



HUMAN RIGHTS IN OUR ACTIVITIES



CONTENTS



- Objectives of the document
- Sanofi's commitment to Human Rights
- The life cycle of drugs
-
- 1 Respecting Human Rights in drugs research & development
- 2 Respecting Human Rights in drugs approval process
- 3 Respecting Human Rights in drugs manufacturing & distribution
- 4 Respecting Human Rights in drugs sales & marketing
- 5 Respecting Human Rights at work
-
- Appendix
 - I. Human Rights: the foundation of Sanofi's CSR approach
 - II. Tools and policies related to Human Rights developed by Sanofi
 - III. Management processes and systems implemented at Sanofi
 - IV. Selection of reference treaties and instruments related to Human Rights
 - Selection of reference treaties and instruments related to Human Rights in the pharmaceutical industry
 - Selection of reference treaties and instruments related to Human Rights at work

SANOFI HUMAN RIGHTS STATEMENT

As a multinational healthcare company that is keenly aware of our social responsibility, Sanofi is committed to integrating respect for human rights into all our business operations and public positions. We are convinced that the principles of human rights apply to people, to nations and, by extension, to businesses. While States and governments have a duty to guarantee human rights through adequate laws and policies, we believe that businesses also have a role to play, which begins with identifying their own impact on human rights compliance and taking measures to prevent human rights violations.

For several years now, Sanofi has expressed and reiterated our commitment to the Ten Principles of the United Nations Global Compact and other international standards in the field of human rights. In addition, we have made it one of the cornerstones of our Corporate Social Responsibility (CRS) approach in line with the UN Guiding Principles on Business and human rights. We are committed to promoting respect for human rights principles in all areas of our business—from improving access to healthcare and upholding ethical standards to respecting fundamental employee rights and taking steps to preserve our planet.

Stakeholders today put increasing pressure on businesses to provide transparent information about their human rights practices, which also have the potential to significantly impact a company's business and reputation as well as to enhance trust between customers and corporations. We believe that responding to stakeholders' expectations and addressing these issues represents an opportunity to improve both our human rights performance and our bottom line.

One of the key success factors in promoting respect for human rights in business is ensuring that all stakeholders are fully aware of their individual and collective rights and are informed about their respective obligations towards one another. With this in mind, we have designed "Human Rights in Our Activities" to be a new stepping stone in Sanofi's approach.

I hope this document will prove to be a valuable tool for all Sanofi managers as we make progress towards the goal of ensuring that human rights are soundly integrated into all our operations worldwide.



Gilles Lhernould
Senior VP CSR

OBJECTIVES OF THE DOCUMENT

Sanofi has designed this “Human Rights in our Activities” document with three aims:

- Inform and familiarize all Sanofi employees with a focus on managers, with the key principles linked to the respect of Human Rights taking into account stakeholders expectations.
- Describe a selection of Sanofi good practices, at every step of drugs’ life cycle and in the workplace.
- Act as a reference point for all of Sanofi’s managers making decisions about potential issues linked to Human Rights in their daily activity.

Human Rights are the basic rights to which every individual is entitled to benefit without discrimination. They are universal, and thus apply to all human beings across boundaries and civilizations. They are inalienable, and thus cannot be taken away from individuals under normal circumstances. Lastly, they are interrelated, interdependent and indivisible in that improving or degrading one of them impacts directly or indirectly on all of the others.

Human Rights encompass a vast range of social, civil, economic, political and cultural rights of individuals or groups, such as:

- The right to life, liberty and security
- The right to health
- The right to work under equitable conditions
- The right to freedom from discrimination
- The right to a healthy environment.

They are expressed in several international reference treaties & instruments, such as the United Nations International Bill of Human Rights, the International Labour Organization (ILO) Conventions, the Declaration of Helsinki, etc. These treaties are ratified by States, which thus commit to assume a series of obligations to promote and protect Human Rights.

This document does not provide Sanofi’s employees and its other stakeholders with an exhaustive inventory of all Human Rights issues related to the pharmaceutical sector, nor with a single answer in case of identified risk or breach in Sanofi’s various commitments in this area.

SANOFI'S COMMITMENT TO HUMAN RIGHTS

Commitment No.1

Comply with local laws and international standards

- Sanofi ensures compliance with local laws and regulations and explicitly expresses its commitment to several international Human Rights reference treaties, instruments and initiatives¹ and to go beyond such frameworks when needed.

Commitment No.2

Define a reference framework and tools for all our organizations

- Sanofi has translated its commitment for Human Rights into internal reference tools and policies², to be considered as the minimum applicable standards should the local regulation be less stringent in any of the Group's countries of operation:



• Sanofi Code of Ethics



• Sanofi Social Charter



• Sanofi Suppliers Code of Conduct

- Sanofi has set up dedicated management processes and systems³ (such as Quality, Health, Safety and Environment – HSE –, Compliance, Drug Safety Monitoring, Internal Audit & Control and Risk Management) to answer patients' rights (right to health, right to access to information, etc.), employees' rights (right to work under equitable conditions, right to freedom from discrimination, etc.) and compliance with all internal reference tools and policies in place. In addition, since 2006, a warning system has been in place to allow early detection and handling of non-compliant behaviors.

Commitment No.3

Engage with our employees and empower our suppliers to reach Sanofi standards

- Self-assessments are performed and monitored using internal dedicated tools to evaluate in-house practices at global and country levels.
- Assessments have also been conducted by Sanofi since 2007 to evaluate the labour practices of Sanofi suppliers, monitor specific topics linked to Human Rights at work and ensure that the Sanofi Suppliers Code of Conduct rules are respected. In 2012, Sanofi implemented a new Procurement Risk Assessment Model which includes CSR and Human Rights criteria.

Commitment No.4

Raise awareness of Sanofi management teams

- Senior executives and heads of a range of functions at Sanofi have attended training sessions on Human Rights tailored specifically to the pharmaceutical industry.
- In order to bring Human Rights issues to the attention of as many employees as possible, the present document will gradually be deployed in all Sanofi organizations, at both corporate and local levels.

1 International reference treaties and instruments related to Human Rights can be found in Appendix iv

2 Further tools and policies related to Human Rights and developed by Sanofi can be found in Appendix ii

3 Further management processes and systems related to Human Rights and implemented at Sanofi can be found in Appendix iii

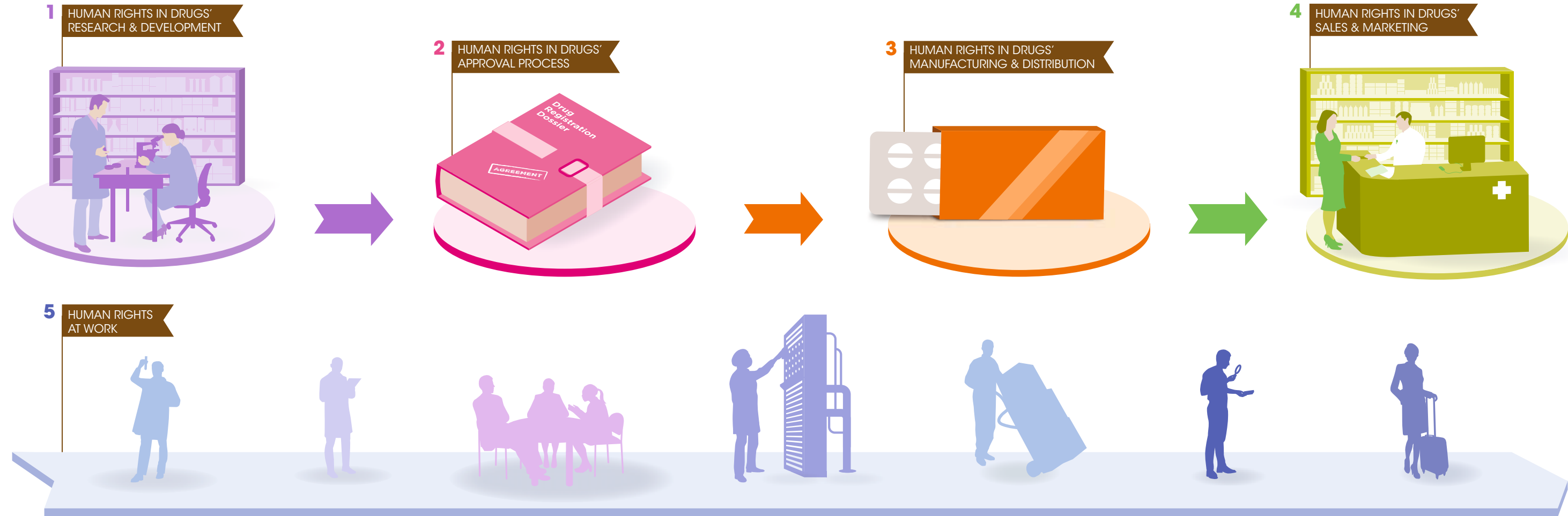
THE LIFE CYCLE OF DRUGS

Using a sectorial approach targeted on Human Rights in the pharmaceutical industry and in the workplace

Because Sanofi's core business is the development and commercialization of medicines and vaccines, we have designed "Human Rights in our Activities" to follow the four steps in the life cycle of a drug, with key human rights principles expected from the stakeholders and illustrations of best practices along the way.

This document also includes a section dedicated to Human Rights at work across various functions, which outlines the best practices a responsible employer should put in place all along the value chain.

We hope this document will provide a practical tool that reflects the reality of our day-to-day business activity.



1

HUMAN RIGHTS IN DRUGS RESEARCH & DEVELOPMENT

Pharmaceutical research and drug development is a long process which can take up to 15 years. It involves understanding the biological foundations of a disease at the level of genes, proteins and cells, mobilizing multidisciplinary teams to identify the right molecule for a future potential drug, and testing the new compound for safety and efficacy through laboratory tests and clinical trials.

Key stakeholders

-  Patients and patient associations
-  **NGO**
N GOs and non-profit organizations
-  Healthcare professionals and scientific community
-  Ethics committees
-  Local communities and citizens
-  Health authorities, governments and international institutions
-  Suppliers
-  Competitors

Human Rights linked to drugs research & development can be found in the international reference treaties, instruments and guidelines listed in Appendix IV of this document.

What are the stakeholders' expectations from the pharmaceutical industry?



Identify on a continuous basis today and tomorrow's unmet medical needs and commit to innovation for all patient categories

- ▶ Set up R&D governance to guarantee the ongoing acknowledgement of patients' care needs in the decision-making processes applied to the development and marketing of therapeutic solutions.
- ▶ Conduct innovative R&D programs on rare and neglected diseases and on diseases for which there are few or no existing treatment options.
- ▶ Adapt R&D programs to specific populations with unmet needs, such as younger or elderly patients or pregnant/breastfeeding women and safeguard their access to healthcare by developing adequate treatments and dosages.



Guarantee the rights, safety and integrity of participants in clinical trials

- ▶ Perform research on health interventions which are relevant to the needs and interests of the involved community, with the likelihood that the local population will benefit from the results of the research.
- ▶ Ensure that all research participants have provided genuine individual informed consent, with specific attention paid to vulnerable persons, and that their fundamental rights, such as the right to information on benefits and risks prior to giving consent, are respected and protected.
- ▶ Apply the highest ethical and safety standards to all clinical trials worldwide.



Prevent bio-piracy

- ▶ Respect the sovereignty of states and the intellectual property of indigenous communities when patenting and commercializing endemic resources identified through bio prospection of traditional practices and know-how.



Adopt an official position on the main topics in bioethics and monitor the risks and minimize potentially negative effects induced by the following processes

- ▶ Use of human embryonic stem cells¹, nanoparticles² and Genetically Modified Organisms (GMOs) for research purposes and therapeutic applications.
- ▶ Use of Human Biological Samples (HBS) (organs, tissues, cells bio fluids, etc.) for research purposes.
- ▶ Use of gene therapy for therapeutic applications and research.



Provide transparency and timely access to research data for scientific and patient communities

- ▶ Ongoing clinical trials and trial results should be disclosed within reasonable timeframes and made publicly available, regardless of negative outcomes, in order to provide patients with the opportunity to contact research centers, and to enable them and the research community to benefit from advancements in scientific and medical knowledge about drugs and diseases, thus avoiding unnecessary duplication of research.

¹ Human embryonic stem cells (hESCs) are cells involved in the processes of tissue regeneration and cell equilibrium (triggered in the event of surgery, injury and disease) for their ability to renew themselves and to differentiate into several types of cells.

² Nanoparticles are compounds which are the same size as most biological molecules and structures and have a wide variety of potential applications in biomedical, optical and electronic fields.

1

SOME EXAMPLES OF SANOFI'S GOOD PRACTICES

Human Rights



Right to health



Right to benefit from scientific progress



Right to access to information



Right to life, liberty

and security



Right to not be subjected without one's free consent to medical or scientific experimentation



Right to privacy

IDENTIFYING UNMET MEDICAL NEEDS FOR PATIENTS

Identify on a continuous basis today and tomorrow's unmet medical needs and commit to innovation by defining a R&D strategy aimed for all patient categories



Set up R&D governance to guarantee the ongoing acknowledgement of patients' care needs in the decision-making processes applied to the development and marketing of preventive and therapeutic solutions.

- Sanofi has created an advisory committee, the Benefit Risk Analysis Committee (BRAC), which has a systematic, continuous and formalized assessment of the benefit/risk balance of Sanofi R&D projects and marketed products. This process, which involves various experts in a cross-functional and cross-regional approach, leads to project development recommendations which can include:
 - Advice on development
 - Discussion of populations to be investigated
 - Endorsement or proposal for investigative/mechanistic studies for specific safety issues
 - Risk management recommendations
 - Go/no go decisions to pursue a drug's development, sometimes under the condition of implementing specific recommendations.

- Once the benefit/risk analysis has proven to bring benefit, a Portfolio Value Proposition Committee (PVP) helps to orientate the R&D project development strategy toward the best interest of the patient, and to optimize its market access conditions taking into account Evidence Based Medicine and the environment. The Committee collectively approves a final value proposition accounting for:
 - Unmet medical needs
 - Target population
 - Economic rationale for all stakeholders.
- The Sanofi Bioethics Committee, created in 2010, is a body chaired by the Corporate Chief Medical Officer and composed of internal and external experts from different disciplines with a three-fold mission:
 - Follow progress in life sciences and their applications
 - Define the Sanofi position in terms of authorized research on current and emerging bioethics issues in full knowledge of existing national and international regulations
 - Foster awareness of ethical issues related to emerging biomedical advances and provide expert advice and recommendations to Sanofi teams on formulation of internal standards and rules of conduct
 - Assist the Sanofi Risk Committee in fulfilling its corporate governance responsibilities by alerting it on bioethics risks.

GUARANTEEING HUMAN RIGHTS IN CLINICAL TRIALS AND PROVIDING TRANSPARENCY TO RESEARCH DATA

Guarantee the rights, safety and integrity of participants in clinical trials



Ensure that all research participants have provided genuine individual informed consent, with a specific focus on vulnerable persons, and that their fundamental rights, such as the right to information on benefits and risks prior to giving consent, are respected and protected.

● In 2012, Sanofi France produced a film for people who are considering taking part in a clinical trial, which explains the rules

of informed consent, gives trial-related information, and describes the documents that must be delivered to patients, the restrictions, and the importance of taking one's time to decide. The film also covers issues related to special cases (such as pediatric clinical trials). It can be seen on: <http://www.notre-recherche-clinique.fr/>

● Based on Sanofi's worldwide initiative to make consent terms more informative and adapted to the needs of patients participating in clinical trials, Sanofi Brazil developed a Free and Informed

Consent form in a comic book format. The initiative aims to present information in a more visual way to improve understanding among prospective participants. The model was approved in 2012 by the Brazilian Ethics Authorities (Institutional Ethics Committee) and the National Committee of Ethics in Research (CONEP) and will be implemented in health centers in 2013.

Provide transparency and timely access to research data for scientific and patient communities



Ongoing clinical trials and trial results should be disclosed within reasonable timeframes and made publicly available, regardless of negative outcomes, in order to provide patients with the opportunity to contact research centers and to enable the research community to benefit from advancements in scientific and medical knowledge about drugs and diseases, thus avoiding unnecessary duplication of research.

All available research data should be shared within reasonable timeframes with third parties such as health advocacy groups and medical data standards organizations to inform clinical care services and encourage scientific innovation.

● Sanofi is committed to publicly disclose information about its clinical study protocols and results, which are available online:

- Clinical study protocols: www.clinicaltrials.gov
- Clinical study results: http://www.sanofi.com/rd/essais_cliniques/nos_engagements/clinical_study_results.aspx

● In order to contribute to innovation in cancer treatment research, Sanofi is involved in Project Data Sphere, a subsidiary of the CEO Roundtable on Cancer, a non-profit organization launched in 2001 and currently chaired by Sanofi's Chief Executive Officer Christopher A. Viehbacher. Project Data Sphere is an open access platform that aims to share oncology clinical trial datasets to accelerate the understanding of this disease. It is designed to form a network of all the

stakeholders in the cancer community and provide the opportunity to use data to find solutions for cancer patients around the world through collaboration and advances in the development of new drugs and treatment approaches. Sanofi is one of the leading contributors to Project Data Sphere and will initially release four datasets, together with the protocols, case report forms, and data descriptors for the June 2013 Launch.

● As one of the world's leading authorities on rare diseases, Genzyme helps to pool knowledge for patients and healthcare professionals by establishing lysosomal storage disorders (LSDs) registries which are large, often multinational databases to which physicians contribute with useful clinical data.

2

HUMAN RIGHTS IN DRUGS APPROVAL PROCESS

After the development phase, a registration file containing the detailed results of all the research conducted on the compound and its formulation is submitted to local or regional health regulatory authorities in charge of assessing the efficacy and safety of the drugs. If analysis proves that the benefits outweigh the risks for a specific disease pattern, and if all regulatory requirements are fulfilled, the regulatory body authorizes the drug to be marketed.

The price of the drug is then either set by health authorities or independent committees based on diverse methods that vary according to countries and healthcare systems, such as the cost-effectiveness ratio, reference pricing (in countries where the prices of drugs are regulated), or set directly by the pharmaceutical company.

Key stakeholders

-  Patients and patient associations
-  Health authorities, governments and international institutions
-  Healthcare professionals and scientific community
-  NGO NGOs and non-profit organizations
-  Competitors

Human Rights linked to drugs approval process can be found in the international reference treaties, instruments and guidelines listed in Appendix IV of this document.

What are the stakeholders' expectations from the pharmaceutical industry?



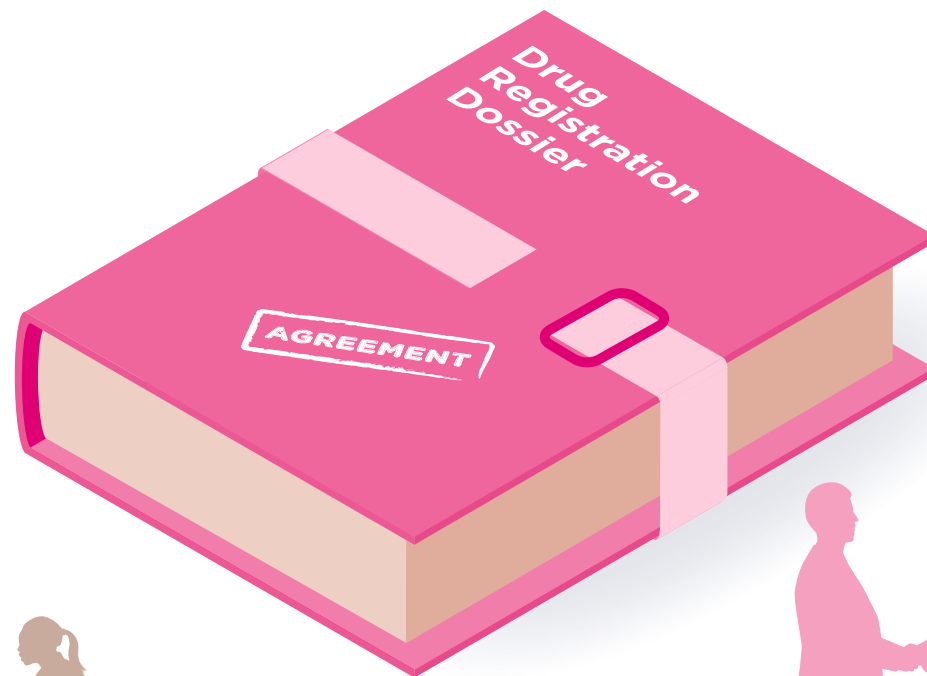
Commit to taking a responsible approach to lobbying

- Do not lobby directly or through industry associations for greater protection than is provided by international intellectual property regulations, hindering or delaying the entry of generic equivalents in markets where they have entered the public domain.
- Advocate with local decision makers to strengthen local health infrastructures, for example by supporting reforms in favor of expanded health coverage or reimbursement policies.



Fight against corruption and prevent conflicts of interest during interactions with third parties

- Adopt strict rules to fight against corruption and prevent conflicts of interest during interactions with third parties (health authorities, public officials, medical experts, etc.), for example to secure an outcome of the drugs' approval process which could ultimately represent a risk for patient safety.



Ensure drugs are affordable for lower-income and disadvantaged patients

- Coordinate with health authorities, reimbursement bodies and NGOs to put in place a pricing policy (including tiered pricing), to make existing drugs affordable for all patients, regardless of their purchasing power.
- Develop and market specific healthcare products and services for lower-income patients.
- Expand the offer of affordable quality products via generics.



Compensate for the length of the drug approval process and ensure the timely registration and availability of drugs where patients' needs have been identified

- In case of severe diseases for which there are no existing or satisfactory treatments, implement mechanisms to make promising experimental drugs available as soon as possible for patients or patient groups.
- Once a drug has been approved in a country, contribute to minimizing the registration delays in other countries to provide timely supply to local markets in need.
- Advocate with local and regional decision makers to strengthen regulatory bodies and harmonize regulatory elements.

2

SOME EXAMPLES OF SANOFI'S GOOD PRACTICES

Human Rights



Right to health



Right to benefit from scientific progress

MINIMIZING REGISTRATION DELAYS

Compensate for the length of the drug approval process and ensure the timely registration and availability of drugs where patients' needs have been identified



In case of severe diseases for which there are no existing or satisfactory treatments, implement mechanisms to make promising experimental drugs available as soon as possible for patients or patient groups.

- Sometimes a drug that has not yet received marketing approval could potentially help patients who face a critical and life-threatening health issue and have run out of other therapeutic options. In such cases, and if the benefit outweighs the risk, Sanofi proactively seeks regulatory approval to allow patients access to the experimental drug.

In France for example, a request for a temporary authorization for use (ATU) can be filed with the national drug safety agency (ANSM). Several Sanofi medicines such as Primaquine (for malaria), Brolene (for ophthalmological infections) and Myocrisin (for rheumatological diseases) have already been made available to specific patients through this process.

- Sanofi actively sought World Health Organization prequalification for a vaccine against meningococcus (Menomune®) in 2013. The prequalification project by the WHO aims to verify that medicines and vaccines awaiting marketing approval meet WHO standards of quality, safety and efficacy, setting up a fast track process for their procurement by UNICEF or other agencies and NGOs, and thus accelerating their distribution to patient communities across the world.

- Sanofi's CRUISE team (Content Re-Use Information System for Electronic Documents) is implementing a structured content management system to streamline existing processes for preparing, reviewing, approving and publishing information for regulatory agencies, public databases and external partners. This increased efficiency allows Sanofi to reduce market approval timelines, to increase the quality of the deliverables and to minimize risk through improved consistency. The CRUISE team won the 2012 Microsoft Life Sciences Innovation Award.

Once a drug has been approved in a country, contribute to minimizing the registration delays in other countries to provide timely supply to local markets in need.

- Sanofi has implemented an early registration program in Asia Pacific to respond to unmet patient needs by focusing on products that have already been approved in other countries.

ENSURING AFFORDABLE DRUGS

Ensure drugs are affordable for lower-income and disadvantaged patients



Coordinate with health authorities, reimbursement bodies and NGOs to put in place pricing policies (including tiered pricing) to make existing drugs affordable for all patients, regardless of their purchasing power.

- As part of the Group's commitment to the global fight against malaria, a parasitic disease which is the third leading cause of mortality among children in Africa, Sanofi's antimalarial medication, Coarsucom/Artesunate-Amodiaquine Winthrop (ASAQ Winthrop®), is sold according to a tiered-pricing policy. This includes "no profit-no loss" prices for public organizations (such as governments, NGOs, UNICEF, the Global Fund, etc.). The established public price, which is less than one dollar to treat an adult and 50 cents for a child, has become the standard reference price for new antimalarial drugs. Over 200 million units of ASAQ have been sold since this pricing policy was set up in 2007, with over 95% on a "no profit-no loss" basis.

- In Brazil, where patients have to cover their own treatment expenses for several drugs, access to reference medicines is directly tied to purchasing power. In 2012, Sanofi Brazil set up a tailored tiered-pricing policy for Lantus®, its insulin for the

treatment of diabetes, with the launch of the Alcance program. It aims at expanding Lantus® access to middle-class/lower-income patients by offering special conditions for the full range of products and services for diabetes therapy and consists of:

- Engaging with multiple stakeholders, to take into account the full treatment environment and reduce the overall treatment cost for cholesterol, hypertension and diabetes prescribed by the physician,
- Selectively targeting patients who could not afford Lantus® drug against Diabetes—for whom it represented more than 20% of their income
- Adjusting benefits to each patient's needs and income level.

This program currently has more than 12,500 active patients enrolled, representing almost 50% of all new Brazilian patients starting on Lantus® in 2012.

Develop and market specific healthcare products and services for lower-income patients.

- Nearly 63 million people in India have diabetes, of whom many are either undiagnosed or have uncontrolled diabetes because of poor compliance. To address this major health problem, Sanofi India Limited has launched AllStar™, the first Indian-manufactured, re-usable insulin pen. This innovative device, an adapted version

of Sanofi's Solostar® insulin pen which is already marketed in several countries, was developed through a three-year collaborative, cross-functional and multi-country team project to respond to patients' needs in emerging markets in terms of affordability and user convenience. AllStar™ was launched in October 2012 and will be progressively marketed in India during 2013.

Expand the offer of affordable quality products via generics.

- For several years, Sanofi has developed its generic portfolio (including auto-generics) through strategic acquisitions in order to reinforce the Group presence in the generics market, and to propose affordable quality products to answer local healthcare needs. The following recent examples illustrate the Group strategy to leverage its generic activities:

- Zentiva has become a key player in the whole European market with one of the major generic portfolio
- An agreement was signed with Medreich India to expand their well-established affordable generic products in Nigeria and other sub-Saharan countries for key therapeutic areas
- Sanofi signed in 2012 an agreement to acquire Genfar S.A., a Colombian pharmaceutical company that is a major player in Colombia and other countries in Latin America. Together with the previous acquisition of Medley, a leading generics company in Brazil, this reinforces our position in Latin America.

3

HUMAN RIGHTS IN DRUGS MANUFACTURING & DISTRIBUTION

Drugs manufacturing and distribution operations range from the production of active ingredient(s), the manufacturing of the finished product (including the procurement of excipients and raw materials from suppliers), as well as its storage and distribution to wholesalers, hospitals and retail pharmacies. These operations can be fully or partly managed by pharmaceutical companies or third parties.

Key stakeholders

- Patients and patient associations
- Healthcare professionals and scientific community
- Health authorities, governments and international institutions
- NGOs and non-profit organizations
- Local communities and citizens
- Suppliers
- Competitors

Human Rights linked to drugs manufacturing & distribution can be found in the several international reference treaties, instruments and guidelines listed in Appendix IV of this document.

What are the stakeholders' expectations from the pharmaceutical industry?



Manage provision of life-saving drugs to ensure a continuous supply in adequate quantities to patients in need

- ▶ In collaboration with local healthcare authorities and NGOs, identify and categorize the medicines and vaccines considered as life-saving drugs (without therapeutic equivalents for which substitutes would be difficult to find) in all geographical zones.
- ▶ Set up a product and supply policy designed to reduce to a minimum the risk of shortage of these drugs on the entire supply chain, and anticipate specific continuity plans in the event of a crisis (industrial accident, natural disaster, pandemic, etc.).
- ▶ Ensure a fair and ethical distribution of limited supplies, prioritizing treatment for the most vulnerable patients regardless of their pay status or geographical location.



Provide complete, updated and understandable information on drugs packaging and labeling

- ▶ Ensure that all essential scientific information required for the safe and effective use and dosage and for the correct storage and disposal of the product is communicated in an understandable way to patients on the packaging or through package inserts.
- ▶ Implement innovative measures on packaging to improve access to medical information for patients with special needs such as visual impairment or to avoid misuse by children.



Respond in a timely manner to humanitarian emergencies and provide access to healthcare for the injured, the displaced and evacuees

- ▶ Donate medicines and develop policies and processes to guarantee their appropriate distribution and administration, raising awareness of intermediaries (aid organizations, NGOs, etc.) to prevent their misuse, waste and diversion.
- ▶ Partner with experienced fieldworkers to carry out emergency and post-emergency access to healthcare operations for victims, for instance by providing scientific information or financial and logistical support.



Limit the impacts of production and distribution processes on the environment and local communities

- ▶ Deploy an environmental management system to assess, monitor and reduce to a minimum all potentially negative impacts of activity processes on the environment and local communities.
- ▶ Roll out a grievance mechanism for receiving and processing potential complaints raised by local communities.
- ▶ Apply a precautionary approach and define emergency procedures in case of industrial accidents.
- ▶ Identify all natural resources used in the production processes and coordinate with local stakeholders to implement specific programs for the protection of biodiversity and the preservation of the local economy and ecosystems.

3

SOME EXAMPLES OF SANOFI'S GOOD PRACTICES

Human Rights



Right to health



Right to access to information



Right to life, liberty and security



Right to dispose freely of one's natural resources / right to benefit from a healthy environment



Right to property

PROVIDING ACCESS TO HEALTHCARE

Respond in a timely manner to humanitarian emergencies and provide access to healthcare for the injured, the displaced and evacuees



Donate medicines and develop policies and processes to guarantee their appropriate distribution and administration to patients.

- The Sanofi Espoir Foundation, in charge of coordinating and validating all medicine and vaccine donations for humanitarian purposes from Sanofi's organizations worldwide, has established a set of guidelines modeled on those used in the World Health Organization, setting stringent criteria to evaluate each donation request submitted to the Group's subsidiaries.

These criteria include an on-the-ground needs assessment, the evaluation of the medical skills of the applicant organization, the adequacy of the drugs with the disease profile in the recipient country, an expiry date of at least 12 months upon arrival in the country, the presence of notices and labels written in an understandable language, and the availability of storage in a secure location with an access limited to authorized people.

Partner with experienced fieldworkers to carry out emergency and post-emergency access to healthcare operations for victims.

- Sanofi and the Sanofi Espoir Foundation provided support to partners to assist Syrian refugees, using various complementary channels:
 - The Sanofi Jordanian subsidiary also donated basic medicines (antibiotics, intestinal antiseptics, gastric protectors and anticoagulants) to the Jordan Health Aid Society, while Sanofi Turkey donated 15,000 boxes of medicines to the Turkish Ministry of Health: paranox (paracetamol), Lasix tb (furosimide) and Lasix amp (furosimide)
 - The Foundation supported the French Tulipe Organization with donations of medication for emergency kits, in collaboration with the NGO "Solidarité Syrie"
 - The Foundation provided financial support to UNICEF, which runs a wide care program, including a vaccination campaign for children
 - The Foundation also provided funds to "Gynaecology Without Borders", an association which has been supporting the health of refugee Syrian women in the Zaatari camp since August 2012. Its main actions involve monitoring pregnant women, providing adequate care in case of gynecological emergencies or sexual assault, and of course helping during deliveries.

PRESERVING LOCAL ENVIRONMENT

Limit the impacts of production and distribution processes on the environment and local communities



Identify all natural resources used in the production processes and coordinate with local stakeholders to implement specific programs for the protection of biodiversity and the preservation of the local economy and ecosystems.

● Artemisinin, one of the active ingredients in the Group's first-line malaria treatment (Coarsucam™/ Artesunate Amodiaquine Winthrop®—ASAQ), is extracted from the leaves of the sweet wormwood plant, which has traditionally been grown in China and Vietnam and, more recently, in Madagascar, East Africa and Southern Africa. Also used as a raw material by other pharmaceutical companies, artemisinin can at times be in short supply, potentially causing tensions among wormwood growers. Besides, the resulting fluctuating prices can induce farmers

to grow artemisinin to the detriment of other food crops, disrupting local food supply for populations. Sanofi took up the challenge of responding to the growing demand for the raw material used to make ASAQ®, while protecting the interests of agricultural communities and the local ecosystems where artemisinin is grown.

Sanofi established a collaborative program with the Institute for One World Health (IOWH) to manufacture semisynthetic artemisinin, developing a cutting-edge biological process to produce this ingredient on an industrial scale with the aim of supplementing agricultural production. The Bill and Melinda Gates Foundation awarded a \$42.6 million grant to the IOWH for this project, and Sanofi contributed with the Group's expertise in fermentation, chemical development techniques and industrial process optimization.

This innovative program is expected to secure a constant raw material supply whilst preventing price speculation, ensuring that sweet wormwood growers and extractors, who were consulted and involved all along the project, will receive proper compensation. It will also contribute to preserving biodiversity and agricultural equilibrium in zones of culture, and to slowing the emergence of malaria-resistant drugs.

Sanofi's production goal of 35 tons in 2013, and, on average, 50-60 tons by 2014 will be a significant contribution to the market demand, translating to between 80 and 120 million ACT treatments. This program will also ensure a steady and affordable price for the product, which will allow the company to set up a no profit-no loss production model and an adapted pricing policy for patients.

4

HUMAN RIGHTS IN DRUGS SALES & MARKETING

Drugs sales & marketing encompasses all actions directed to healthcare professionals to promote the recommendation, prescription, supply and administration of drugs, or those aimed at patients through direct-to-consumer advertising.

Key stakeholders

-  Patients and patient associations
-  Healthcare professionals and scientific community
-  Health authorities, governments and international institutions
-  Competitors
-  Employees and employee representatives

Human Rights linked to drugs sale & marketing can be found in the several international reference treaties, instruments and guidelines listed in Appendix IV of this document.

What are the stakeholders' expectations from the pharmaceutical industry?



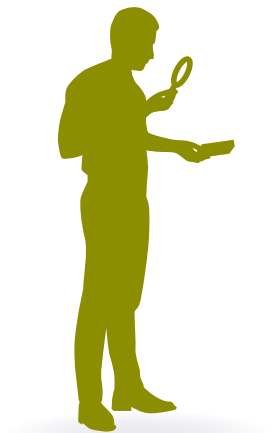
Fight against the selling of counterfeit products via clandestine or legal distribution channels, which present serious risks to the health and lives of patients

- Develop and use devices to protect products against counterfeiting.
- Implement mechanisms to detect counterfeit products at all stages of the pharmaceutical value chain.
- Cooperate with national and international enforcement organizations (governments, healthcare authorities, etc.) to dismantle illegal counterfeit drugs channels.
- Coordinate with authorities to support anti-counterfeit legislation and with third parties to raise awareness of public opinion on the risks related to counterfeit drugs.
- Draw special attention to low-income countries where counterfeit drugs are known to be rampant due to a lack of regulatory and enforcement mechanisms.



Raise awareness and promote the appropriate use of drugs' among healthcare professionals in charge of prescribing, administrating and selling drugs

- Deliver complete and clear information on product ingredients and the importance of adherence to treatments, especially for over-the-counter drugs or in countries where drugs can be sold without packaging and/or package inserts.
- Inform and train healthcare professionals about the risks related to medication errors or off-label use (whether involuntary or deliberate, such as product diversion for drug abuse).



Promote drugs in compliance with ethical marketing and advertising standards, minimizing the risks of inappropriate or excessive use of drugs by patients, or of misrepresentation of drugs' properties

- Ensure information is complete, objective, balanced, substantiated, accurate, up-to-date and reliable, whether it is delivered by pharmaceutical sales representatives to healthcare professionals or directly to patients and consumers.



Implement pharmacovigilance processes to identify and minimize the risks related to the use of drugs

- Detect, evaluate and monitor all adverse side effects of a drug from the development stage to after it has been released on the market, and implement the appropriate notification, changes in labeling or recall measures in case an imbalance in its benefit/risk profile in favour of the risk.
- In countries where drug safety and monitoring systems are limited, engage in local capacity building programs to help set up efficient pharmacovigilance "systems", and raise awareness among healthcare professionals about the importance of adverse drug reaction reporting.



Monitor the sales practices of pharmaceutical representatives and prevent any risk of corruption or conflict of interest designed to influence the prescribing behavior of healthcare professionals

- Set up and communicate a policy establishing ethical rules for the approach and practices which should be observed by pharmaceutical representatives during sales visits.
- Determine the limit of appropriate benefits and donations provided by pharmaceutical representatives to healthcare professionals (gifts, promotional materials, free drug samples, sponsored congresses and symposia, etc.).

4

SOME EXAMPLES OF SANOFI'S GOOD PRACTICES

Human Rights



Right to health



Right to access to information



Right to life, liberty and security

FIGHTING AGAINST COUNTERFEIT DRUGS

Fight against the selling of counterfeit products via clandestine or legal distribution channels, which present serious risks to the health and lives of patients



Develop and use devices to protect products against counterfeiting

● To reduce risks of falsification and enable a quick verification of product authenticity, Sanofi has developed the Sanofi Security Label (SASL). This specific label allows for visible verification (by distributors and patients) as well as invisible verification (which only Sanofi can determine). In 2012, Sanofi enlarged the application of this label to all new drugs around the world and is complying with new regulations from Turkey, China, Europe, etc.

● Sanofi also uses serial numbers and Data Matrix codes, two-dimensional barcodes printed on each product box that provide information such as a product code, a batch number and the expiration date, to improve the traceability and identification of its drugs and enable the detection of falsified or expired products.

Implement mechanisms to detect counterfeit products at all stages of the pharmaceutical value chain

● Sanofi has created a Central Anti-Counterfeit Laboratory in charge of analyzing all suspected drug samples (some 4,000 were analyzed in 2012). Relying on a dedicated team of specialists and state-of-the-art technologies, the Sanofi Central Anti-Counterfeit Laboratory pursues a three-fold mission:

- Perform direct technical examinations of packaging and product inserts as well as sophisticated chemical analyses on suspected samples
- Design and share new analytical methods with each

industrial site worldwide to allow them to apply the same criteria when examining and analyzing all suspected products

- Centralize so-called "identity cards" containing information about counterfeit products in a single, centralized database which enables Group-wide cross-referencing of various counterfeit drugs.

Cooperate on dismantling illegal counterfeit drugs channels with national and international enforcement organizations such as:

- the World Customs Organization (WCO)
- the International Criminal Police Organization (INTERPOL)
- National and international health agencies.

Coordinate with authorities to support anti-counterfeit legislation and with third parties to raise awareness of public opinion on the risks related to counterfeit drugs.

● Sanofi has worked with the Council of Europe, an international organization comprising 47 member states in Europe whose aim is to protect Human Rights in Europe, for the adoption of the Medicrime Convention in December 2010, the first binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health.

RAISING AWARENESS AND MINIMIZING THE RISKS RELATED TO THE USE OF DRUGS

Raise awareness and promote the appropriate use of drugs among healthcare professionals in charge of prescribing, administrating and selling drugs



Inform and train healthcare professionals about the risks related to medication errors or off-label use (whether involuntary or deliberate, such as product diversion for drug abuse)

- Patients suffering from mental disorders, which can include a variety of disorders such as depression, anxiety, addictions and schizophrenia, are often neglected in developing countries as a consequence of inadequate medical resources

and stigma. Patients often favor traditional healing to cure psychiatric symptoms which they associate with religious or magical origins. To address this issue, Sanofi's Access to Medicines department has supported a Pilot Program focusing on schizophrenia in Nouadhibou, Mauritania, in association with the Mauritanian Ministry of Health, aimed at developing access to mental healthcare through:

- Suitable training in Mental Health services: 37 health professionals trained

- Educational content on the screening and diagnosis of mental disability: information has been developed and used by several NGOs to reach more than 1,000 people
- Since the start of this program, 452 patients with schizophrenia (of a total estimated population of 1,000 patients with schizophrenia in Nouadhibou) have taken part in the program (an improvement of 48% in 3.5 years). Following these results, the program was extended to other provinces of Mauritania to include epilepsy and other major mental disorders in addition to schizophrenia.

Implement pharmacovigilance processes to identify and minimize the risks related to the use of drug use



In countries where drug safety and monitoring systems are limited, engage in local capacity building programs to help set up efficient pharmacovigilance "systems", and raise awareness among healthcare professionals about the importance of adverse drug reaction reporting.

- Sanofi and the Drugs for Neglected Diseases initiative (DNDi) have developed a field-monitoring program to gather quality information in malaria endemic countries about the safety and efficacy of Sanofi's antimalarial combination, ASAQ Winthrop®. With more than 20,000 malaria treatment episodes expected to be recorded in more than 12 countries, this is one of the most ambitious drug monitoring program ever launched in Africa.

- In 2011, Sanofi engaged in establishing and supporting the creation of a newly developed pharmacovigilance system in Egypt, through a partnership with the Egyptian Pharmacovigilance Center (EPVC). With the aim of increasing pharmacovigilance awareness among the medical community and developing new regulatory guidelines matching international standards, the project delivered:

- Sanofi-sponsored EPVC trainings for Alexandria Pharmacists in October 2011
- Sanofi-sponsored trainings for EPVC staff and printed out the "Yellow Cards" to be used by healthcare professionals to report potential pharmacovigilance information to EPVC
- The first Egyptian pharmacovigilance guidelines for Marketing Authorization Holders (MAHs) of Human Pharmaceutical products (Drugs and Biological) were released in January 2012

- In Hungary, where reporting rates of adverse drug reactions were 2.5 times lower than other EU countries, Sanofi set up a specific research program in 2012, involving over 1,000 physicians and 1,200 patients, to investigate the root cause of this underreporting. The results of the research highlighted that lack of medical knowledge—due to inappropriate education—was one of the main causes of physicians' resistance to this otherwise compulsory reporting. Consequently, Sanofi initiated an educational campaign on pharmacovigilance, including undergraduate training, lectures in universities and free e-learning for healthcare professionals.

5

HUMAN RIGHTS AT WORK

The right to work under equitable conditions is a fundamental human right and also a way for individuals to participate in their community and wider society. Human Rights at work are recognized in a number of international reference treaties as well as by local laws and regulations.

Providing a workplace where Human Rights are respected equally for all employees represents a vast array of challenges for an employer, and most of these challenges can be addressed through Human Resources and Social Relations policies and processes. Beyond internal policies and processes, companies also need to closely monitor the labor practices of business partners such as suppliers, subcontractors or security forces to ensure the respect and compliance of Human Rights across the supply chain.

Key stakeholders

 Governments and international institutions

 Employees and employee representatives

 Suppliers

Human Rights at work can be found in the several international reference treaties, instruments and guidelines listed in Appendix IV of this document.

What are the stakeholders' expectations from the pharmaceutical industry?



Respect freedom of association and collective bargaining

- ▶ If trade unions do not exist in the area of operation, facilitate alternative measures to allow employees to organize employee-only meetings to discuss concerns regarding their working conditions.
- ▶ Ensure that company representatives engage in collective bargaining and hold regular consultations with authorized workers' representatives.
- ▶ Provide reasonable notice of future changes in operations that will affect employment at the company.



Fight against child labor

- ▶ Put in writing the minimum applicable working age in the company and make this information clear to recruiters and hiring agencies.
- ▶ Refer to the national legal minimum working age as a standard in countries where it is higher than the one set by the company.
- ▶ Accommodate young workers who also attend school with schedule adjustments.
- ▶ Map employees by age and task and ensure that no child or young worker is engaged in tasks that could prove to be mentally, physically, socially or morally dangerous and harmful to them.



Eliminate all forms of forced and bonded labor

See description on next page.



Apply a responsible compensation policy

- ▶ Provide wages which are sufficient to cover employees' basic needs.
- ▶ Issue payslips on a regular basis, which include wages and all charges, calculations, etc. and are clear to understand.
- ▶ Contribute to national unemployment, sickness and pension benefit schemes.



Prohibit all forms of discrimination

See description on next page.



Guarantee occupational Health and Safety and protect from physical and psychological violence

- ▶ Implement an occupational Health and Safety risk management system to continually assess potential occupational injury and health risks for all workers on site.
- ▶ Take the appropriate preventive and protective measures and control their implementation, such as continually informing and educating on-site workers on potential Health and Safety hazards and providing them with free and adequate protective equipment.



Respect employee privacy

- ▶ Respect the right to employee privacy in recruitment procedures.
- ▶ Prohibit abusive and intrusive monitoring practices in the workplace.
- ▶ Respect the right to employee privacy regarding the storage and use of personal information and access rights according to applicable law.



Commit to workforce development

- ▶ Assess employees' performance and ability to keep pace with ongoing business challenges through a formalized process, and identify their individual development needs accordingly.
- ▶ Provide regular education and development opportunities to all employees, regardless of their age, status or any other discriminatory criteria.



Manage Human Rights risks when dealing with suppliers

- ▶ Raise awareness and obtain commitment of suppliers and subcontractors on the principles of Human Rights at work, especially in countries where they are not guaranteed by local labor law.
- ▶ Set up a secure control environment to monitor suppliers and subcontractors' labor practices and monitor corrective action plans when necessary.
- ▶ Impose realistic deadlines to suppliers, thus preventing to indirect encouragement to breach labor standards in order to deliver.



5

SOME EXAMPLES OF SANOFI'S GOOD PRACTICES

Human Rights



Right to freedom from forced or bonded labor



Right to freedom from discrimination

ELIMINATING ALL FORMS OF FORCED AND BONDED LABOR

“Forced labor occurs where work or service is exacted by the State or by individuals who have the will and power to threaten workers with severe deprivations, such as withholding [...] wages or restricting peoples’ movements. Intimidation can range from revealing the victim’s illegal status with the police, to physical assault and sexual abuse.” *

- Sanofi’s commitment to abolish forced or compulsory labor is expressed in:
 - Sanofi’s Social Charter (principles 2, 8, 9, 11 and 12)
 - Sanofi’s Code of Ethics (page 7: “Message from Global Compliance”)
 - Sanofi’s Suppliers Code of Conduct (“Forced Labor”).

This commitment translates into the following HR practices and processes, which must be implemented by all the Group’s organizations. Some aspects may be adapted to local legal requirements, but never abbreviated nor made less restrictive.

Ensure that all job applicants and employees understand their general working terms and conditions

- Whatever the type of document provided (contract or other document), the following general terms of employment must be presented clearly to all applicants before accepting a position, the terms must be in their local language, and easily accessible to all employees: wages, working hours including overtime policy, leave and internal mobility policy, contract duration and contract termination policies.
- Special attention must be paid to vulnerable populations like lower-income, migrant, unskilled or illiterate workers.
- These commitments must be communicated to hiring agencies if relevant, and their implementation monitored by the company to guarantee compliance.

Monitor working hours and compensate overtime

- Employees’ working hours must be limited to the maximum authorized in the country of operation and employees must be entitled to adequate and mandatory rest periods.
- Employees must not be coerced to work involuntary overtime hours by the use of threat or force or by having an unrealistic workload imposed upon them.
- Overtime must be monitored and compensated with transparency. Employees must be allowed to refuse to work overtime without any threat of punishment.

Forbid unreasonable restrictions on workers’ human basic liberties, such as the fulfillment of their essential needs and the freedom of movement

- Employees must have the right to fulfill their essential needs during working hours, such as the use of toilets, access to drinking water and the use of external medical facilities if needed.
- Under no circumstances must Human Resources and operational managers:
 - Withhold wages and/or pay employees in a non-timely manner
 - Withhold original ID, passports or other travel documents in employee files
 - Withhold letters of release in case the employee wishes to apply for another position inside the company in accordance with the Group’s mobility commitment, or to leave his position permanently after giving reasonable notice.

Prevent debt-induced labor, i.e. situations where employees are compelled to work overtime or to remain in their position to repay a debt they have contracted with the company

- Under no circumstances must Human Resources and operational managers:
 - Provide loans or salary advancements to employees in exchange for a labor service
 - Provide loans, salary advances or equipment advances to employees and require them to remain within the company until repayment is complete.

PROHIBITING ALL FORMS OF DISCRIMINATION



"Discrimination in employment or occupation may be direct or indirect. Direct discrimination exists when laws, rules or practices explicitly cite a particular ground, such as sex, race, etc. to deny equal opportunities. Indirect discrimination occurs where rules or practices appear on the surface to be neutral but in practice lead to exclusions."*

"Equality at work means that all individuals should be accorded equal opportunities to develop fully the knowledge, skills and competencies that are relevant to the economic activities they wish to pursue."*

- Sanofi's commitment to fight against discrimination is expressed in:
 - Sanofi's Social Charter (principles 2, 8, 9, 11 and 12)
 - Sanofi's Code of Ethics: (page 7: "Message from Global Compliance" and pages 8 & 9: "Respect for the individual")
 - Sanofi's Suppliers Code of Conduct ("Equal opportunities")
 - Sanofi CSR Diversity Policy

This commitment translates into the following HR practices and processes, which must be implemented by all the Group's organizations. Some aspects may be adapted to local legal requirements, must never be abbreviated nor made less restrictive.

Commit to fight discrimination by stating and communicating to all employees that no distinction, exclusion or preference must be made on the basis of race, ethnic background, color, social origin, regional or national background, gender, religion, sexual orientation, marital status, family responsibilities, political opinion, age, disability, illness, trade-union membership or activity and other personal characteristics

- All Human Resources or operational managers must deploy the Sanofi Diversity Policy as the reference framework and principles governing non-discrimination, equal opportunities and respect for the individuals in the company.
- All employees must be clearly informed of the possibility to report violations of one or more of the rules and principles laid down in the Code of Ethics and in the Sanofi Diversity Policy, and refer themselves to the Complaint management policy.

Implement Human Resources processes based on this non-discrimination engagement guaranteeing that recruitment, remuneration, conditions of employment, access to training and advancement, granting of company benefits and services, and termination of the employment relationship are based exclusively on objective criteria such as qualifications, skills and experience. For instance, regarding recruitment:

- Employment advertisements, whether internal or external, must never reference discriminatory criteria such as race, gender or age (exceptions made for specific protection reasons, for example to indicate the minimum age required for the performance of potentially difficult tasks).

- Recruiting managers must never require job applicants or employees to take pregnancy tests, undergo abortions, or sign agreements not to become pregnant.
- Special attention must be paid to vulnerable groups like lower-income, migrant, unskilled or illiterate workers.
- The processes described above must be communicated to hiring agencies if relevant, and their implementation monitored by the company to guarantee compliance.

Adapt the work environment to guarantee appropriate working conditions to vulnerable groups or to employees who, for reasons such as gender, age, disability, family responsibilities or social and cultural status, require special protection or assistance

- All Human Resources or operational managers must establish a list of job functions that may be potentially harmful to the health, safety or moral development of young workers and children, and ensure that they are not assigned to such jobs.
- Adjustments to schedules must be arranged to allow young workers to attend school in parallel with their job when necessary.
- Disabled employees must benefit from specific measures aiming to adapt their working stations to guarantee their physical comfort.
- Pregnant women or employees suffering from health conditions must be granted flexible working hours and more frequent breaks, and the right to attend medical visits during their working hours.

*Source: "The International Labour Organization's Fundamental Conventions" (2002).

APPENDIX

I.

HUMAN RIGHTS: THE FOUNDATION OF SANOFI'S CSR APPROACH

Please refer to the Download Center:
Human Rights Factsheet
<http://csr.sanofi.com/downloadcenter>

II.

TOOLS AND POLICIES RELATED TO HUMAN RIGHTS DEVELOPED BY SANOFI

- The Code of Ethics
- The Social Charter
- The Suppliers Code of Conduct
- The Good Research Practices
- The Interacting with Patients Association Global Principles
- The Good Clinical Practices
- The Health, Safety and Environment (HSE) Policy
- The Good Promotional Practices
- The Good Marketing and Scientific Information

- The Charter on the Ethical Principles Governing Scientific / Medical Publications for the Group's Techniques / Compounds / Vaccines
- The Conflict of Interest Directive
- The Risk Committee Charter
- The Best Practices and Recommendations for Model Compliance Committee Charter
- The Code of Financial Ethics
- The Anti-corruption Policy
- The IT Audit Charter
- The Data Protection Charter
- The Code of Internal Control Principles

III.

DEALING WITH HUMAN RIGHTS WITHIN EXISTING MANAGEMENT PROCESSES AND SYSTEMS IMPLEMENTED AT SANOFI

Please refer to the 2012 Corporate Social Responsibility (CSR) Report – Ethics, Human Rights (page 10)
http://en.sanofi.com/Images/32419_CSR_Report_2012.pdf

IV.

SELECTION OF REFERENCE TREATIES, INSTRUMENTS AND INITIATIVES RELATED TO HUMAN RIGHTS

The United Nations International Bill of Human Rights

- The Universal Declaration of Human Rights (1948)
- The International Covenant on Civil and Political Rights (1966)
- The International Covenant on Economic, Social and Cultural Rights (1966)

The Guiding Principles on Business and Human Rights (endorsed by the United Nations Human Rights Council in 2011)

The 8 Fundamental Conventions of the International Labour Organization (ILO)

- Freedom of Association and the Effective Recognition of the Right to Collective Bargaining
 - Freedom of Association and Protection of the Right to Organise Convention, 1948 (No. 87)
 - Right to Organise and Collective Bargaining Convention, 1949 (No. 98)

- Elimination of all Forms of Forced and Compulsory Labour
 - Forced Labour Convention, 1930 (No. 29)
 - Abolition of Forced Labour Convention, 1957 (No. 105)
- Effective Abolition of Child Labour
 - Minimum Age Convention, 1973 (No. 138)
 - Worst Forms of Child Labour Convention, 1999 (No. 182)
- Elimination of Discrimination in Respect of Employment and Occupation
 - Equal Remuneration Convention, 1951 (No. 100)
 - Discrimination (Employment and Occupation) Convention, 1958 (No. 111)

The Guidelines for Multinational Enterprises of the Organization for Economic Co-operation and Development (2011 update)

The 10 Principles of the United Nations Global Compact (2004)

The International Standard ISO 26000

SELECTION OF REFERENCE TREATIES AND INSTRUMENTS RELATED TO HUMAN RIGHTS IN THE PHARMACEUTICAL INDUSTRY

1 DRUGS RESEARCH & DEVELOPMENT

Identify on a continuous basis today and tomorrow's unmet medical needs and commit to innovation for all patient categories

- UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (2008)
- The European Directive on medicinal products for pediatric use (entry into force in 2007)

Guarantee the rights, safety and integrity of participants in clinical trials

- IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) Code of Practice (2012)
- Declaration of Helsinki (as amended in 2008)
- WHO Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products (1995)
- ILO (International Labour Organization) Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984)

Prevent bio piracy

- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (2011)
- UN Declaration on the Rights of Indigenous Peoples (2007)
- TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights, into effect in 2005)

Adopt an official position on the main topics in bioethics, monitor the risks and minimize the potentially negative effects associated with bioethics processes

- HUGO (Human Genome Organization) Statement on Stem Cells (2004)
- Universal Declaration on the Human Genome and Human Rights (1997)
- European Convention on Human Rights and Biomedicine "Oviedo Convention" (1997)

Provide transparency and timely access to research data for scientific and patient communities

- WHO Trial Registration Data Set
- WHO International Standards for Clinical Trial Registries (2012)

2 DRUGS APPROVAL PROCESS

Commit to taking a responsible approach to lobbying, fight against corruption and prevent conflicts of interest during interactions with third parties

- UN Convention against Corruption (2000)
- OECD (Organization for Economic Co-operation and Development) "Ten Principles for Transparency and Integrity in Lobbying" (2009)
- OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions & Related Documents (2011)

Compensate for the length of the drug approval process, ensure the timely registration and availability of drugs where patients' needs have been identified and ensure drugs are affordable for lower-income and disadvantaged patients

- WHO Access to essential medicines as part of the right to health (2011)
- OHCHR (Office of the High Commissioner for Human Rights) Human Rights Guidelines for Pharmaceutical companies in relation to Access to Medicines (2008)

3 DRUGS MANUFACTURING & DISTRIBUTION

Manage provision of life-saving drugs to ensure a continuous supply in adequate quantities to patients in need

- WHO Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care (1996)

Provide complete, updated and understandable information on drugs packaging and labeling

- WHO Good Manufacturing Practices for pharmaceutical products: main principles (2011)
- WHO Good Distribution Practices for pharmaceutical products (2010)
- ONCDP (Office of National Drug Control Policy Guidelines) on Proper Disposal of Prescriptive Drugs (2007)

Respond in a timely manner to humanitarian emergencies and provide access to healthcare for the injured, the displaced and evacuees

- WHO Guidelines for Medicine Donations (revised 2010)

Limit the impacts of production and distribution processes on the environment and local communities

- Permanent Peoples' Tribunal Charter on Industrial Hazards and Human Rights (1994)
- Rio Declaration on Environment and Development (1992)
- UNECE (United Nations Economic Commission for Europe) Convention on Environmental Impact Assessment in a Transboundary Context (1991)

4 DRUGS SALES & MARKETING

Fight against the selling of counterfeit products via clandestine or legal distribution channels, which present serious risks to the health and lives of patients

- Council of Europe – The Medicrime Convention (2010)
- Europharm Forum – Framework for a Guide on Counterfeit Medicines for Pharmacists (2009)
- WHO Guidelines for the Development of Measures to Combat Counterfeit Medicines (1999)

Raise awareness and promote the appropriate use of drugs among healthcare professionals in charge of prescribing, administering and selling drugs & treatments and promote drugs in compliance with ethical marketing & advertising standards, minimizing the risks of inappropriate or excessive use of drugs by patients or of misrepresentation of drugs' properties

- IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Pharmaceutical Marketing Practices (2012)
- WHO Ethical Criteria for Medicinal Drug Promotion (1988)

Implement pharmacovigilance processes to identify and minimize the risks related to the use of drugs

- UN Guidelines for Consumer Protection (1999)
- CIOMS (Council for International Organizations of Medical Sciences) Reporting Adverse Drug Reactions (1999)

Monitor the sales practices of pharmaceutical representatives and prevent any risk of corruption or conflict of interest designed to influence the prescribing behavior of healthcare professionals

- PhRMA Code on Interactions with Healthcare Professionals (2009 revision)

SELECTION OF REFERENCE TREATIES AND INSTRUMENTS RELATED TO HUMAN RIGHTS AT WORK

5 HUMAN RIGHTS AT WORK

Respect of freedom of association and collective bargaining

- ILO (International Labour Organization) Termination of Employment Convention, 1982 (No. C158)
- ILO (International Labour Organization) Workers Representatives Convention, 1973 (No. C135)
- ILO (International Labour Organization) Right to Organise and Collective Bargaining Convention, 1949 (No. C98)*
- ILO (International Labour Organization) Freedom of Association and Protection of the Right to Organise Convention, 1948 (No. C87)*

Fight against child labor

- UNICEF & Global Compact: Children's Rights and Business Principles framework (2012)
- ILO & IPEC (International Programme on the Elimination of Child Labour) Guidelines for Developing Child Labour Monitoring Processes (2005)
- ILO (International Labour Organization) Worst Forms of Child Labour Convention, 1999 (No. C182)*
- ILO (International Labour Organization) Minimum Age Convention, 1973 (No. C138)*

Eliminate all forms of forced and bonded labor

- ILO (International Labour Organization) Combating Forced Labour: A Handbook for Employers and Business (2008)
- UN Convention on the Protection of the Rights of All Migrant Worker and Members of Their Families (1990)
- ILO (International Labour Organization) Abolition of Forced Labour Convention, 1957 (No. C105)*
- ILO (International Labour Organization) Forced Labour Convention, 1930 (No. C29)*
- ILO (International Labour Organization) Recommendation concerning Indirect Compulsion to Labour, 1930 (No. R35)

Apply a responsible compensation policy

- ILO (International Labour Organization) Workers with Family Responsibilities Recommendation (R165, 1981), Article 30 (2)
- ILO (International Labour Organization) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy (1977), Article 34
- ILO (International Labour Organization) Minimum Wage Fixing Convention (C131, 1970), Article 3
- ILO (International Labour Organization) Protection of Wages Convention (C95, 1949), Article 14

Prohibit all forms of discrimination

- UN Convention on the Elimination of All Forms of Discrimination against Women (1979)
- ILO (International Labour Organization) Discrimination (Employment and Occupation) Convention, 1958 (No. C111)*
- ILO (International Labour Organization) Equal Remuneration Convention, 1951 (No. C100)*
- UN Convention on the Rights of Persons with Disabilities (2007)
- UN Declaration on the Rights of Indigenous Peoples (2007)

Guarantee occupational Health and Safety and protect from physical and psychological violence

- BS OHSAS 18001 Occupational Health and Safety Management Systems Requirements Standards
- ILO (International Labour Organization) Prevention of Major Industrial Accidents Convention, 1993 (No. C174)
- ILO (International Labour Organization) Occupational Safety and Health Convention, 1981 (No. C155)

Respect employee privacy

- ILO (International Labour Organization) Code of Practice: Protection of Workers Personal Data (1997)
- UN Guidelines for the Regulation of Computerized Personal Data Files (1990)
- ICC (International Chamber of Commerce) Policy Statement: Employee privacy, data protection and Human Resource

Commit to workforce development

- UN International Covenant on Civil and Political Rights (1966), Article 1.1
- UN International Covenant on Economic, Social and Cultural Rights (1966), Article 6.2
- Voluntary Principles on Security and Human Rights (multi-stakeholder initiative, 2000)

Manage Human Rights risks when dealing with suppliers

- See texts above

*These ILO Conventions have been identified as fundamental, and are at times referred to as the core international labor standards.

BUILDING “HUMAN RIGHTS IN OUR ACTIVITIES”



BUILDING THIS DOCUMENT IN A BOTTOM-UP, COLLABORATIVE APPROACH MANAGED BY CSR EXCELLENCE

In order to take into account the extent and nature of Human Rights issues faced by Sanofi, this document was built in two steps **using a cross-functional and participative approach including 37 representatives from more than 12 internal functions.**

STEP 1

Five working groups were established to address potential human rights issues in the drug’s lifecycle or in the workplace. Sanofi best practices were identified by each working group.

List of Corporate functions that participated in the working groups:

- **CSR Excellence**
- **CSR** (Access to Medicines, Diversity, Sanofi Espoir Foundation)
- **Corporate affairs** (Procurement, Corporate Economic Security - Counterfeit, Environment, Health and Safety)
- **Global compliance**

- **Global operations** (Intercontinental, Japan-Pacific Region, PSI-patient centered solutions)
- **Global quality** (Risk Management & Intelligence, Global Quality Organization, Training and Communication)
- **Human Resources**
- **Industrial Affairs** (Operational Units – Chemistry & Biotechnologies)
- **Internal Audit**
- **Legal**
- **Public Affairs**
- **R&D** (Administration & Management, Compliance, Global Medical Operations, Global Pharmacovigilance & Epidemiology, Global Regulatory Affairs)

STEP 2

In order to ensure that this document reflects the reality of our day-to-day business activity, a test working group was set up including Sanofi Managers to proofread the final version of the document and to assess its relevance and clarity.

List of countries and functions that participated in the test working group:

- **Brazil** (R&D)
- **France** (Corporate Industrial Affairs, Sanofi Pasteur, Corporate CSR Management Risks and Corporate Communication)
- **Germany** (Human Resources)
- **Singapore** (Diversity)
- **UK** (Compliance)
- **US** (Communication)

Photo credits: Benoît Rajau, Gabo Morales / CAPA Pictures • Illustration: IP3 / Comillus

This document was designed and produced by the Sanofi CSR Excellence Department of Sanofi with the support of Deloitte and the communication company BABEL.



This document is conform to Web content accessibility standards, WCAG 2.0, and is certified ISO 14289-1. Its design enables people with motor disabilities to browse through this PDF using keyboard commands. Accessible for people with visual impairments, it has been tagged in full, so that it can be transcribed vocally by screen readers using any computer support. It has also been tested in full and validated by a visually-impaired expert. E-accessible version by Ipedis.

Contacts:

Didier Terrolle

Tatiana Campos Rocha

email: corporate-responsability@sanofi.com



Each day, across the globe, Sanofi's 110,000 employees are working to protect your health and improve access to healthcare for as many patients as possible. As a healthcare company, Sanofi places quality, safety, ethics and respect for the planet at the heart of our business.

