement steps, remuneration impacts, and verbal or written warnings.

4.3.9. 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 intra-group 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.

Income taxes are described in detail in our consolidated financial statements, included at Item 18 of our 2021 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.

4.3.10. Environment

Environmental protection at Sanofi comes within the overall scope of our Health, Safety and Environment (HSE) approach, as described in section “4.4.7., Employee health and safety”.

4.3.10.1. 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 established our roadmap to reflect current and future issues, stakeholder concerns, and the risks and opportunities, in line with Sanofi’s global strategy.

“Planet Mobilization” is our global environmental sustainability program, which sets objectives for our entire value chain for 2025 and 2030.

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 Social Responsibility, 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: achieve carbon neutrality by 2030 and net zero greenhouse gas emissions (all scopes) 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.

Because we want to play our part in combating climate change, we pledged in 2021 to achieve carbon neutrality by 2030 across our entire value chain and net zero greenhouse gas emissions by 2050. That brought our target date forward by 20 years compared with our previous pledge, made in 2015 after COP21 and the Paris Agreement. We also extended our target to cover our entire value chain (Scopes 1, 2 and 3). 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%. Our objectives have been 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.

In order to achieve carbon neutrality in 2030, Sanofi focuses above all on reducing its emissions across its entire value chain (Scopes 1, 2 and 3). A carbon offsetting plan for residual emissions alone is being developed. The selection of compensation mechanisms will focus on effective projects that associate a positive social impact on communities with standards of “best in class” international certifications recognized by financial regulators.

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. Sites identified as priority 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. This change in approach will have an overall positive impact on water withdrawals, leading to a 15% reduction by 2030 (against a 2019 baseline).

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 those of 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. By 2030, all of our sites will have dedicated initiatives in place to support biodiversity. Finally, we are committed to continuing 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 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. Those 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.

4.3.10.2. Resilience to climate change

In December 2020, Sanofi publicly pledged its support to the Task Force on Climate-related Financial Disclosures (TCFD), with the aim of helping disseminate best practice, improve transparency about the risks and opportunities, and provide responses and solutions.

In adopting the TCFD recommendations, we pledged to work towards aligning all of our operations with the climate objectives of the Paris Agreement and rethinking traditional growth models, in particular through economic, technical and organizational transformation.

Our commitment is based on in-depth analyses of the impacts of climate change on what we do, and on robust systems put in place for each of the four TCFD pillars.

A summary of those analyses is presented below. More detailed information is available on our corporate website, and in our public response to the CDP Climate Change Questionnaire.

Thematic area	TCFD recommendation	CDP 2020/2021 Reference	Outcomes and areas for work
GOVERNANCE	a) Describe the Board's oversight of climate-related risks and opportunities	CDP C1.1	Our supervisory and executive bodies are committed to making an ambitious response to the challenges of climate change, delivered through an approach focused on constant progress and joint working across the whole of Sanofi. **Board level engagement** (see "Item 6. Directors, Senior Management and Employees — A. Directors and Senior Management" of our 2021 Annual Report on Form 20-F) Our Board of Directors approves the strategic orientations of the company, oversees their implementation, and regularly monitors delivery. As part of this role, the Board of Directors follows the company's social and environmental commitments, including climate objectives. Since 2020, 15% of the variable component of our CEO's compensation has been linked to the achievement of Sanofi's CSR objectives, including climate change. **A mobilized Executive Committee and organization** The Planet Mobilization program is piloted by a steering committee consisting of the heads of Global Industrial Affairs (also a member of our Executive Committee); Environment, Corporate social responsibility, Procurement, External Manufacturing, and R&D France; and senior representatives from our various operations. This committee submits to the Executive Committee the company's strategic orientations and commitments in the area of climate change. The Executive Committee validates and ratifies these proposals with a view to their operational implementation. We have also set up a dedicated Climate-related Risk & Opportunities Committee (CROC) that works closely with the Planet Mobilization Steering Committee to ensure that the TCFD recommendations are applied across all levels of our organization and that robust systems are put in place to manage climate risks and opportunities. The committee, which meets monthly, consists of our heads of CSR, HSE, Environment, Risk Management and Insurance; and; senior representatives from Corporate Strategy, Finance, Legal, CSR and HSE.
	b) Describe management's role in assessing and managing climate-related risks and opportunities	CDP C1.1	
STRATEGY	a) Describe the climate-related risks and opportunities the organization has identified over the short, medium and long term	CDP C2.3a	We have undertaken to drill ever deeper to identify all the climate-related risks and opportunities we face. Our ongoing analysis of forward-looking scenarios provides a coherent framework for tailoring strategic decisions to address the uncertainties of socio-economic change, and to formalize our financial resilience under two possible futures (global warming of 1.5 °C or 4 °C relative to pre-industrial levels).
	b) Describe the impact of climate-related risks and opportunities on the organization's businesses, strategy and financial planning	CDP C2.3a, C3.1, C3.4	
	c) Describe the resilience of the organization's strategy, taking into consideration different climate-related scenarios, including a 2 °C or lower scenario	CDP C3.2	

Thematic area	TCFD recommendation	CDP 2020/2021 Reference	Outcomes and areas for work
RISK MANAGEMENT	a) Describe the organization's processes for identifying and assessing climate-related risks	CDP C2.1, C2.2	Our Risk Management and CSR departments have fully embedded climate-related risks into the Sanofi risk mitigation system, and support all our functions and operations in implementing and monitoring action plans. **Our processes for identifying and assessing climate-related risks** We have a robust process in place to identify, evaluate and rank: - risks to which we may be exposed over the next three years: We identify risks through a process of observation and analysis of our operating environment, and interviews with key managers and experts within Sanofi. Those risks are then ranked by criticality (a combination of probability and impact), and by level of control. The formal output generated by this process is a risk profile; - emerging trends that may constitute opportunities and/or threats over the next ten years: The identification process is the same as for risks. Emerging trends are classified into the disruption categories highlighted in the World Economic Forum report. Trends are evaluated and ranked based on their probability, impact, and velocity (i.e. how quickly they could become a risk for Sanofi). The formal output generated by this process is an emerging trends scan. In the "Environmental and Climate Disruptions" category, one of the emerging trends identified is adapting our business model to climate change, which requires us to anticipate the changes we need to make to our business model to align it on the TCFD recommendations. **Our processes for managing climate-related risks** Line managers are designated to manage each of the risks evidenced in our risk profile. They are tasked with preparing, implementing and monitoring delivery of mitigation plans. This process applies to climate-related risks. Because emerging trends are not yet risks, our Risk Management department works with in-house experts to develop scenarios to show how those trends could transform into risks, identifying the tipping points and early warning signs to look out for.
	b) Describe the organization's processes for managing climate-related risks	CDP C2.1, C2.2	**How processes for identifying, assessing and managing risks are integrated into our overall risk management** Climate-related risks and emerging trends are subject to the same governance as the overall Sanofi risk management process. Our risk profile and emerging trends scan, and scenarios for a selection of emerging trends, are presented annually to the Executive Committee, the Audit Committee, and the Board of Directors. The Executive Committee monitors risk mitigation and obtains assurance that adequate resources are allocated to it, and decides what anticipatory action should be taken to seize opportunities and protect Sanofi from threats arising from emerging trends.
	c) Describe how processes for identifying, assessing and managing climate-related risks are integrated into the organization's overall risk management	CDP C2.1, C2.2	
METRICS AND TARGETS	a) Disclose the metrics used by the organization to assess climate-related risks and opportunities in line with its strategy and risk management process	CDP C4.2, C9.1	Our Planet Mobilization roadmap incorporates outcome and target metrics to 2025; these include indicators for our carbon footprint (indicators available in the subsections below). In line with the latest TCFD "Guidance on Metrics, Targets and Transition Plans" (October 2021), we are currently working on a set of climate-related risk metrics that will facilitate reconciliations with financial accounting data.
	b) Disclose Scope 1, Scope 2, and, if appropriate, Scope 3 greenhouse gas (GHG) emissions, and the related risks	CDP C6.1, C6.3, C6.5	
	c) Describe the targets used by the organization to manage climate-related risks and opportunities, and performance against targets	CDP C4.1, C4.2	

Our performance is also being evaluated by the Carbon Disclosure Project (CDP) using their Climate Change questionnaire. In the 2021 CDP scores based on 2020 data, Sanofi was ranked A.

4.3.10.2.1. Energy

[GRI 302-1, GRI 302-4]

4.3.10.2.1.1. 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 2021, 30 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. More than ten of our administrative buildings are 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. As a result, we have raised our use of renewables from 26% of our electricity consumption in 2020 to 59% in 2021. 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.

4.3.10.2.1.2. Energy consumption

Energy consumption (MWh)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
Natural gas	2,059,052	2,100,357	2,092,377	-2%
Electricity[(a)]	637,196	1,172,250	1,409,604	-55%
Renewables[(b)] (electricity and biofuels)	953,545	440,332	191,134	+399%
Other energy sources (bought-in steam, waste-to-energy, etc.)	455,219	486,255	471,606	-3%
Total	**4,105,012**	**4,199,194**	**4,164,721**	**-1%**

(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.

The 2% reduction in energy consumption in 2021 relative to 2020 reflects energy efficiency programs, and also the concentration of operations on a single site (as was the case for our Allston and Framingham sites in the United States, and our R&D operations in France).

4.3.10.2.2. Greenhouse gas emissions

4.3.10.2.2.1. 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 55% reduction by 2030 from the 2019 baseline. The ultimate goal is to be carbon neutral in 2030.

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 CO_2 emissions by 47% between 2019 and 2021.

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. Since 2019, we have reduced the impact of refrigerant discharges by 28%, equivalent to 20,000 tonnes of CO_2 equivalent.

Greenhouse gases (Tonnes of CO2e)[(a)]		2021	2020	2019 (baseline year)	Change vs 2019 (%)
Scope 1	Direct emissions	424,709	447,975	449,596	-6%
	Direct emissions from medical rep vehicle fleet	43,071	50,116	80,522	-47%
Scope 2	Indirect emissions	192,701	255,835	352,435	-45%
Total		**660,481**	**753,926**	**882,553**	**-25%**

(a) CO2e = CO2 equivalent.

Total direct and indirect CO_2e emissions showed a sharp fall of 25% between 2019 and 2021, against a target reduction of 10%, mainly due to the ramp-up of our renewable electricity supply plan; the start-up of a decarbonized value supply chain via initiatives such as biomethane use; and the concentration of certain of our activities.

In France, in 2021, such emissions represented 147,611 tonnes of CO_2e in 2021 (including 3,900 tonnes for our medical rep vehicle fleet), down 16% on the 2020 level (175,729 tonnes of CO_2e, including 4,234 tonnes for our medical rep vehicle fleet).

4.3.10.2.2.2. Other indirect emissions: Scope 3

[GRI 305-3]

Including Scope 3 emissions gives a broad indication of total CO_2e 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 the 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.

During 2021, we developed an online tool to consolidate, analyze and simulate data sourced from all our stakeholders. Thanks to this data analysis tool and the structure of our database, we can compare data by model, organization and year, and recalibrate baseline year values. This reflects our aim to improve transparency by disclosing values that are comparable from one year to the next, because they use the same scope and apply the same assumptions.

Scope 3 (Tonnes of CO_2e)[(a)]	2021	2020	2019 (baseline year)	Change vs 2019 (%)
Calculated Scope 3 emissions (upstream)				
Category 1: Purchased goods and services	2,716,530	3,082,857	2,975,540	-9%
Category 2: Capital goods	685,832	688,278	674,169	+2%
Category 3: Fuel and energy-related activities	208,340	219,529	233,552	-11%
Category 4: Upstream transportation and distribution	187,526	179,730	192,750	-3%
Category 5: Waste generated in operations	328,461	340,594	317,833	+3%
Category 6: Business travel	37,946	87,403	168,521	-77%
Category 7: Employee commuting	102,441	163,688	163,516	-37%
Sub-total: calculated Scope 3 emissions (upstream)	4,267,076	4,762,079	4,725,881	-10%
Estimated Scope 3 emissions (downstream)				
Category 9: Downstream transport and distribution	904	769	874	+3%
Category 10: Processing of sold products	117,736	141,422	112,518	+5%
Category 11: Use of sold products	90,109	70,156	55,855	+61%
Category 12: End-of-life treatment of sold products	263,079	258,967	215,593	+22%
Sub-total: estimated Scope 3 emissions (downstream)	471,828	471,314	384,840	+23%
TOTAL[(b)]	**4,738,904**	**5,233,393**	**5,110,721**	**-7%**

(a) CO_2e = 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 movement in Category 1 is directly related to a reduction in the volume of goods and services purchased between 2019 and 2021.
- Our major efforts to transition to renewable energy are reflected in Category 3 (Fuel and energy-related activities).
- Throughout the period, COVID-19 led to a significant reduction in travel, including business trips and employee commuting.
- Downstream emissions (Categories 9, 10, 11) are directly related to the volume of sold products included in the calculation scope (such as intermediate products), which increased in 2021.

4.3.10.2.3. Taxonomy

4.3.10.2.3.1. EU Taxonomy framework & requirements

The European Union (EU) has published European Regulation 2020/852 of June 18, 2020 (the so-called "Taxonomy" Regulation) on the establishment of a framework to promote sustainable investments within the EU[1].

At present, sustainable activities are mapped with reference to the first two climate objectives: mitigation and adaptation (Annex I & II of the Climate Delegated Acts[2]). They will be extended to the four other environmental objectives during 2022, with a requirement to disclose in respect of operations for the 2023 financial year. Annex I and II provide definitions of eligible activities, including the corresponding NACE (statistical classification of economic activities) codes, and technical criteria to determine whether activities can be classified as effectively sustainable. Consequently, activities that do not meet those definitions are regarded as not defined in the reference framework (and as such, are deemed "not eligible").

The disclosure requirements for the 2021 financial year relate solely to "eligibility": Sanofi is required to publish key performance indicators (KPIs) highlighting the proportion of its eligible revenues, capital expenditure (CAPEX) and operating expenditures (OPEX) resulting from products and/or services associated with economic activities defined as "sustainable" in Annex I & II of the Climate Delegated Acts[2][3].

4.3.10.2.3.2. Key performance indicators required for 2021 financial year

With reference to the regulatory framework described above, Sanofi has not identified any eligible activities, nor any revenue, CAPEX or OPEX related to such activities. However, the Company has identified CAPEX and OPEX related to "individual measures", which contribute to making its activities low-carbon or to leading to greenhouse gas reductions, as defined in the EU Taxonomy Regulation[3].

The financial information used for this analysis was sourced from Sanofi's information systems (capex tracking, consolidation) as of the end of the 2021 financial year. It was jointly analyzed and verified by local and central teams to ensure its consistency with consolidated revenue, OPEX and CAPEX for the 2021 financial year. The outcome of that analysis is detailed below.

Revenue

In respect of the first two climate change objectives applicable from the 2021 financial year (mitigation and adaptation), the European Commission has prioritized those sectors of activity that emit the most greenhouse gases within the European Union. Sanofi's activities are essentially related to research, development, manufacturing and commercialization in the Pharmaceuticals and Vaccines businesses. Those activities are not currently considered to make a substantial contribution to the two climate objectives defined by the Taxonomy. In particular, a detailed analysis of industrial raw materials production activities did not reveal any revenues related to activity 3.14 ("Manufacture of basic organic chemicals") covered by the Taxonomy.

Due to the absence of eligible revenues, CAPEX and OPEX related to those activities cannot be classified as eligible. Consequently, our analysis of the eligibility of OPEX and CAPEX related solely to "individual measures" enabling the target activities to become low-carbon or to lead to greenhouse gas reductions as defined in the EU Taxonomy Regulation[3].

CAPEX

In accordance with the Taxonomy Regulation, the CAPEX denominator includes acquisitions of property, plant and equipment (IAS 16[4]) and intangible assets (IAS 38[4]); acquisitions of right-of-use assets (under IFRS 16[4], a right-of-use asset is recognized on commencement of a lease); and acquisitions related to business combinations (IFRS 3[4]). Overall, the denominator amounts to €6.8 billion (as shown in the table below).

Investments related to	Amount (€ billion)*
Property, plant and equipment (IAS 16)	1.5
Intangible Assets (IAS 38)	0.6
Right-of-use assets (IFRS 16)	1.0
Business combinations (IFRS 3)	3.7
Total CAPEX Denominator	**6.8**

** Refer to Notes D.3 and D.4. to our consolidated financial statements, included at Item 18 of our 2021 Annual Report on Form 20-F.*

Eligible CAPEX as reflected in the numerator includes:

- acquisitions of right-of-use assets, mainly relating to long-term real estate leases (corresponding to activity 7.7, "Acquisition and ownership of buildings") and to a lesser extent to car fleet leases (Activity 6.5, "Transport by motorbikes, passenger cars and light commercial vehicles"), and amounting to a total of €1 billion. In 2021, the substantial increase in right-of-use assets was mainly due to two leases relating to new office space in the United States, accounted for in accordance with IFRS 16; and

[1] *European Regulation 2020/852 of June 18, 2020. Available at : https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0852&from=EN*
[2] *EU Climate Delegated Act of June 4, 2021 and its appendices supplementing Regulation (EU) 2020/852 by specifying the technical criteria for determining under which conditions an economic activity may be considered to contribute substantially to climate change mitigation or adaptation. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM:C(2021)2800*
[3] *Commission Delegated Regulation (EU) 2021/2178 of 6 July 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by specifying the content and presentation of information to be disclosed by undertakings subject to Articles 19a or 29a of Directive 2013/34/EU concerning environmentally sustainable economic activities, and specifying the methodology to comply with that disclosure obligation. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2178&from=EN*
[4] *IFRS accounting standard applied by Sanofi.*

- other individual measures aimed at improving energy efficiency and mitigating greenhouse gas emissions, amounting to €0.3 billion in total, and relating mainly to:
  - installation, maintenance and repair of energy efficiency equipment (Activity 7.3);
  - renovation of existing buildings (Activity 7.2); and
  - installation, maintenance and repair of instruments and devices for measuring, regulation and controlling energy performance of buildings (Activity 7.5).

Consequently, our CAPEX ratio amounts to 20%**,** with a major contribution from right-of-use assets recognized under IFRS 16. Excluding IFRS 16, our eligible CAPEX would be 6%.

OPEX

In accordance with the Taxonomy Regulation, the OPEX denominator mainly comprises research and development expenses, mostly incurred on the discovery and development of medicines and vaccines. These OPEX do not qualify as eligible under the Taxonomy Regulation. Consequently, our review of the OPEX ratio concluded that this KPI was immaterial for Sanofi (refer to our consolidated financial statements, presented at Item 18 of our Annual Report on Form 20-F).

4.3.10.2.3.3. Sanofi's Planet Mobilization roadmap

Given the evolving nature of the European regulatory framework and the information available to date, Sanofi will revise this methodology and the figures on the basis of regulatory developments, in particular with the publication of the Delegated Acts which are likely to expand the list of eligible activities to the four other environmental objectives.

Beyond disclosure requirements related to the EU Taxonomy Regulation, the Company has defined an ambitious policy to limit the direct and indirect impacts of its operations and products on the environment. Actually, as part of its environmental policy, Sanofi's Planet Mobilization roadmap includes its new ambition to achieve carbon neutrality by 2030 and zero net greenhouse gas emissions by 2050 all scopes (see section "4.3.10.1., The Planet Mobilization roadmap").

4.3.10.2.4. Adapting to the consequences of climate change[(5)]

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.

4.3.10.2.5. 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.

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

- fine-tuning an oral treatment for sleeping sickness; and
- developing a novel cell-culture yellow fever vaccine specifically for Latin America.

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.

(5) *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.*

4.3.10.3. Water: a limited resource

4.3.10.3.1. 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.

Water is 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.

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.

We seek to use this resource responsibly and sustainably, by implementing water management plans at all of our industrial sites. The aim is that all our sites will have such a plan by 2030, and that those with a high level of water-related risks (especially those in water stress zones) will have one by 2025.

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.

There are many water-related risks, but they can be classed in three main categories: physical, regulatory and reputational. In 2020, we launched a large-scale campaign to update water risk mapping across all our industrial sites, with the help of an external consultant. This enabled us in early 2021 to update our list, which now has 12 priority sites, located in Algeria (two), India (three), Mexico (two), South Africa (one), Italy (one), Pakistan (one), China (one), and Saudi Arabia (one).

4.3.10.3.2. Water consumption

[GRI 303-1]

Water used directly and indirectly during manufacturing is essentially withdrawn directly by Sanofi itself 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.

We reviewed our water program in 2021 in order to improve our response to current and future challenges. Water is a local resource, so it is for each site to determine the priority issues in their catchment; that's why our water management plans incorporate context-driven targets. At global level, we define our target for reducing water withdrawal by aggregating our local targets (rather than vice versa); after all, France does not face the same challenges as India.

We have estimated that implementing our sustainable water management program will reduce our global water withdrawals by 15% by 2030 versus the 2019 baseline, despite the ongoing development of our industrial capacities.

Water consumption (millions of m^3 per year)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
Withdrawal of surface water (lakes, rivers)	7.0	8.0	8.9	-21%
Withdrawal of groundwater	16.9	17.7	18.6	-9%
Withdrawal of water from public supply	7.3	7.5	7.4	-1%
Other sources	0.2	0.2	0.2	0%
Total	**31.4**	**33.4**	**35.1**	**-11%**

4.3.10.4. 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. In 2021, we prevented 94,015 tonnes of solvent waste by regenerating solvents and feeding them back into our industrial processes.

4.3.10.4.1. 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 end 2021, our 3R rate was 74% (excluding on-site recycling of solvents).

The landfill disposal rate in 2021 was 7% and 74 sites no longer used landfill (versus 66 sites in 2020).

Waste (tonnes)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
Hazardous waste				
Recycled hazardous waste	17,747	20,179	27,908	-36%
Hazardous waste incinerated with thermal recovery	56,296	55,177	57,997	-3%
Hazardous waste incinerated without thermal recovery	40,744	42,371	38,482	+6%
Hazardous waste sent to authorized landfills	1,807	2,630	2,067	-13%
Sub-total: hazardous waste	**116,594**	**120,357**	**126,454**	**-8%**
Non-hazardous waste				
Recycled non-hazardous waste	86,574	96,499	90,306	-4%
Non-hazardous waste incinerated with thermal recovery	27,752	26,065	23,237	+19%
Non-hazardous waste incinerated without thermal recovery	7,211	13,432	7,413	-3%
Non-hazardous waste sent to authorized landfills	16,599	15,835	18,000	-8%
Sub-total: non-hazardous waste	**138,136**	**151,831**	**138,956**	**-1%**
TOTAL hazardous and non-hazardous waste	**254,730**	**272,188**	**265,410**	**-4%**

NB: Data provided in this section relate to waste from Sanofi's production activities. Data for waste not related to our production activities and for non-recurring waste are not consolidated; this can include waste generated by construction of new buildings or decontamination of land, and other types of non-recurring waste generation.

Overall, total waste generated by Sanofi was 4% lower than in 2019.

The quantity of hazardous waste has been reduced by the implementation of a new ammonia adsorption process at one of our chemistry plants in France, which saved over 5,000 tonnes of waste.

4.3.10.4.2. 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; and
- 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.

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.

4.3.10.4.3. Eco-design

Eco-design is a systemic approach that aims to embed environmental criteria not only in the initial design of a product, but also in continuous improvements through the product's life cycle. Sanofi has adopted the Life Cycle Assessment (LCA) environmental metric, which ensures that impacts are not simply displaced to another phase of the life cycle. Not only is this a holistic, multi-criteria approach, it is also governed by an international standard (ISO 14040), allowing for comparisons between products in the same category that serve the same purpose.

Through the eco-design pillar of our Planet Mobilization program, we have pledged that by 2025 all new products we bring to market will have been eco-designed. By 2030, this will be extended to the main products (by net sales and number of units sold) already commercialized by Sanofi.

We are keen to protect our brand image on environmental issues, so our entire eco-design approach is based on transparent, recognized scientific methodologies. We have called in experts in environmental science and metrics to help us with this, and since 2016 we have been working on life cycle assessments of a range of medicines, vaccines and medical devices.

That enabled us to identify elements with the greatest environmental impact and kick-start the eco-design approach, by developing an action plan to improve the product's environmental performance.

Our environment team also collaborates with pharmaceutical industry working groups at various institutional levels with the aim of standardizing environmental metrics approaches and methodologies across the sector.

With its experience in eco-packaging, such as the Compact Box project for which Sanofi Pasteur obtained the "Eco-design – Pharmapack Europe" prize in 2017, Sanofi has deployed, this year, an eco-packing tool based on the life cycle approach, as the first stone in the building of eco-design. The Compact Box reduces the volume of vaccine packaging by 50% and eliminates the need for PVC blister packs. The Compact Box is also accompanied by an upgrade in packaging that allows for an optimization of the cold chain for distribution. Sanofi undertakes to have blister free vaccine packaging by 2027. In 2021, the percentage of blister free vaccines was 29%.

4.3.10.4.4. Protecting biodiversity

We seek to protect biodiversity and ensure that natural resources are used fairly and sustainably. As well as addressing industry-specific issues, we are continually adapting our practices to stay in line with international agreements (such as the Nagoya protocol and the Convention on Biological Diversity) and to ensure that we do not use endangered natural resources and their derivatives.

In 2021, we renewed our support (initiated in 2018) for Act4Nature International, a proactive alliance of French multinational companies committed to biodiversity.

We have carried out an assessment of our biodiversity footprint and associated risks. During 2021, we worked on identifying and analyzing biodiversity dependencies and pressures facing Sanofi, using recognized frameworks such as the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES). We supplemented this analysis by using the Global Biodiversity Score methodology to quantify the extent to which our business puts pressure on biodiversity. We then used this to compile biodiversity risk mapping for Sanofi. This exercise confirmed that the actions being taken under our Planet Mobilization program are on the right track, and helped consolidate our environmental roadmap.

Furthermore, we launched an update of the biodiversity risk mapping for our sites in 2021. The aim is to identify and characterize the extent to which our sites are exposed and vulnerable to biodiversity risk, so that we can focus attention and resources appropriately. This involved working with a specialist consultancy firm to develop a customized tool. An in-depth analysis, based on our own local data and a comprehensive independent review, will help us fine-tune our list of priority sites potentially subject to biodiversity risk and those where additional investigation is needed at local level to confirm the situation. This new list will be distributed internally during 2022, and biodiversity protection plans will be implemented at those sites by 2025.

4.3.10.4.5. Educating and mobilizing our people on environmental issues

Because we promote an environment-friendly culture across our entire business, we engage all our people in supporting our environmental ambitions and in helping us achieve our objectives through the work they do every day. We are keen not just to raise awareness, but also to give our people the resources and tools they need to take account of the environment when making decisions.

Every year, we organize an Environment Day around a specific issue, at all our sites around the world. In 2021, protecting biodiversity was the theme, with a global event backed up by local conferences and activities. Despite COVID-19, more than 120 sites across 50 countries helped organize our 2021 Environment Day.

We also launched a collective engagement and intelligence program in 2020. This gave all our people the opportunity to join a community within Sanofi where they could improve their understanding of current environmental issues, share initiatives and good practices, and work together on new solutions to help the environment. During 2021, over 500 employees from 63 sites in 29 countries took part in a brainstorming session on environmental sustainability at Sanofi. A full program of bootcamps, hackathons and design thinking workshops – led by one of our in-house innovation labs – helped the teams transform their ideas into sustainable projects. In this inaugural year, three winning projects were selected for implementation, backed by funding from the Planet Mobilization fund.

Through the Plan Bee® initiative, first rolled out in 2016, Sanofi promotes the installation of beehives at sites around the world. By 2021, the initiative had reached 24 sites, and was supported by 275 highly committed volunteers. During the year, 403 kg of honey was produced, and sold to employees. Income from the sales was donated to an in-house charity, or reinvested in the Plan Bee® initiative.

Also in 2021, Sanofi launched a training program devoted to environmental issues. The aim is to reinforce the environmental culture within Sanofi by giving basic insights into each of the environmental pillars covered by our Planet Mobilization program. Accessible to all, it's an opportunity for everyone to take a closer look at the environmental challenges they face, and to better understand Sanofi's environmental ambitions.

4.3.10.5. 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.

4.3.10.5.1. Managing pharmaceutical discharges and fighting antimicrobial resistance

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; and
- encouraging responsible disposal of unused or date-expired medicines, by raising patient awareness and supporting collection programs.

We also signed up to the Antimicrobial Resistance (AMR) roadmap 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.

4.3.10.5.2. 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.

4.3.10.5.3. Managing air 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).

4.3.10.5.4. Performance indicators

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

4.3.10.5.4.1. 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 2021, this program covered 63% 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 47% of those substances.

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.

4.3.10.5.4.2. Managing other types of wastewater discharge

Chemical oxygen demand (COD) is the most relevant parameter for assessing the quality of wastewater discharges, since it measures the overall quantity of organic material (biodegradable and non-biodegradable) in the wastewater.

Most of our industrial facilities have wastewater treatment plants, whether or not the wastewater is discharged directly to the natural environment. If discharge is to a public or private sewerage system, then treatment is handled by a third party who complies with locally applicable regulations.

Consequently, the overall quantity of COD calculated within our site boundaries (rather than at the point of discharge into the natural environment, as reported in previous years) would appear to be a more reliable and relevant indicator of our efforts to reduce the environmental impacts of our operations on aquatic ecosystems.

Wastewater discharge (tonnes)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
COD	6,233	7,010	7,186	-13%

The many programs under way to upgrade our onsite treatment plants, and the embedding of new environmental criteria into the design of our facilities, suggest that levels will stabilize in the years ahead despite the ongoing expansion of our industrial capacities.

The quantity of COD generated by our sites accounts for the majority of the footprint from our chemical and biochemical production, including manufacturing facilities belonging to the new EUROAPI entity. In 2021, the overall reduction on COD discharges mainly reflects lower intensity of production at those facilities, as a result of modernization works or other events affecting how production is organized.

4.3.10.5.4.3. Managing air emissions: optimizing the use of solvents and control over volatile organic compound emissions

[GRI 305-7]

Solvents (tonnes)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
Solvents used	164,938	190,691	184,456	-11%
% regenerated	57%	63%	62%	-8%

Volatile organic compounds (VOCs) (tonnes)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
VOCs (estimated)	2,708	2,861	2,932	-8%
SO_x - direct emissions	110	176	203	-46%

NOx (tonnes)	2021	2020	2019 (baseline year)	Change vs 2019 (%)
NO_x - direct emissions	471	490	493	-4%

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

4.3.10.5.5. Remediation

4.3.10.5.5.1. 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 2021 were immaterial.

4.3.10.5.5.2. 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. In 2021, Sanofi spent €49 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 that review, we adjusted our provisions to €649 million as of December 31, 2021, compared with €713 million in 2020. 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 2021 Annual Report on Form 20-F.

4.3.11. Animal protection

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.

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. During 2021, for example, the Committee drew up guidelines on ethical crisis management, drawing on experience gained during the COVID-19 pandemic. Our Chief Veterinary Officer is also responsible for liaising with animal dealers, vets, and site-level Ethics Committees. In 2020, we instituted a global forum - which convenes twice a year - to help members of our Ethics Committees develop their ethical competencies.

Sanofi is committed to developing alternative approaches and subscribes fully to the "3Rs" (Replacement, Reduction and Refinement) principle on the use of animals in research and production. This means that we do not use animals unless there are no adequate alternative methods that can achieve the same purpose (replacement); we minimize the number of animals used to the extent compatible with good science (reduction); and 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.

During 2021, we continued with our efforts to reduce our use of animals. The total number of animals used at Sanofi sites in 2021 was 252,312[(1)]. That compares with 302,890 animals in 2020, a reduction of 17%. Since 2013, we have reduced the number of animals used by 54%.

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.

At the end of 2021, 15 Sanofi sites in 10 countries were using animals. Of those 15 sites, 13 have obtained AAALAC International accreditation, one site located in Thailand is discontinuing its animal experimentation activities, and the remaining site is a new Sanofi acquisition not yet accredited.

One entity had its accreditation renewed in 2021, and a second is due to have it renewed early in 2022 (no significant comments were made during the field visit in October 2021).

Three new entities joined the Sanofi group in 2021: Kymab, Kiadis and Translate Bio. The use of animals at those three entities is currently being reviewed in order to bring them into compliance with our own animal protection policies.

In 2021, 51 contracted research organizations or universities conducting tests on animals, and 6 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).

(1) *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.*

4.4. Vigilance plan

4.4.1. 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 of 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 those risks is presented in the table in section “4.4.2., Duty of vigilance risk table”; the related policies and action plans are described in section “4.3., Detailed description of SEFP risks and issues” (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 those 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 procurement categories 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.

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 “4.8., Corporate social responsibility cross-reference tables”.

4.4.2. 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.	4.4.7. 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.	4.3.4. Product safety for patients and consumers (SEFP risk)
Human rights and fundamental liberties	**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.	4.3.5. 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.	4.4.13. 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.	4.4.10. 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.	4.4.6. 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.	4.3.10.3. 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.	4.3.10.5. 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 "4.4.14., Procurement and subcontracting", for measures taken to manage risks within our supply chain relating to employee health and safety, environmental releases and human rights.*

4.4.3. 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, 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.

4.4.4. 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. Since the publication of the initial plan, regular meetings have been held to discuss issues such as risk mapping relating to human rights at work, sustainable procurement, whistle-blowing, and supplier assessments. One meeting was held in 2021, during which the issues presented included a follow-up on internal control points relating to policies on human rights at work; progress on sustainable procurement; and a status update on whistle-blowing reports under the duty of vigilance.

4.4.5. Whistle-blowing systems and report-handling

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 "4.3.8.2.3., 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.

4.4.6. Fundamental human rights at work

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

We employ more than 95,000 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. Fundamental human rights at work refer mainly to rights associated with ILO standards (International Labour Organization), and in particular the following 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 has committed to applying international standards on human rights, including the United Nations Guiding Principles on Business and Human Rights, and to carrying on its activities in compliance with national regulations such as the French Duty of Vigilance law.

To do this, we identify the nature and extent of potential human rights violations in every country in which we, our suppliers and direct subcontractors operate, and take action to 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 fundamental human rights is provided below.

4.4.6.1. 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; and
- 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 we use to identify and evaluate the criticality of human rights risks are related to the characteristics of the labor force used (level of qualification, working conditions, potential presence of vulnerable workers) and of countries where we do business (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.

4.4.6.2. 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.

4.4.6.3. 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 to reflect our risk mapping, revising our existing policies to make risk assessment questionnaires compulsory and more operational, and to ensure that data are reported up to our CSR department.

4.4.6.4. 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. Those countries represent approximately one-third of the Sanofi workforce. Of those 18 countries, seven (representing more than a quarter of the Sanofi workforce) have already been subject to audit.

In 2021, 17 countries (Algeria, Brazil, China, Colombia, Egypt, India, Indonesia, Mexico, Pakistan, Russia, Saudi Arabia, South Africa, Thailand, Tunisia, Turkey, Venezuela and Vietnam) responded to the internal control questionnaire. The main findings are summarized below:

Issue	Findings
Child labor Principal control points: • 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: • Existence of written, transparent employment contracts • Regularity of wage payments	No major compliance breaches reported
• 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	Difficulties reported by some countries relating to issues around decent wages and audit of recruitment agency practices
Working hours Principal control points: • 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: • 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, on top of collective actions taken at company-wide level (see above).

4.4.7. 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.

4.4.7.1. Sanofi HSE strategy

4.4.7.1.1. 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; and
- 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-19 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-19 response, refocusing on the fundamentals and prioritizing business continuity in production and in critical R&D activities. 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.

4.4.7.1.2. 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.

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

4.4.7.1.3. 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, physical stress factors, noise, vibrations, and ergonomic issues;
- 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.

4.4.7.1.4. 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, our HSE 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.

4.4.7.1.5. 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.

Those 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.

	2021	2020
Number of internal HSE audits, including Biosafety	50	38
Number of auditors trained	17	22
Number of employees who have performed audits	71	80

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).

During 2021, we carried out a global certification campaign.

In 2021, 52 of our sites had one or more certifications: ISO 14001 (37 sites), OHSAS or ISO 45000 (21 sites), and ISO 50001 (30 sites). That 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, 127 visits were carried out by technical experts on behalf of Sanofi's insurers during 2021.

4.4.7.2. Workplace health and safety programs

[GRI 403-2]

4.4.7.2.1. 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 time-frame). The datasheets are prepared by experts and disseminated through the entire HSE network, and to operational and site managers (R&D, industrial and administrative). A total of 24 datasheets were distributed in 2021 to the whole global HSE network.

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

4.4.7.2.2. Road safety

During 2021, 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 was in line with the 2020 level, but sharply down on previous years.

The practical training cycles originally scheduled were disrupted, and were once again 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. A large-scale campaign, "One Hour Stop for Safety", was conducted in many countries where we operate. This involved employees stopping work for an hour so they could get together and talk about road safety risks and safer driving techniques. Consequently, road accident injuries is relatively stable (19, versus 17 in 2020), while field activity has resumed in a less restrictive containment context.

4.4.7.2.3. 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 work-stations 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).

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 reported and recognized within Sanofi during 2021 in accordance with local administrative criteria was the musculoskeletal disorder category.

4.4.7.2.4. 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 2021 include:

- Training delivery was adapted to meet the challenges of the COVID-19 pandemic, with increased use of remote learning. Alongside existing modules including technical and regulatory training, auditor training, leadership and safety culture, managerial safety visits, and ATEX (explosive atmosphere) training, we also rolled out new modules such as one on hygiene in the workplace.
- The onboarding program for HSE managers we developed in 2020 continued to be delivered remotely, with around one hundred staff following the course across all our sites worldwide.
- All our training programs were developed in multiple language versions. More than 500 HSE employees worldwide have received training in 2021, and nearly 100,000 Sanofi employees have taken the “Life saving rules” modules since the launch of the program.

4.4.7.3 Occupational injury/disease indicators

Health and safety in the workplace	2021	2020
Reduce the total occupational injury frequency rate (FR) – any employee[(a)] to below 2 by 2021	1.98	1.73
Reduce the lost time injury frequency rate – any employee[(a)] to below 1.4 by 2021	1.24	1.13

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

Safety indicators	2021	2020
Lost time injury frequency rate[(a)] – Sanofi personnel	1.0	0.9
Lost time injury frequency rate[(a)] – Contractors	2.0	2.0
Total occupational injury frequency rate – Sanofi personnel	1.6	1.4
Total occupational injury frequency rate – Contractors	2.9	3.2
Number of deaths	0.0	0.0
Number of occupational diseases reported[(b)]	29.0	21.0

(a) For definitions, see section “4.6.2.2., Safety indicators”.
(b) In 2021, Sanofi opted to consolidate data based on the reporting rate, so as to avoid adjusting prior-period data.

During this period of COVID-19, our HSE performance deteriorated, primarily on ground-level falls and contact with objects. However, the ground-level falls prevention program initiated in 2018 had a positive impact in 2019 and 2020. In 2021, the number of accidents of this type remained well below the 2018 level (125 in 2021, 207 in 2018)

A total of 29 occupational diseases were reported to local authorities in 2021.

A total of 23 occupational diseases were reported in Europe (France), four in North America (United States), and two in Latin America (Colombia) where systems for identifying and reporting such diseases are less well established. Most of the occupational diseases (76%) related to musculoskeletal disorders.

Thanks to the preventive measures implemented at our sites, only two cases were reported of COVID-19 infections attributable to exposure at work.

We also used an additional medical reporting system (Mood), which showed a resurgence in mental health issues that may be partly due to the effect of the pandemic on our people’s working lives.

To remedy this situation, we are currently drafting worldwide guidelines on workplace wellness (including mental health), which will be rolled out in 2022.

4.4.8. Product safety for patients and consumers

See section “4.3. Detailed description of SEFP risks and issues — 4., Product safety for patients and consumers”.

4.4.9. Patient safety in clinical trials

See section “4.3. Detailed description of SEFP risks and issues — 5., Medical ethics and bioethics”.

4.4.10. 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.

4.4.10.1. 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.

4.4.10.2. 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.

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.

4.4.11. Water resource management

See section “4.3. Detailed description of SEFP risks and issues — 10.3., Water: a limited resource”.

4.4.12. Environmental releases

See section “4.3. Detailed description of SEFP risks and issues — 10.5., Environmental releases”.

4.4.13. Biopiracy

Sanofi is committed to complying with conventions on the protection of biodiversity and combating 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.

The COVID-19 pandemic has highlighted the difficulties around including human pathogens in the scope of the Nagoya Protocol, and reignited the debate at international level[1].

4.4.14. 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	2021	2020	2019
Procurement spend (€ billion)	14.1	14.8	14.5
in OECD countries	*12.7*	*13.3*	*12.2*
in non-OECD countries	*1.4*	*1.5*	*2.3*
Number of suppliers	52,563	54,507	68,000
Number of countries where we have suppliers	128	138	152

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 2021, PSCI held virtual training courses for Indian and Chinese suppliers on pharmaceutical residues in the environment, cutting greenhouse gas emissions, explosions and dangerous reactions, and new labor legislation. In total, 95 of our suppliers of active ingredients took part (49 from India, and 53 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.

At the end of 2021, we have resigned from the Together for Sustainability (TfS) initiative, a worldwide program from the chemical industry to evaluate and improve sustainable procurement practices adopted by suppliers to concentrate on our involvement in PSCI. 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.

We have rolled out a dedicated system (eVendor) to assess at-risk suppliers, which by end 2021 had covered 81 of the 91 countries where we carry on procurement. 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. Further investigations (such as EcoVadis questionnaires, compliance audits, or internal inspections) may be carried out if risks are identified or our in-house experts advise us to do so.

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.

[1] *https://www.ifpma.org/subtopics/public-health-implications-of-the-implementation-of-the-nagoya-protocol/*

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. Those 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 2021, 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 406 suppliers in 2021. Of those, 222 were undergoing a reassessment, and 62% 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 carry out audits of all our high-risk suppliers of active pharmaceutical ingredients (APIs) and all our contract manufacturing organizations (CMOs).

	2021	2020	2019
Number of Sanofi CMO audits[(a)]	60	42	72
Number of audits of active pharmaceutical ingredient (API) suppliers[(a)]	88	44	87
Number of audits of miscellaneous suppliers: packaging, distribution, contract research organization (CRO) categories, etc.[(a)(b)]	24	35	-

(a) Includes shared PSCI audits.
(b) Data available from 2020.

Of the 386 suppliers reaudited (follow-up audits) annually in 2019, 2020 and 2021, 96 improved their performance and 240 have reached an acceptable level of performance

Sustainable procurement is one of our priorities. That's why in 2021, 60% of our spend was subject to some form of evaluation (EcoVadis, audit, or Sustainability questionnaire).

We have also developed new CSR criteria on issues such as diversity and inclusion, the environment (energy, waste, water management and biodiversity) and CO_2 emissions, which are being incorporated in new calls for tender from January 2022.

4.5. Sanofi's contribution to Sustainable Development Goals

Today we are confronted by societal challenges like a growing and aging 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 those challenges and demonstrate that they are making a positive contribution to society.

Sanofi's primary contribution is to serve patients' needs throughout their health journeys, whether they be someone with a rare disease 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 "4.3.2., Access to healthcare"

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

		Progress			
Topic	**Ambition**	**2021**	**2020**	**Contribution to SDGs**	
Access to Healthcare					
Sanofi Global Health	Make affordable 30 essential medicines to treat cardiovascular diseases, diabetes, tuberculosis, malaria, certain neglected tropical diseases, and cancer in the 40 countries with the lowest per capita GDP Help establish and enhance sustainable healthcare systems for people with chronic diseases that require long term care	See section "4.3.2., Access to healthcare".	See section "4.2.2., Access to healthcare".	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 **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
Infectious diseases	To help eradicate sleeping sickness by 2030 To help eradicate polio	See section "4.3.2., Access to healthcare".	See section "4.2.2., Access to healthcare".		**SDG 3.3**
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 Donate 100,000 vials a year to treat people with rare diseases, via the Humanitarian Program launched by Sanofi Genzyme	See section "4.3.2., Access to healthcare".	See section "4.2.2., Access to healthcare".		**SDG 3.4**
Human Capital					
Gender balance	Achieve gender balance in Sanofi Senior Leaders by 2025	40.1%	38.8%	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
	Achieve 40% of women in executive posts by 2025	34.2%	31.3%		
Corporate citizenship					
Decent work	Reduce the total occupational injury frequency rate (FR) – any employee[(a)] to below 2 by 2021 Reduce the lost time injury frequency rate – any employee [(a)] to below 1.4 by 2021	Total occupational injury FR – any employee: 1.98 Lost time injury FR – any employee: 1.24	Total occupational injury FR – any employee: 1.73 Lost time injury FR – any employee: 1.13	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, reach 10% of work/study placements occupied by young people from deprived urban areas	8.5 %	5.3 %	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)	Industrial, R&D and tertiary sites for Scopes 1 & 2 (including medical rep fleet): 55% reduction in greenhouse gas emissions (CO_2 equivalent) by 2030 (relative to 2019) Carbon neutrality by 2030 and net zero emissions by 2050 (Scopes 1, 2 & 3)	-25%	-15%	SDG 13: Climate action	**SDG 13:** Take urgent action to combat climate change and its impacts
Water	Industrial, R&D and tertiary sites - Quantitative objective: 15% reduction in water consumption by 2030 (relative to 2019)	-11%	-5%	SDG 6: Clean water and sanitation	**SDG 6.4:** By 2030, considerably increase rational use of water resources in all sectors, and guarantee the viability of all withdrawals and supplies of fresh water so as to take account of water scarcity and sharply reduce the number of people suffering from water shortages
	Qualitative objective: implementation of efficient water management plans : - By 2025 for 100% of our priority sites - By 2030 for all our sites	See section "4.3.10.3.1., Water resource management plan".	See section "4.2.10.3.1., Water resource management plan".		
Waste	Reuse/recycle/recover at least 90% of our waste by 2025	74%	73%	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 **SDG 12.5:** By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse
	Achieve landfill disposal rate of below 1% of total waste by 2025	7%	7%		
Sustainable management of products	All new products to be eco-designed by 2025 No vaccines supplied in blister packs by 2027	See section 4.3.10.4.3., "Eco-design".	See section 4.2.10.4.3., "Eco-design".		
Pharmaceutical products in the environment	Implement a life cycle management plan at all priority production sites by 2025	100%	75%	SDG 6: Clean water and sanitation	**SDG 6.3:** By 2030, improve water quality by reducing pollution, eliminating dumping of waste at sea, reducing emissions of chemicals and hazardous materials to a minimum, reducing by half the proportion of untreated waste water, and significantly scale up recycling and reuse globally with no threat to water
Biodiversity	Biodiversity protection programs at all sites located close to sensitive natural spaces by 2025	Local initiatives: we hold the "Environment Day" in 120 sites across 50 countries	Local initiatives[(b)]	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) "Any employee" includes Sanofi employees, temporary workers and subcontractors.
(b) Because of COVID-19, we were unable to hold our "Environment Day" event in 2020.

4.6. Methodological note on data reporting

[GRI 102-46, GRI 102-48, GRI 102-49, GRI 102-50]

4.6.1. General comments

4.6.1.1. 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 CO_2 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;
- and 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 2021 Annual Report on Form 20-F.

4.6.1.2. Changes in scope of consolidation

See “Item 4. Information on the Company — D. Property, Plant and Equipment”, of our 2021 Annual Report on Form 20-F.

Kymab, Kiadis, Tidal Therapeutics, Translate Bio, Kadmon, and Origimm Biotechnology GmbH were acquired in 2021.

Closure with transfer of operations within Sanofi (historical data retained in prior-year calculations): Allston (Specialty Care/US), Mirador Lab (external manufacturing/Argentina), Frankfurt TIDES DS (EUROAPI/Germany), Great Valley (R&D/US).

Closure without transfer of operations within Sanofi (historical data deleted from the environmental and health and safety data calculation): Guarulhos (Supply Chain/Brazil), Tongi (General Medicines and Supply Chain/Bangladesh).

4.6.1.3. 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;

  – streamlining IT mapping; and

  – 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 health, 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.

We use the SHERPA system to collect and consolidate health, safety and environmental data across our entire reporting scope.

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 quarterly campaigns except for indicators relating to wastewater discharge and VOC, which are collected annually.

As regards the Planet Mobilization roadmap targets set for 2025 and 2030, companies acquired after 2019 are included in the baseline year according to the following example: a company acquired in 2020 is included in the 2019 baseline year with 2020 values, so that data can be presented on a like-for-like basis.

4.6.1.4. 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.

4.6.1.5. 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.

4.6.2. Detailed indicators

4.6.2.1. Social indicators

4.6.2.1.1. 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.

4.6.2.1.2. 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.

4.6.2.1.3. 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.

4.6.2.1.4. Training hours

Difference between the number of employees receiving training via iLearn in 2021 (105,959) and our total workforce as of December 31, 2021 (95,442):

This difference arises because:

- employees receiving training via iLearn during 2021 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.

4.6.2.1.5. Employee 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.

4.6.2.1.6. Gender pay gap

- Data effective December 31, 2021.
- Data includes all employees except the Executive Committee.
- Excludes all contingent workers.
- In France, also excluded employees who have taken different pre-retirement plans and not working for Sanofi anymore.
- Data sourced from 91 countries.

4.6.2.2. Safety indicators

4.6.2.2.1. 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. Since 2021, work accidents occurring when teleworking have been included in this indicator.

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.

4.6.2.2.2. 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.

4.6.2.2.3. 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.

4.6.2.3. Environmental indicators

4.6.2.3.1. 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 vehicles in our medical rep vehicle fleet owned or leased by Sanofi are included in Scope 1. Emissions from vehicles owned by an employee and regularly driven for work purposes (medical reps) are included in Scope 3.

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 V3.7 database; for sub-categories not included in that database, we have used other standard calculation methods:
- since 2021, emissions relating to purchased goods and services (Category 1) have been based on our actual volumes, for the same period as our other environmental indicators (October 1 of the previous year to September 30 of the current year). Using an online tool has enabled us to refine the data, giving a more precise analysis of the links between products, models and emission factors:
  - category 1 is calculated based on quantity;
  - category 2 is calculated on a monetary basis;
  - categories 3, 5 and 7 are calculated with Sherpa, our reporting tool for safety and environmental data;
  - category 9 (downstream transport and distribution) excludes the impacts of travel by doctors and nurses; and
  - category 11 (use of sold products) excludes travel by patients to pharmacies.

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

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

4.6.2.3.2. Wastewater discharge

The data presented correspond to effluents after internal treatment within the footprint of our sites.

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

4.6.2.3.3. 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%.

4.6.2.3.4. Volatile organic compounds

Current-year emissions determined by extrapolating prior-year emissions and weighting them for actual quantities of solvents purchased in the current year.

4.7. Report of the Independent Third Party

[GRI 102-50, GRI 102-56]

Year ended December 31, 2021

Independent third party's report on consolidated non-financial statement presented in the management report

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 an independent third party accredited by COFRAC under no. 3-1681 (for the scope of our accreditation, go to www.cofrac.fr) and as a member of the network of one of the statutory auditors of your company (the "Entity"), we have conducted procedures in order to provide a conclusion expressing a limited level of assurance on the compliance of the consolidated non-financial statement for the year ended December 31, 2021 (the "Statement") with the provisions of Article R. 225-105 of the French Commercial Code and on the fairness of the historical information (observed or extrapolated) disclosed pursuant to paragraph 3 of I and II of Article R. 225-105 of the French Commercial Code (the "Information"), as prepared in accordance with the Entity's procedures (the "Reporting Framework") and presented in the management report pursuant to Articles L. 225 102-1, R. 225-105 and R. 225-105-1 of the French Commercial Code.

1. Report on the compliance and fairness of the Statement

Conclusion

Based on the procedures performed, as described in "Nature and scope of the work", and on the elements we have collected, we did not identify any material misstatements that would call into question the fact that the consolidated non-financial statement is not presented in accordance with the applicable regulatory requirements and that the Information, taken as a whole, is not presented fairly in accordance with the Guidelines, in all material respects.

Responsibility of the Entity

It is the responsibility of the Board of Directors to:

- select or establish appropriate criteria for preparing the Information;
- 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 and the disclosures required under Article 8 of Regulation (EU) 2020/852 (the "green taxonomy"); and
- implement the internal control procedures it deems necessary to ensure that the Information is free from material misstatement, whether as a result of fraud or error.

The Statement was prepared in accordance with the Entity's Reporting Framework as described above.

Responsibility of the independent third party

It is our responsibility, based on our procedures, to provide a report expressing a limited assurance conclusion on:

- the compliance of the Statement with Article R. 225-105 of the French Commercial Code; and
- the fairness of the historical information (actual or extrapolated) 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.

Since it is our responsibility to express an independent conclusion on the Information as prepared by management, we are not permitted to be involved in preparing the Information, as that could compromise our independence.

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 and identified by the symbol * in Appendix 1 (the "Selected Information") has been prepared, in all material respects, in accordance with the Reporting Framework (Part 2, "Limited assurance report on the Selected Information"); and
- 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 ¤ 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").

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 disclosures required under Article 8 of Regulation (EU) 2020/852 (the "green taxonomy"), the French duty of care law and anti-corruption and tax avoidance legislation;
- the fairness of the Information required under Article 8 of Regulation (EU) 2020/852 (the "green taxonomy"); or
- the compliance of the Entity's products or services with applicable regulations.

Regulatory requirements and applicable professional standards

Our procedures as described below were performed in accordance with Articles A. 225-1 *et seq* of the French Commercial Code; the professional standards of the professional guidance of the French Institute of Statutory Auditors ("CNCC") applicable to this engagement, as equivalent to a program of verification; and international standard ISAE 3000 as revised[(1)]:

Independence and quality control

Our independence is defined by reference to Article L. 822-11 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 the ethical requirements and French professional guidance.

Resources

Our procedures involved eleven professional staff and took place between September 2021 and February 2022, over a total engagement period of twelve weeks.

In carrying out those procedures, we obtained assistance from our specialists in the fields of sustainable development and social responsibility. We conducted about thirty interviews with the persons responsible for preparing the Statement, including representatives from Corporate Social Responsibility, Human Resources, Product Quality and Pharmacovigilance, Bioethics, Ethics and Business Integrity, HSE and Procurement.

Nature and scope of our procedures

In planning and conducting our procedures, we took account of the risk of material misstatements in the Information.

We believe that the procedures performed, based on our professional judgement, are sufficient to provide a limited level of assurance:

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

(1) *ISAE 3000 (as revised) - Assurance engagements other than audits or reviews of historical financial information*

- we consulted documentary sources and conducted interviews to:
  - assess the process for selecting and validating the principal risks, and the consistency of outcomes (including the key performance indicators used) with respect to 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 certain risks (product pricing, product quality, product safety for patients and consumers, patient safety in clinical trials, animal protection, 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 China, Sanofi Mexico, Marcy IO, Sisteron Chemistry, ICF Unit API (DBO), Frankfurt R&D, Ocoyoacac Pharma, Ocoyoacac Vaccines, Vitry SCO, Vitry Research, Val-de-Reuil, Aramon Chemistry, EUROAPI Chemistry (Frankfurt Chemistry), Ujpest Chemistry, Singapore 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
  - analytical procedures to verify that the data collected had been correctly consolidated, and to check the consistency of data trends;
  - substantive tests using sampling or other selection 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 9% and 75% of the consolidated data selected for those entities (9% of the workforce, 32% of hazardous waste, 40% of VOC emissions, and 75% of COD emissions); and
- we assessed the overall consistency of the Statement based on our knowledge of all the entities included in the scope of consolidation.

The procedures carried out in a limited assurance engagement are less extensive in scope than those that would be required for a reasonable assurance engagement conducted in accordance with professional standards; a higher level of assurance would have required us to perform more extensive verification procedures.

2. Limited assurance report on the Selected Information

Conclusion

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

Nature and scope of our procedures

For the Selected Information as identified by an asterisk (*) in Appendix 1, we performed procedures of the same nature as described in section 1 of this report. We performed those procedures in accordance with ISAE 3000[(2)] and with professional standards applicable in France.

The sample selected represents between 18% (water consumption) and 29% (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; a higher level of assurance would have required us to carry out more extensive procedures.

[(2)] *ISAE 3000 - Assurance engagements other than audits or reviews of historical financial information.*

3. Reasonable assurance report on the Selected Information

Conclusion

Based on the procedures performed, the Selected Information has been prepared in compliance with the Reporting Framework in all material respects.

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 3000 and with professional standards applicable in France.

The sample selected represents 57% (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.

Paris-La Défense, February 22, 2022

The Independent Third Party

EY & Associés

Christophe Schmeitzky

Partner, Sustainable Development

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*.	Health and safety in the workplace*.
Lost time injury frequency rate – any employee*.	Measures taken to attract and retain talents (Talent Management, Talent Marketplace, Sanofi University, Play to Win cultural change strategy, Diversity and Inclusion strategy).
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, 2021, 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 hiring rate for all employees, executive posts, and Grade 5 levels.	
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*.	
Improvement in “Culture Barometer” score*.	
Succession planning (executive posts)*.	
Staff turnover (Voluntary, High Potential)*.	
Internal promotion rate (STI)*.	

Environmental information	
Quantitative information (including key performance indicators)	**Qualitative information (actions and outcomes)**
Total quantity of hazardous waste.	Measures to prevent, recycle and eliminate hazardous waste.
Quantity of hazardous waste recycled/incinerated with energy-recovery.	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.
Quantity of hazardous waste recycled.	
Quantity of hazardous waste incinerated with thermal recovery.	
Quantity of hazardous waste incinerated without thermal recovery.	Water consumption and supply in light of local constraints*, percentage reduction in water consumption versus the 2019 baseline year*.
Quantity of hazardous waste sent to authorized landfills.	
Total quantity of non-hazardous waste*.	Measures to improve energy efficiency and the use of renewables*.
Quantity of non-hazardous waste recycled/incinerated with energy-recovery*.	Percentage reduction in direct and indirect emissions (Scopes 1 & 2) versus the 2019 baseline year*.
Quantity of non-hazardous waste recycled*.	
Quantity of non-hazardous waste incinerated with thermal recovery*.	Proportion of production sites assessed for pharmaceutical substances emissions (cumulative, since 2016).
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).	
Air emissions (total consumption of solvents, percentage of solvents recycled, emissions of volatile organic compounds).	
Total water consumption, and split by source of supply*.	
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.*	

Societal 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 doses of inactivated polio vaccine (IPV) supplied to UNICEF*.	Actions on access to healthcare*.
Number of doses of inactivated polio vaccine (IPV) supplied to Brazil, India, Indonesia and the Philippines*.	Measures taken in product quality.
Number of GQA internal audits.	Measures taken in product safety (pharmacovigilance).
Number of regulatory inspections, and split by authority.	Combating falsified medicines and illicit trafficking.
Number of recalls, including Class 1 recalls.	Measures taken in medical ethics and bioethics.
Number of internal audits and inspections relating to pharmacovigilance.	Measures taken in animal protection.
Percentage of individual pharmacovigilance cases submitted to European health authorities within the regulatory deadline.	Actions in support of human rights, especially compliance with International Labor Organization (ILO) fundamental conventions*.
Number of signals.	Measures taken in supply chain continuity.
Number of clinical trials with information-sharing.	Consideration of social and environmental responsibility in relations with suppliers and subcontractors*.
Number of inspections conducted on activities relating to clinical trials.	
Number of scientific papers published.	
Number of evaluations of compliance with animal protection principles conducted on suppliers and contract research organizations.	
Number of AAALAC International accreditations for Sanofi sites.	
Number of animals used by Sanofi sites.	
Number of countries that responded to the internal control questionnaire on compliance with human rights policies*.	
Number of Sanofi Contract Manufacturing Organization (CMO) audits*.	
Number of audits of active pharmaceutical ingredient (API) suppliers*.	
Number of audits of miscellaneous suppliers: packaging, distribution and contract research organization (CRO) categories, etc*.	
Global service level.	
Number of doses seized in efforts to combat falsified medicines and illicit trafficking.	

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

4.8. Corporate social responsibility cross-reference tables

4.8.1. Statement of Extra-Financial Performance (SEFP)

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 and the European Regulation 2020/852 of June 18, 2020 (the so-called "Taxonomy" Regulation) on the establishment of a framework to promote sustainable investments within the EU.

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"	36
Marketing practices: direct sales, tenders	• 20-F: Item 18, Note B.13., "Revenue recognition"	F-25
b) Prescribers	• 20-F: Item 4, B.6.1., "Marketing and distribution"	36
c) Competition	• 20-F: Item 4, B.6.2., "Competition"	36
d) Regulatory framework	• 20-F: Item 4, B.6.3., "Regulatory framework"	37
e) Payers		
Government health insurance systems	• 20-F: Item 4, B.6.4., "Pricing and reimbursement"	38
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"	36
g) Net sales		
3-year trend in net sales	• 20-F: Item 18, "Financial Statements"	F-1
Net sales by segment and geographical region	• 20-F: Item 5, A.2.1., "Net Sales"	64
Organization and structure		
Sanofi		
a) Number of employees		
Total, and split by segment, geographical region, gender, and type of contract	• Chapter 4: "4.3.1.2.1., A glance at our global workforce"	10
Split by function	• Chapter 4: "4.3.1.2.1., A glance at our global workforce"	10
b) Sanofi sites		
Number of countries in which Sanofi operates	• 20-F: Item 4, B.6.1., "Marketing and distribution"	36
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"	43 48 48
c) Operations and product life cycle		
Research and development	• 20-F: Item 4, B.5., "Global research & development"	27
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"	43 48 48
Sales and distribution	• 20-F: Item 4, B.6.1., "Marketing and distribution"	36
End of life cycle management	• Chapter 4: "4.3.10.5., Environmental releases"	55
d) Therapeutic areas and associated products		
Pharmaceuticals Consumer Healthcare Vaccines	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Vaccine products" • 20-F: Item 4, B.4., "Consumer Healthcare"	17 25 27
Number of products	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Vaccine products" • 20-F: Item 4, B.4., "Consumer Healthcare"	17 25 27
Product types (vaccines, biologics, pills, injectables)	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Vaccine products" • 20-F: Item 4, B.4., "Consumer Healthcare"	17 25 27
e) Global Business Unit (GBU) structure		
Overview of GBUs	• 20-F: Item 4, B.2., "Main pharmaceutical products" • 20-F: Item 4, B.3., "Vaccine products" • 20-F: Item 4, B.4., "Consumer Healthcare"	17 25 27
Net sales by GBU	• 20-F: Item 5, A.2.1, 1/ "Net sales by operating segment and global business unit"	64
Suppliers/Subcontractors		
Total amount of purchases Number and type of suppliers Geographical location	• Chapter 4: "4.4.14., Procurement and subcontracting"	68

SEFP topic	Cross-reference to the present document (Chapter 4) or to the 2020 Annual Report on Form 20-F	Page(s)
Partnerships/alliances		
Regeneron and Bristol-Myers Squibb agreements Alliance with Alnylam	• 20-F: Item 18, Note C, "Principal alliances"	F-30
Financial performance		
Management report	• 20-F: Item 5, "Operating and Financial Review and Prospects"	51
Trends, objectives and strategies		
a) Trends	• 20-F: Item 4, B.1., "Strategy" • 20-F: Item 4, B.6., "Markets"	15 36
b) Objectives and Strategy	• 20-F: Item 4, B.1., "Strategy"	15
Principal extra-financial risks		
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	• Chapter 4: "4., Corporate Social Responsibility"	1
Taxonomy		
Key performance indicators (KPIs) highlighting the proportion of eligible revenues, capital expenditure (CAPEX) and operating expenditures (OPEX) resulting from products and/or services associated with economic activities defined as "sustainable" in Annex I & II of the Climate Delegated Acts	• Chapter 4: "4.3.10.2.3. Taxonomy"	50
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	• Chapter 4: "4.3.10., Environment"	45
Societal commitments in support of sustainable development	• Chapter 4: "4.3.2., Access to healthcare"	25
Circular economy	• Chapter 4: "4.3.10.4., Waste: towards a circular economy"	52
Reducing food waste	• Chapter 4: "4.3.10.4.2., Initiatives to reduce food waste"	53
Combating food insecurity and promoting responsible, fair and sustainable food	• N/A	–
Respect for animal welfare	• Chapter 4: "4.3.11., Animal protection"	58
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	• Chapter 4: "4.3.1.4.2.1., Social dialogue"	17
Initiatives to combat discrimination and promote diversity, and measures to support people with disabilities	• Chapter 4: "4.3.1.5., Creating our diversity edge"	19

4.8.2. Duty of vigilance

The cross-reference table below shows the disclosures required pursuant to law no. 2017-399 of March 27, 2017 on the duty of vigilance of parent companies and companies acting as principals.

Duty of vigilance topic	Cross-reference to the present document (Chapter 4)	Page(s)
Identification and evaluation of risks generated by operations		
	• 4.4.2., Duty of vigilance risk table	60
Regular evaluation procedures		
Product safety for patients and consumers	• 4.3.3.1., Organization • 4.3.4.1.1., Organization	33 35
Biopiracy	• 4.4.13., Biopiracy	67
Personal data protection	• 4.4.10., Personal data protection	67
Employee health and safety	• 4.4.7., Employee health and safety	62
Environmental releases	• 4.3.10.5., Environmental releases	55
Water resource management	• 4.3.10.3.1., Water resource management plan	52
Human rights	• 4.4.6.1., Human rights risk mapping	61
Procurement and subcontracting	• 4.4.14., Procurement and subcontracting	68
Appropriate actions to mitigate risk or prevent serious harm		
Product safety for patients and consumers	• 4.3.3.2., Policy and action plans • 4.3.4.2.2., Policy and action plans	33 37
Biopiracy	• 4.4.13., Biopiracy	67
Personal data protection	• 4.4.10., Personal data protection	67
Employee health and safety	• 4.4.7.2., Workplace health and safety programs	65
Environmental releases	• 4.3.10.5., Environmental releases	55
Water resource management	• 4.3.10.3.1., Water resource management plan	52
Human rights	• 4.4.6.3., Policies and action plans	61

Duty of vigilance topic	Cross-reference to the present document (Chapter 4)	Page(s)
Procurement and subcontracting	• 4.4.14., Procurement and subcontracting	68
Whistle-blowing systems and report-handling		
	• 4.4.5., Whistle-blowing systems and report-handling	60
Arrangements for monitoring actions taken and assessing their effectiveness		
Product safety for patients and consumers	• 4.3.3.3., Performance indicators • 4.3.4.2.3., Performance indicators	35 38
Biopiracy	• 4.4.13., Biopiracy	67
Personal data protection	• 4.4.10., Personal data protection	67
Employee health and safety	• 4.4.7.3., Occupational injury/disease indicators	66
Environmental releases	• 4.3.10.5.4., Performance indicators	56
Minimizing the use of water resources	• 4.3.10.3.2., Water consumption	52
Human rights	• 4.4.6.4., Performance indicators	62
Procurement and subcontracting	• 4.4.14., Procurement and subcontracting	68

4.8.3. Sustainability Accounting Standards Board (SASB) index

The cross-reference table below shows the disclosures in line with SASB.

Code	Metrics	Cross-reference to the present document (Chapter 4) or to the 2020 Annual Report on Form 20-F	Page(s)
Safety of Clinical Trial Participants			
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	• 4.3.5.1.2.2. Medical ethics and clinical trials	39
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	• 4.3.4.1. Pharmacovigilance: ◦ *4.3.4.1.2. Policy and action plans* ◦ *4.3.4.1.3. Performance indicators*	35
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	• Form 20-F 2021: Item 8, A., "Consolidated Financial Statements and Other Financial Information"	139
Access to Medicines			
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	• 4.3.2. Access to healthcare	25
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	• 4.3.2. Access to healthcare	25
Affordability & Pricing			
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period	• Form 20-F 2021: Item 8, A., "Consolidated Financial Statements and Other Financial Information"	139
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	• 4.3.2.4. Product pricing	28
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	Not reported	–

Code	Metrics	Cross-reference to the present document (Chapter 4) or to the 2020 Annual Report on Form 20-F	Page(s)
Drug Safety			
HC-BP-250a.1	List of products listed in the Food and Drug administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	• Form 20-F 2021: Item 5, A.2.1., 5/ "Net sales – Consumer Healthcare segment/GBU"	68
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	• Information available on the FDA - MedWatch website	–
HC-BP-250a.3	Number of recalls issued, total units recalled	• 4.3.3.3. Performance indicators	35
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	• 4.3.10.5. Environmental releases	55
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	• 4.3.3.3. Performance indicators	35
Counterfeit Drugs			
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	• 4.3.4.2. Fight against falsified medicine and illicit trafficking	37
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	• 4.3.4.2. Fight against falsified medicine and illicit trafficking	37
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	• 4.3.4.2. Fight against falsified medicine and illicit trafficking	37
Ethical Marketing			
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	• Form 20-F 2021: Item 8, A., "Consolidated Financial Statements and Other Financial Information"	139
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	• 4.3.8. Ethics and business integrity	42
Employee Recruitment, Development & Retention			
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	• 4.3.1.3. How we attract and retain talent to deliver on our strategy	13
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	• 4.3.1.3.1. Efficient hiring and fostering internal mobility	13
Supply Chain Management			
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	• 4.3.3. Product quality • 4.3.4.1. Pharmacovigilance	33 35
Business Ethics			
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	• Form 20-F 2021: Item 8, A., "Consolidated Financial Statements and Other Financial Information"	139
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	• 4.3.8. Ethics and business integrity • Form 20-F 2021: Item 4, B.6., "Markets"	42 36
Activity Metric			
HC-BP-000.A	Number of patients treated	• 4.3.2. Access to healthcare	25
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	• Form 20-F 2021: Item 4, B.2., "Main pharmaceutical products" • Form 20-F 2021: Item 4, B.3., "Vaccine products" • Form 20-F 2021: Item 4, B.4., "Consumer Healthcare"	17 25 27

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