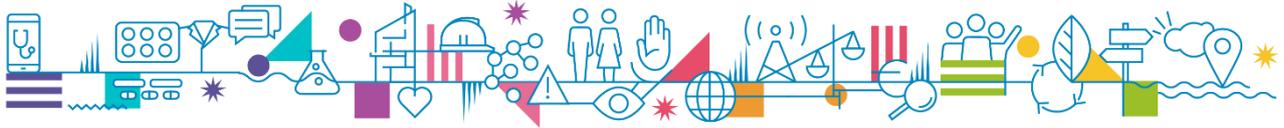


Duty of Care Vigilance Plan

2019-2020 Fiscal Year



The elements presented below have been prepared by the working group, comprised of the CSR, Purchasing, Legal and Compliance Departments, assigned to meet the legal obligations arising from the Duty of Care Act. The following elements have been presented to and validated by members of the Executive Committee, sponsors of project implementation.

Regulatory framework

In accordance with the provisions of the French Commercial Code, companies employing more than 5,000 employees in France or more than 10,000 employees worldwide are subject to French Law No. 2017-399 of 20 March 2017 on the Duty of Care. The scope of the Act includes: Activities of the parent company, subsidiaries and controlled companies within the meaning of Article II of Article L 233-16 of the French Commercial Code as well as the activities of subcontractors or suppliers with whom an established commercial relationship is maintained.

Article L 225-102-4 of the French Commercial Code obliges companies to draw up a duty of care vigilance plan to identify and prevent serious risks and violations of human rights and fundamental freedoms, the health and safety of persons and the environment resulting from their activities as well as those of their subcontractors and suppliers.

The vigilance plan must include:

- Risk mapping focused on human rights and fundamental freedoms, human and environmental health and safety;
- Regular assessment procedures of the situation of all Group subsidiaries, subcontractors and suppliers;
- Appropriate actions to mitigate risks or prevent serious harm;
- Alert and alert collection mechanism;
- Monitoring of the measures implemented and evaluation of their effectiveness.

Governance and management of vigilance plan

Since the publication of the Duty of Care Act, the Servier Group has set up a working group, made up of the CSR, Purchasing, Legal and Compliance Departments, to meet the obligations arising from this law.

The progress of the project, the actions implemented and the resulting outcomes are regularly presented to the Group Risk Committee and the Executive Committee.

Identification methodology and prioritization

With the help of an external firm, the working group identified the best possible approach to take into account all of the Group's activities, as well as those of its subcontractors and suppliers. Given the major stakes of Duty of Care directly linked to the activities of the Group and the countries of operations, the manufacture of products and the provision of services, and following a preliminary scoping stage based on initial interviews, a sector study and a documentary analysis, priority risk mapping is focused on the following perimeters:

- Production (including subcontracting) of Princeps medicines and supply chains;
- Research & Development (including subcontracting) of Princeps medicines and supply chains.

Vigilance plan

- 1- **Risk mapping: Identification, analysis and assessment of risks generated by Servier's activity**
- 2- **Regular assessment procedures of the situation of subsidiaries, subcontractors or suppliers with whom a commercial relationship is established**
- 3- **Appropriate actions to mitigate risks or prevent serious harm**
- 4- **Alert and alert collection mechanism**
- 5- **Monitoring of the measures implemented and evaluation of their effectiveness**

1- Risk mapping: Identification, analysis and assessment of risks generated by Servier's activity

The identified risk-mapping method is based on the requirements of ISO 31000 and ISO 31010 standards. The use of these standards is intended to ensure the robustness of the proposed method, which is as follows: Identification, Analysis, Assessment.

First, the working group, with the support of an external firm, defined the risk universe of Servier Group, which consists of the following pillars:

- Environmental risks;
- Human risks, fundamental freedoms, health and safety of workers;
- Human risks, fundamental freedoms, health and safety of local communities;
- Human risks, fundamental freedoms, health and safety of patients.

Second, rating scales were established based on those previously used in the Group's risk mapping:

- "Severity" scale, which measures the impact of the risk on third parties and the environment;
- "Probability" scale, which measures the occurrence of the risk;
- "Control" scale, which measures the level of control.

Finally, in addition to a documentary analysis, interviews were carried out in order to identify, analyze and evaluate the activities related to the priority perimeters likely to have an impact on third parties and the environment.

Description of stakes

- Environment

The activity of the Group's sites, as well as some suppliers and subcontractors, involves significant water consumption inherent to the pharmaceutical industrial activity, which can have an impact on the ecosystem in areas under stress, contributing to the weakening of resources. In addition, as part of their activities, the Group's sites, its subcontractors and suppliers generate greenhouse gas emissions which have an effect on climate change. Part of the emissions are linked to the combustion of fossil fuels depending on the energy mix of the countries where the sites are located.

- Human Rights, Fundamental Freedoms, Health and Safety of Workers

Workers' health and safety are stakes inherent to industrial activity with risks of occupational accidents on sites or risks of occupational diseases (prolonged exposure to chemicals, musculoskeletal disorders, psychosocial risks, etc.).

In addition, the Group must be attentive to the respect for human rights and fundamental freedoms in the countries where it operates, as well as in the countries where its suppliers and subcontractors are located.

- Human Rights, Fundamental Freedoms, Health and Safety of Patients

The patient is at the heart of the Servier Group's vocation and preoccupations. To achieve this priority, Servier must meet legal and regulatory requirements in terms of product safety throughout the drug life cycle.

- Human Rights, Fundamental Freedoms, Health and Safety of Local Communities

Servier Group sites, as well as those of some of its subcontractors and suppliers, include facilities classified for the environment (ICPE), some of which are SEVESO. These classifications characterize the sites potentially at risk for residents and local populations. Factories can indeed expose residents to the risk of fires, explosions, gaseous or liquid effluent emissions, as well as noise or odor disturbances.

2- Regular assessment procedures of the situation of subsidiaries, subcontractors or suppliers with whom a commercial relationship is established

The pharmaceutical industry must meet a high level of quality, safety and respect for the environment at all stages of a drug's life cycle, from research through development and manufacture to disposal.

Pharmaceutical production is governed by very strict national, European and international quality standards: Good Manufacturing Practices (GMP). GMPs require a high level of control over the risk of contamination of products and the production environment to provide patients with safe and quality medicinal products. Like any pharmaceutical industry, Servier Group scrupulously follows these standards. To be marketed, a medicinal product must be the subject of a Marketing Authorization (MA), issued by supranational or national competent authorities.

Subsidiaries

- Environment

Seven of our industrial sites and the Group's headquarters in France are certified or in the process of being certified ISO 14001 (environmental management system) and/or ISO 50001 (energy management system). In addition, the Group is committed to a low-carbon strategy, validated at the end of 2019 by the *Science Based Target initiative* (SBTi), aimed at reducing its carbon footprint by 25% by 2030. This approach began with a comprehensive review of emissions to put in place a relevant action plan involving all the Group's sites and activities. As such, an update of the carbon footprint is currently underway.

- Human Rights, Fundamental Freedoms, Health and Safety of Workers

Servier reaffirmed the importance of protecting the health and safety of employees in its new Health, Safety and Environment (HSE) policy. The Group is preparing a "safety culture" program that aims to deploy common elements of a safety culture and reduce the risk of accidents. This program will gradually be rolled out to all industrial and research sites. At some sites, including three ISO 45001 certified, it will strengthen the systems already in place and revitalize the programs already launched.

- Human Rights, Fundamental Freedoms, Health and Safety of Patients

The Group is adopting responsible practices at each stage of the medicinal product chain. Servier Group has in fact chosen an integrated industrial model for its Princeps medicines. The design and manufacture of the Group's Princeps medicines are therefore mainly carried out in-house, which allows control of all stages in the production chain. Servier Group's Industry Quality Department ensures continuous improvement of the quality standards of production sites. It also ensures that each of the Group's sites complies with national and international quality and traceability standards. In accordance with regulations, Servier Group and its subsidiaries are subject to regular inspections by the competent authorities on activities linked to manufacturing, clinical trials and pharmacovigilance:

o Princeps Medicines Manufacturing Activities

Inspections of manufacturing activities allow health authorities to check the quality control of our medicinal products, to verify compliance with good manufacturing practices, compliance of batch files and operations carried out in accordance with the MA dossier and applicable standards (*Good Manufacturing Practices*).

After an inspection, an action plan is systematically implemented and then monitored periodically by the Quality Department of each site.

At a central level, the Industry Department ensures transmission to all our sites of observations notified by the authorities and ensures follow-up through "corporate" audits carried out on-site and periodic quality reviews carried out remotely.

o Clinical Trials

Servier Group conducts clinical trials all around the globe and therefore makes sure to comply with national/international regulations and international standards, such as Good Clinical Practices (GCP). All of our studies also comply with the Declaration of Helsinki.

Servier is subject to inspection by health authorities to ensure compliance with the ethical rules of the current legislation in force.

- [Pharmacovigilance Activities](#)

Pharmacovigilance activity inspections are intended to control the pharmacovigilance practices of companies.

Servier Group's commitment is to continuously monitor adverse effects and situations at risk for patient safety such as misuse, medication errors and off-label use (Marketing Authorization). Also, in addition to a central Pharmacovigilance role, each subsidiary has an internal Pharmacovigilance Manager.

Locally, pharmacovigilance departments are audited at least every five years by the Regulatory Affairs Department.

- [Human Rights, Fundamental Freedoms, Health and Safety of Local Communities](#)

The Group's ambition is to create economic, social and civic value in each of the territories where the sites are located, through their activities, communication with elected officials and local communities. As part of the Local Shared Value CSR project, in 2020, the Group measured its socio-economic footprint in 18 countries using the recognized methodology, Local Footprint®.

[Subcontractors/Suppliers](#)

- [Regulatory Requirements for Industrial Subcontractors](#)

The "Quality" requirements for subcontractors involved in the production of Princeps medicines are very similar to those for manufacturers of raw materials for pharmaceutical use (Active Ingredients and Excipients) as well as manufacturers of critical packaging items.

The "Quality" management of subcontractors provided by the Industry Quality Department and the quality structures of Servier production sites meets the requirements of national and international provisions in force, such as *Good Manufacturing Practices*, European Directive 2003/94/EC, and the risk management process (ICH Q9).

These so-called "Quality" rules are enforceable and their correct application on industrial sites is assessed during periodic inspections of manufacturing activities carried out by the health authorities of each country.

Compliance with these rules is also periodically assessed during audits carried out internally on our industrial sites or those of our subcontractors and critical suppliers.

- [Industrial Quality Management](#)

Quality Management teams help to ensure that quality standards are respected on production sites and include the selection of subcontractors, the preparation of draft manufacturing/supply agreements, the annual review of product quality, etc.

Internal "Quality" documents within Servier Group have been drawn up to harmonize "Quality" rules at sites and serve as a basis for audits carried out by the Group internally and externally.

- [Clinical Trials](#)

To verify compliance with the company's Quality standards and the regulations in force, Servier defines an annual audit plan for clinical trials, associated systems and subcontractors involved in the conduct of these trials, according to a *risk-based* approach.

This program complements subcontractor monitoring provided by business units.

- [Supplier Risks Identification and Assessment Program within the Purchasing Department](#)

To better manage supply chains, Servier Group carries out supplier and subcontractor evaluations within the scope of buyers' operations (purchases paid from France):

- New suppliers (legal entity);
- Contract renewals;
- Finalist prospects in a call for tenders.

Supplier evaluations are carried out regarding the following types of risk:

- Financial health and economic dependency
- Preventing corruption and influence peddling
- Respect for human rights, health and safety, and the environment
- Compliance with personal data regulations
- Measures against illegal/undeclared work
- IT Data security

The program is designed firstly to identify potential risks based on criteria related to the category of purchase the country of production or service performance and to the amount contracted. Depending on the outcome of this preliminary phase, the supplier may be subject to a more in-depth assessment on potential risk(s) identified. Elements pertaining to the evaluations are archived in the supplier evaluation program tool and replicated in the group's supplier repository.

To assess the CSR practices of suppliers and subcontractors, Servier has chosen Ecovadis. An independent evaluation is conducted by Ecovadis experts and involves an analysis of the responses provided by suppliers and subcontractors, and verification of the data with external resources (reports or appeals from NGOs, unions, governments, databases, the media, etc.). At the end of this assessment, and depending on the level of risk, prevention and mitigation measures are proposed.

3- Appropriate actions to mitigate risks or prevent serious harm

Group

- Risk Management Department

The Risk Management Department is tasked with supervising the management and prevention of risks to which the Group is exposed. In particular, it is responsible for defining and implementing a fire/industrial risk prevention policy and related action plans by deploying prevention engineering at Group level. Activities related to risk prevention include reducing the probability of an unwanted event (fire, machine breakdown, etc.) to limit its impact on third parties and especially the Environment.

- Health Safety and Environment

A Group-wide Health, Safety and Environment (HSE) policy outlines the main principles and guidelines in this area. *Corporate HSE* is in charge of steering and coordinating the HSE policy.

- Corporate Social Responsibility

Following the ISO 26000 guidelines and its 7 core issues, the Group formalized its CSR strategy in 2016. Based on a materiality analysis involving interviews with more than 50 internal and external stakeholders, as well as existing approaches and practices in the company, the Group identified its major CSR issues. **Four commitment areas** and **17 priority challenges** were identified in order to address issues as broad as product safety and quality, clinical trials, access to therapeutic care, workers' health and safety, non-discrimination, and the impact of sites on the environment and climate. Five key projects validated and regularly monitored by the Executive Committee supplement the Group's CSR roadmap:

- Ecodesign program, *EcoDesign by Servier*, is focused on integrating social and environmental issues into stages of the drug's life cycle;
- Diversity is an asset for the company. #ServierDiversity demonstrates the Group's commitment to fighting discrimination, promoting diversity, and developing an even more inclusive working environment;
- With the *Servier 1st class Partner* project, we defined a partnership model that places collaboration and reciprocal respect for economic, ethical and responsible commitments at the forefront of relations with our suppliers and partners;
- *Servier Local Shared Value* for a positive and sustainable social and economic contribution in the territories;
- *Servier Climate Commitment* to help in the fight against climate change through a low-carbon strategy aimed at reducing greenhouse gas emissions by 25% by 2030.

The role of the CSR Department is to propose a strategy and orientations, and carry out their deployment within departments and business units. It also provides tools to allow each team and each employee to take ownership of the process. The CSR Department also monitors the progress of action plans, the achievement of objectives, and the associated non-financial indicators, previously defined within the Group's various departments.

To ensure the implementation of its roadmap and alignment with the Group's strategy, the CSR Department relies on several bodies: the CSR Strategy Committee and the CSR Operational Committee. The CSR approach is regularly reported to the Executive Committee, the CSR Strategy Committee, and the CSR Operational Committee.

This information is available for employees as well as external stakeholders at the following website page: <https://servier.com/fr/engagements/demarche-rse/>

- [Responsible Purchasing and Supplier Risk Management](#)

Servier Group is committed to a responsible purchasing process, and ensures that its suppliers are selected based on their ethical and compliance practices, and that they develop a responsible relationship with them.

In 2019, a Responsible Purchasing Director for the Group was appointed with the objective of deploying the principles of Responsible Purchasing based on the ISO 20400 standard. As part of this initiative, the buyers were sensitized on the risks covered by the Duty of Care Act through an e-learning module on responsible Purchasing.

A Supplier Risk unit was also created within the Purchasing Department to meet new regulatory obligations (Duty of Care, GDPR, Sapin II Law) and to support, inform and empower the business units on risks when selecting suppliers and subcontractors. The unit coordinates the Supplier Risk Identification and Assessment Program.

[Subsidiaries](#)

Most Production and Research sites rely on a local team of HSE specialists responsible for putting in place the appropriate technical, organizational and human resources to control risks to human and environmental health and safety.

Deploying the CSR/HSE strategy across the Group's subsidiaries is a key step in the CSR Department's roadmap. In a continuous-improvement approach, the deployment of the CSR/HSE strategy is aimed at incorporating social and environmental issues into all of the Group's activities, regardless of country of operation. Many good practices were identified during the risk-mapping exercise. A system dedicated to identifying good practices is now in place with a view to their gradual roll-out at Group level.

[Subcontractors/Suppliers](#)

As part of any commercial relationship with Servier, suppliers and subcontractors are expected to subscribe to and comply with the principles set out in the following Group reference documents:

- Code of Ethics and Code of Conduct
- Servier Group HSE policy
- Responsible Purchasing Policy

To secure its contractual relationship with third parties on CSR aspects, Servier Group has inserted a specific appendix relating to corporate social responsibility in its general terms and conditions of orders. The content of this clause, available in French and English, invites the parties to subscribe to the principles outlined on the Servier Group's CSR website available at the following address: <https://servier.com/fr/engagements/demarche-rse/>. In the long term, the Group plans to insert this clause in all contracts.

4- Alert and alert collection mechanism

An alert line is accessible to all Servier Group employees and third parties allowing them to confidentially report situations that may affect the health and safety of employees and facts/occurrences (within the Group or externally) that may be contrary to the Group's legal obligations and/or ethical principles. This system covers the risks covered by French law on the Duty of Care.

In addition to this system, Servier has set up specific alert mechanisms to ensure the quality of its medicinal products and the monitoring of adverse reactions and situations that could affect patient safety.

5- Monitoring of the measures implemented and evaluating their effectiveness

Currently, the working group is continuing to implement the legal obligations on the Duty of Care Act in order to gradually cover all activities of the Group, its subsidiaries and subcontractors.

In parallel, the definition of additional action plans and complementary measures is underway within the relevant Departments to ensure the consistency of risks identified on the areas already covered.