

## HUMAN RIGHTS DUE DILIGENCE

### GRI Standards :

- 102: General Disclosures
- 103: Management approach
- 414: Supplier Social Assessment

### EXECUTIVE SUMMARY

Sanofi's commitment to respect internationally recognized human rights and to exercise human rights due diligence in all its activities is disclosed in this "Human Rights due diligence" Factsheet. We have structured our reporting along the lines of the UN Guiding Principles on Business and Human Rights since 2014 as it is the framework we use to deploy our approach, by referring to the UN Guiding Principles Reporting Framework<sup>1</sup>. For the convenience of our readers, a matching table based on the UN Guiding Principles Reporting Framework appears at the end of this document. Using the UN Guiding Principles together with the UN Guiding Principles Reporting Framework enable Sanofi to provide a reporting that is complete, meaningful and aligned with the global standards on corporate respect for human rights.

Following the adoption of the French Duty of Vigilance Law in March 2017, Sanofi SA now has a legal obligation to establish and implement a vigilance plan<sup>2</sup> to identify and prevent the risks of serious harm to human rights, personal health and safety and the environment caused by its activities, those of its controlled subsidiaries or those of its suppliers or subcontractors (within the framework of the joint commercial relationship). This "human rights vigilance plan" is clearly in line with the Group's previous commitments to respect human rights and to exercise vigilance regarding the consequences of its activities on individuals and builds on the Group's existing processes; these commitments and processes are described in this factsheet.

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<sup>1</sup> The UN Guiding Principles Reporting Framework is the first comprehensive guidance for companies to report on human rights issues in line with their responsibility to respect human rights. This responsibility is set out in the UN Guiding Principles on Business and Human Rights, which represent the authoritative global standard in this field. For more information, see: <http://www.ungreporting.org/consult-the-reporting-framework/download-the-reporting-framework/>

<sup>2</sup> As required by law, the vigilance plan is made public in the 2017 *Document de Reference* and the report on its effective implementation will be published annually in the future *Documents de reference*.

## OUR COMMITMENT TO RESPECT HUMAN RIGHTS BY EXERCISING HUMAN RIGHTS DUE DILIGENCE IN ALL OUR ACTIVITIES

1. *Commitment: how do we embed our commitment to respect human rights?*
  - a) Adopting a Human Rights Statement from the top management
  - b) Upholding international standards on human rights as a minimum requirement for conducting business
  - c) Embedding Sanofi's commitment into our internal reference documents and processes
2. *The Human Rights risks mapping*
  - a) A thorough understanding of Sanofi's potential human rights impacts and salient human rights issues (Human Rights Guide)
  - b) Focus on human rights risks mapping linked to suppliers practices
3. *Risk-management measures:*
  - a) Global policies
  - b) Dedicated actions to manage salient human rights issues
  - c) Training senior executives and operational managers on human rights
  - d) Stakeholder engagement
4. *Grievance mechanisms:*
  - a) For our workforce
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## 1. COMMITMENT: HOW DO WE EMBED OUR COMMITMENT TO RESPECT HUMAN RIGHTS?

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### 1.1. Adopting a Human Rights Statement from the top management

Sanofi's Human Rights Statement is embedded from the top of the business through its endorsement by the Senior Vice President in charge of Corporate Social Responsibility.

The statement specifies that as a multinational healthcare company keenly aware of its social responsibility. Sanofi is committed to integrating respect for human rights into all its business operations and public positions. We are convinced that, while states and governments have a duty to protect human rights through adequate laws and policies, businesses also have a role to play, which begins with identifying their own impacts on human rights and taking measures to prevent human rights violations.

For several years now, Sanofi has expressed and reiterated its commitment to respect the principles of the United Nations Global Compact and other international standards in the field of human rights. Since 2015, Sanofi has also committed to uphold the international reference framework: the United Nations Guiding Principles.

The Human Rights Statement was developed during the development of the Sanofi Human Rights Guide in 2012-2013.

*For more information, see Human Rights in Our Activities Guide, page 3, in the [Document Center](#).*

### 1.2. Upholding international standards on Human Rights as a minimum requirement for conducting business

Beyond complying with national laws and regulations in all of its countries of operation, Sanofi is committed to respecting the principles listed in the following international reference instruments:

- The UN Guiding Principles for Businesses and Human Rights
- The UN Global Compact
- The Children's Rights and Business Principles
- The Universal Declaration of Human Rights
- The International Labor Organization Declaration on Fundamental Principles and Rights at Work
- The Organization for Economic Co-operation and Development Guidelines for Multinational Enterprises

#### Our commitment to respect Children's Rights

Sanofi commits to respecting the Children's Rights and Business Principles developed by UNICEF in March 2012 alongside the UN Global Compact and Save the Children as the first comprehensive guidance for companies on how to integrate children's rights into their policies and business processes.

These Principles are at the foundation of the targeted programs that we develop for children worldwide; children's health is an acknowledged business and CSR priority for Sanofi.

*For more information, see the Children's Rights Factsheet in the [Document Center](#)*

### 1.3. Embedding Sanofi's commitment into our internal reference documents and processes

For Sanofi, it is essential to ensure the coherence between our responsibility to respect human rights and the policies and procedures that govern our wider business activities and relationships.

In addition, the human rights principles which Sanofi commits to are listed in our key internal reference documents, such as:

- The Code of Ethics
- The Social Charter
- The Suppliers' Code of Conduct

These internal documents present human rights as a core element of the company's values and contribute to embedding human rights principles into our company culture. They also set out our expectations towards our stakeholders to meet their responsibility to respect human rights, explicitly stating that the mentioned criteria are to be considered as the minimum applicable standard should local regulations be less stringent in any of Sanofi's countries of operation.

Sanofi has set up rigorous management processes and systems—such as Quality, Health, Safety and Environment (QHSE), Compliance, Drug Safety Monitoring, and Risk Management—enabling Sanofi to deploy its CSR policies at every level across the company.

Human rights criteria are broken down and integrated into various issue-specific processes and systems, contributing to prevent employees, patients and local communities' rights violations and ensuring compliance with internal reference tools and Sanofi policies.

All the Sanofi Human Rights Commitments described above are publicly available and communicated internally and externally to all our employees, business partners, suppliers and others relevant stakeholders.

*For more information, see the Code of Ethics, the Suppliers' Code of Conduct and the Social Charter in the [Document Center](#)*

## 2. THE HUMAN RIGHTS RISKS MAPPING

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### 2.1. A thorough understanding of Sanofi's potential human rights impacts and salient human rights issues

#### 2.1.1. Identifying all our human rights challenges in the value chain

By 2012-2013, Sanofi organized a wide-scope internal self-assessment to identify the nature and extent of potential human rights impacts linked to its activities, i.e., in the pharmaceutical industry and in the workplace. This participatory evaluation involved 37 representatives from more than 12 Sanofi Directions, who participated in five cross-functional working sessions. Each session focused on the human rights impacts, which can potentially arise at each step of Sanofi's value chain, from research and development of medicines to distribution and use. One interdisciplinary working session was focused on human rights at work.

The results of this self-assessment led to the design of a guide for Sanofi employees, *Human Rights in our Activities*. It maps potential human rights impacts of Sanofi's business activity along the four steps of a drug's life cycle, with a transverse section on human rights at work. It was designed with four aims:

- To inform and familiarize all Sanofi employees with the key concepts and principles of respect for human rights
- To raise awareness on the spectrum of human rights risks related to the functional responsibilities of our personnel and business partners
- To describe a selection of relevant best practices implemented at Sanofi
- To act as a reference point for Sanofi managers making decisions about potential issues linked to human rights in their daily activity

The *Human Rights in our Activities Guide* is deployed through internal tools such as a slide kit for managers and a dedicated website to help Sanofi managers better understand their role and responsibilities in applying human rights principles.

For more information, see *Human Rights in Our Activities Guide* in the [Document Center](#).

### 2.1.2. Defining our salient human rights issues

Sanofi has mapped out the major challenges facing the Group as part of the application of the law on the duty of vigilance and its requirement to identify the risks of harm to people and the environment. In order to do so, Sanofi relied in particular on returns experiences of existing internal policies and processes (as the Human Rights guide and internal policies on Environment and Health & Safety).

These analyses, supported by external data, enabled Sanofi to identify eight major risks to negatively impact people or the environment, considered as the human rights salient issues for The Group.

- Risks related to patient protection:
  - > ensure patient safety;
  - > preserve the physical integrity of participants in clinical trials;
  - > protect patients' personal data.
- Risks related to respect rights of employees:
  - > offer the highest health and safety working conditions;
  - > guaranteeing employees' fundamental rights;
  - > protect employees' personal data.
- Risks related to respect for the environment and rights of local communities:
  - > Minimize environmental impacts and control use of resources;
  - > fight against bio piracy.

These issues are linked to the activities of Sanofi, conducted directly by the company or indirectly by its commercial relationships.

## 2.2. Focus on human rights risks mapping linked to suppliers practices

We work with many suppliers worldwide to procure the materials, goods and services that Sanofi requires to manufacture our products, serve patients and supply our facilities worldwide.

Since 2007, our responsible procurement approach, embedded into our overall procurement strategy, has aimed to ensure that our suppliers uphold high ethical standards and take social and environmental responsibilities seriously. We expect suppliers to meet the standards set out in the Sanofi Suppliers' Code of Conduct.

We have developed a risk-based approach to concentrate our efforts on those supplier segments considered to be most at risk in terms of key CSR criteria — for example, human rights, labor and environmental practices, governance and anti-corruption. This approach was reinforced in 2017 as part of the implementation of the Due Diligence plan for 2018. It is based on the identification of the most risky purchasing categories according to their inherent risks. The country risk is used in second place to prioritize suppliers. This risk assessment was updated in 2020.

An overall and composite rating was calculated for each procurement category and 44 procurement categories were considered a priori to be very high risk in terms of environmental protection, personal safety/health and respect for human rights. These purchasing categories are related to the following areas: waste management, demolition activities, remediation, major works, hazardous products, active ingredients, natural products, pharmaceutical subcontracting, clinical trials, transportation and distribution, site operations, security services, travel and events and recruitment agencies.

This new mapping made it possible to define response typologies for each category identified as being at risk with regard to the vigilance plan (health and safety, environment and human rights). These responses depend on the risk rating, the country of activity, the characteristics of the service provided (e.g. whether on-site or not, the service provider's organization, recurrence, etc.) and the volume of purchases. Possible risk management responses include: audits (internal or via PSCI or TfS sector initiatives), evaluations, prevention plans, specific awareness raising actions, etc.

### 3. RISK – MANAGEMENT MEASURES

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In order to manage salient human rights issues identified, the company has developed responses that can be cross-cutting across all subjects or specific to a particular risk.

#### 3.1. Global policies

- **The Code of Ethics and its implementation**

The Sanofi's Code of Ethics explicitly defines the company's principles on human rights with reference to international standards. This code is deployed within the company, through mandatory training actions and Sanofi's compliance program, led by the Ethics & Business Integrity Department and overseen by the Executive Committee Compliance, chaired by the CEO.

(For more information, See *the Ethics & Business Integrity Factsheet in the [Document Center](#)*)

- **The responsible procurement approach**

The Responsible Purchasing approach asks suppliers to compliance with Sanofi's Human Rights commitments through the Suppliers code of conduct (Suppliers code of conduct) and provides for CSR assessments of suppliers. It is supplemented by membership of sectoral initiatives, such as TfS (Together for Sustainability) and PSCI (Pharmaceutical Supply Chain initiative), which enable the company to pool audits and supplier support actions.

This approach has been reviewed in 2017 (see above) within the framework of the implementation of the French law on the duty of vigilance by the redesigning the identification methodology and supplier ratings. Priorities actions were also identified for 2018, such as the redefinition of the responses to be provided by buyers according to the supplier risk rating or the revision of Suppliers

Code of Conduct. The challenge is also to improve coordination and sharing of internal actions relating to management of suppliers from the various departments for optimize and rationalize them.

To ensure that Sanofi buyers have a sound grasp of the issues and of the responsible procurement approach, Sanofi has implemented a worldwide training program. This training program helps to integrate a deep understanding of the principles contained in the U.N. Global Compact, the conventions of the ILO and other specific standards (in particular, SA 8000 and ISO 14000).

The training program has greatly enriched our procurement community, contributing to the implementation of our responsible procurement approach throughout the company's affiliates. In addition, this topic is addressed in procurement seminars and steering committee meetings on a regular basis. The program now includes the use of our dedicated responsible procurement platform.

The Supplier Relationships Charter, based on the Sanofi Code of Ethics, sets out the rules of conduct that must be respected by all Sanofi employees in their relationships with suppliers, and governs the issues relating to invitations, gifts, meetings and correspondence.

*For more information, see the Sustainable Procurement Factsheet in the [Document Center](#).*

- **The protection of personal data**

In the area of personal data protection, Sanofi has developed a global policy of respect for the right to privacy and personal data protection that applies to all the company's activities (employee data, patient data and data of any third parties in general).

*For more information, see Protection of personal data Factsheet in the [Document Center](#)*

### 3.2. Dedicated actions to manage salient human rights issues

- **Human rights issues linked to the patient safety:**

Patient safety issues are managed by processes related to pharmacovigilance (which is intended to monitor and continuously assess the risk-benefit balance of products), the quality of medicines and the fight against the counterfeiting.

*For more information, see Pharmacovigilance Factsheet, Fighting Falsified Medical Products Factsheet and Serialization: Medicine Identification, Authentication & Traceability factsheet in the [Document Center](#).*

Regarding clinical trials, specific rules compliant with international and national standards have been developed to ensure in particular the free and informed consent of participants. A clinical trial audit program is developed to verify compliance of operations with internal and external standards of reference.

*For more information, see Medical Ethics & Bioethics and Clinical trials Factsheet in the [Document Center](#).*

- **Human rights issues linked to respect for workers' rights:**

In the area of health and safety, the company has developed a strong health and safety policy that aims to maintain the health and well-being of employees and suppliers working at Sanofi sites. Led by the HSE Department of the company and benefiting from dedicated governance, this policy is deployed within the entities, in particular by the definition of operational rules targeted on key areas of vigilance, an audit program and training activities.

*For more information, see Health and safety in the workplace Factsheet in the [Document Center](#).*

The company pays particular attention to respecting the fundamental rights of workers, employed



by Sanofi or by its business relationships. It developed internal policies that ask for implementation of due diligence processes by entities at the operational level (identification and management of risks) with reference to commitments based on ILO international conventions, in particular:

- > ILO Convention No. 87 and No. 98 on Freedom of Association and the right to collective bargaining
- > ILO Convention 138 and 182 on Child Labor;
- > ILO Convention No. 29 and 105 on Forced Labor.

The monitoring of the implementation of these policies is integrated into the system of Sanofi's internal control.

*For more information, see Human Rights at work Factsheet in the [Document Center](#).*

- **Human rights issues linked to the protection of the environment and local communities:**

Minimize the use of natural resources by company's activities is an objective of the environmental policy of Sanofi, and in particular water resources. Specific operating actions have been implemented to best manage water supply and use for the production of medicines and vaccines.

The company's environmental policy also aims to reduce the environmental impacts of its activities, in particular through prevention of accidental pollutions and the management of drug residues in the environment. For example, different types of sites (chemical and biochemical production, solid pharmaceuticals production etc.) have been assessed to define specifically the tools and appropriate means to the management of the drug substances by site category.

*For more information, see Water Stewardship Factsheet, Pharmaceuticals in the environment factsheet and HSE Management system Factsheet in the [Document Center](#).*

The company is committed to complying with the conventions relating to protection of biodiversity and the fight against bio piracy and in particular the respect of intellectual property rights of indigenous peoples. To do this, it ensures compliance with international standards through the implementation of due diligence processes and investigations, for example in the event of the use of a new product from natural sources by the R&D division.

*For more information, see Biodiversity Factsheet in the [Document Center](#).*

### **3.3. Training senior executives and operational managers on human rights**

With the aim of embedding Sanofi's human rights vision and approach into day-to-day responsibilities and developing employees' understanding of the importance of exercising human rights due diligence, the company provides tools and builds capacities in support of corporate and operational-level decision-makers.

Between 2009 and 2019, the company has been delivering inter-company human rights training sessions (via EDH), to foster employees' understanding and to promote respect for human rights as an integral part of their business conduct. To ensure the effective application of its internal policies, Sanofi organized also human rights training for its team of internal auditors covering Europe, Africa, the Middle East and South Asia.

A new human rights training action plan is being formalized in 2021, which will include an e-learning module for all employees and targeted training for specific functions (auditors, HR, buyers etc) or at-risk countries.

### 3.4. Stakeholder engagement

We believe that one of the key success factors in promoting respect for human rights in business is ensuring that all stakeholders are informed about their individual and collective rights, and are aware of their respective obligations towards one another. Sanofi is convinced that continuously and progressively responding to stakeholders' expectations on human rights constitutes an opportunity to improve both our human rights performance and our bottom line.

As instance, Sanofi regularly presents the deployment and monitoring of the vigilance plan to the trade unions, via a dedicated working group mandated by the Group Committee. Several meetings were organized to discuss the mapping of human rights risks in the workplace, the responsible purchasing approach, the alert mechanism and the assessment of supplier evaluations..

Aware of the importance of the issues at stake and concerned about building a solid and sustainable approach, Sanofi wanted to compare the content of its human rights approach, with the views of external stakeholders such as: the association Entreprises pour les Droits de l'Homme (an association of French companies working on the implementation of human rights vigilance approaches in companies, [www.e-dh.org](http://www.e-dh.org)), TfS (Together for Sustainability) or PSCI (Pharmaceutical Supply Chain Initiative). It has also shared its approach with French bodies such as AFEP, France Chimie and international bodies such as the World Bank and the World Business Council on Sustainable Development (WBCSD).

## 4. IMPLEMENT GRIEVANCE MECHANISMS

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### 4.1. For our workforce: An internal dedicated compliance helpline well known by employees

All Sanofi employees have access to a secured compliance helpline system available 24/7 with a dedicated web page and a toll-free number available in 28 languages. If employees have a concern or if they believe in good faith that a law, a rule or one of the principles in our Code of Ethics has been or is about to be violated, they can inform their superior or the Ethics & Business Integrity Department by using the compliance helpline. Employees will not be disciplined or discriminated against provided that they act in good faith and with no malicious intent; even if the facts reported prove to be inaccurate or no further action is taken. In the United States, a toll-free external compliance helpline has been set up for Sanofi employees in accordance with local regulations and practices.

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

In 2020, the E&BI department received 718 reports, of which, following investigations, a total of 352 reports were found to be founded. These resulted in 85 dismissals and resignations for misconduct.

## 4.2. For our patients, consumers and others

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

In its effort to be a patient-centric healthcare company, Sanofi partners with Patient Advocates and Groups (PAGs) to gather patients' inputs, in an active listening and open dialogue approach, helping Sanofi ensure that designed solutions genuinely address patients' underlying needs.

In addition, Sanofi appointed an internal ombudsman, independent of the procurement function, who is in charge of facilitating the resolution of work-related differences between Sanofi and our suppliers with neutrality, impartiality and confidentiality.

## 5. MONITORING OF THE HUMAN RIGHTS DUE DILIGENCE PROCESS:

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Steering of the human rights due diligence process is provided by the CSR Department, which ensures the coordination and implementation of various measures of the process. The CSR Department works closely with the HSE, Purchasing and Ethics & Business Integrity departments.

Monitoring of risk management measures and grievances mechanisms are provided by specific directions in charge. Sanofi discloses performance indicators on human rights, including those developed by the Global Reporting Initiative (GRI), in its integrated CSR reports.

*For monitoring indicators for each of the key issues identified, please refer to the corresponding factsheet.*

Within the scope of its commitment to the UN Global Compact Human Rights Principles, the company is also required to issue an annual Communication on Progress (COP), signed by the Senior VP of CSR and the CEO, to report Sanofi's progress to the Secretary General of the United Nations.

The United Nations Global Compact (UNGC) is a strategic public-private initiative for organizations committed to social and environmental sustainability. As a signatory to the UNGC since 2000, Sanofi is fully committed to upholding the 21 advanced criteria in connection with the Global Compact's ten principles in the areas of human rights, labor standards, environmental sustainability and anti-corruption. In 2015, Sanofi reached the UN Global Compact Advanced Level, which was renewed in 2019 and received an attestation of external assessment following the peer review of our Communication on Progress.

*For more information, see the [UN Global Compact, and Sanofi's Communication on Progress to the United Nations](#).*

**INDICATORS SELECTED BASED ON THE REPORTING FRAMEWORK LINKED TO THE KEY ELEMENTS OF UN GUIDING PRINCIPLES AND IN CORRESPONDANCE WITH THE 5 STEPS OF THIS REPORT**

<b>UN GUIDING PRINCIPLES REPORTING FRAMEWORK</b>	<b>CORRESPONDANCE WITH SECTIONS OF THIS REPORT</b>
<b>POLICY COMMITTEMENT</b> <b>A1</b> What does the company say publicly about its commitment to respect human rights?	<b>see I. Commitment (PAGE 2)</b>
<b>EMBEDDING RESPECT FOR HUMAN RIGHTS</b> <b>A2</b> How does the company demonstrate the importance it attaches to the implementation of its human rights commitment? <b>C1</b> Does the company have any specific policies that address its salient human rights issues and, if so, what are they?	<b>see I. Commitment and III. Risk-management measures</b>
<b>ASSESSING IMPACTS</b> <b>B1</b> Statement of salient issues <b>B2</b> Determination of salient issues <b>B3</b> Choice of focal Geographies <b>B4</b> Additional severe impacts <b>C2</b> What is the company’s approach to engagement with stakeholders in relation to each salient human rights issue? <b>C3</b> How does the company identify any changes in the nature of each salient human issues over time?	<b>see II. Human rights risks mapping (PAGES 3-4)</b>
<b>INTEGRATING FINDINGS AND TAKING ACTION</b> <b>C4</b> How does the company integrate its findings about each salient human rights issue into its decision-making processes and actions?	<b>see III. Risk-management measures (PAGES 4-5)</b>
<b>TRACKING PERFORMANCE</b> <b>C5</b> How does the company know it its efforts to address each salient human rights issue are effective in practice? <b>COMMUNICATING PERFORMANCE</b> Application of the UN Guiding Principles reporting framework	<b>see III risk-management measures (PAGES 4-5) and V. monitoring of human rights due diligence process (PAGE 6)</b>
<b>REMEDIATION</b> <b>C6</b> How does the company enable effective remedy if people are harmed by its actions or decisions in relation to a salient human rights issue?	<b>see IV grievances mechanisms (PAGE 6)</b>

*For more information, see in our [Documents Center](#):*

- *Human Rights in our Activities Guide*
- *Children’s Rights Factsheet*
- *Code of Ethics*
- *Social Charter*