Sustainability Standards for LEO Pharma Business Partners

LEO

Dermatology beyond the skin

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Introduction

At LEO Pharma, integrity is one of our core values. We acknowledge that our performance is not only measured by the results we achieve. How we achieve these results is also crucial. We therefore aim to know the social and environmental impact in our supply chain and actively work with our business partners to continuously improve practices.

LEO Pharma is member of the Pharmaceutical Supply Chain Initiative (PSCI), which is an industry initiative that promotes responsible supply chain management. The 'Sustainability Standards for LEO Pharma Business Partners' are based on the PSCI Principles for Responsible Supply Chain Management (v2.0), which set the standard for human rights, ethics, labor, health and safety, environment and related management systems.

Business partners are external entities with which LEO Pharma has a business relationship, meaning they are part of our value chain and are directly linked to our business operations, products or services.

Sustainability at LEO Pharma

To achieve long-term success, we aim to deliver our business strategy in a way that delivers wider value to society and the planet. We focus on improving health outcomes and quality of life of people with skin diseases. This is underpinned by a responsible business culture, centered on measuring and managing our impact on society and the planet.

We are committed to sustainable procurement and these Sustainability Standards are part of our due diligence efforts in upholding our commitment to maintaining ethics and integrity in everything we do.

At LEO Pharma, we support the UN Sustainable Development Goals (SDGs) as part of the overall framework for our sustainability strategy.

Partnerships play an important role in reaching the goals; therefore, we are committed to cooperating with our business partners to understand their impacts and how they align their activities to support the progress of the SDGs.

Our commitment to business partners

LEO Pharma will focus on four areas when implementing these Standards:

- **Prioritize**: We will make our assessments and evaluations based on a risk-based approach and focus on where negative impacts in our supply chain and business partner collaborations are most likely to occur and where the consequences are most severe.

- **Respect**: We will act in a fair, objective, transparent and professional manner towards our business partners.

- **Communicate and train**: We will ensure that our employees are aware of these Standards and that those who are responsible for collaborating with business partners are appropriately trained.

- **Improve**: We know that supply chain sustainability is a journey and we continuously review our program and practices in order to improve.

Sustainability Standards for LEO Pharma Business Partners

As LEO Pharma supports the PSCI Principles, we understand that society and business are best served by responsible business behaviors and practices. Fundamental to this understanding is that a business must, at a minimum, operate in full compliance with all applicable laws, rules and regulations. Therefore, we require this of all business partners.

LEO Pharma is aware of differences in culture and the challenges associated with interpreting and applying these Standards globally. The requirements in these Standards are universal, but we understand that the methods for meeting them may differ depending on size and location. We believe that they are best implemented through a continuous improvement approach that advances business partner performance over time.

In order to comply with international requirements on due diligence and reporting, LEO Pharma regularly conducts screenings of business partners in relation to these Standards and maintains documentation.

Business partners are expected and required to willingly cooperate on assessment and monitoring activities. These activities may include self-assessments, questionnaires, interviews, desktop assessments, audits or any other necessary measures. LEO Pharma expressly reserves the right to terminate any potential or existing business relationship with a business partner, if:

– there is reluctance or no willingness to cooperate on assessment and evaluation in relation to these Standards, or

– there is reluctance or no willingness to work on improving management systems in order to manage risk of negative impact in relation to ethics, human rights, labor, health and safety, and environment, or

– a business partner fails to comply with these Standards.

1. ETHICS

Business partners shall conduct their business ethically and act with integrity. The Ethics elements include:

Anti-Corruption

All forms of corruption[1], bribery, extortion and embezzlement are prohibited. Business partners shall not pay or accept bribes or participate in other illegal inducements in business or government relationships, or through the use of intermediaries. Business partners shall ensure they have adequate systems in place to prevent corruption and comply with applicable laws.

Fair Competition and Marketing Laws

Business partners shall conduct their business consistent with fair and vigorous competition and in compliance with all applicable anti-trust laws. Adherence to anti-trust laws secures fair and balanced market condition for business operations and practices to the benefit of the patient.

Business partners shall employ fair business practices including accurate and truthful advertising.

Export Controls and Trade Sanctions

Business partners shall adhere to all governing export control and trade sanction regulations. Non-Compliance with export controls and/or EU and international sanctions may expose LEO Pharma and/or the business partner to substantial fines and losses which may have a significant adverse effect on the business relationship.

Animal Welfare

Animals shall be treated humanely with pain and stress minimized. Animal experimental work should be performed after consideration to replace and reduce the use of animals and refine the procedures performed on experimental animals to minimize distress. Alternatives should be used wherever these are scientifically valid and acceptable to regulators.

As a minimum requirement, all animal experimental work and care must comply with the standards set by EU and Danish legislation, regardless of where the use of animals is taking place.

Data Privacy and Security

Business partners shall safeguard and make only proper use of personal and confidential information to ensure that company, worker, patient, subject[2] and donor[3] privacy rights are protected. Business partners shall comply with applicable privacy and data protection laws and ensure the protection, security and lawful use of personal data.

Intellectual Property Rights

Business partners shall fully respect and abstain from infringement or violation of any intellectual property rights belonging to LEO Pharma or any other companies or individuals.

[1] We use the term "corruption" in these Standards to refer to the abuse of entrusted power for private gain

[2] We use the term "subject" to refer to any person who participates as a subject in scientific and medical experimentation or product testing

[3] We use the term "donor" to refer to any person who donates tissues, cells, organs and any other body parts for research purposes.

Patient Safety and Access to Information

Business partners shall ensure that adequate management systems are in place to minimize the risk of adversely impacting on the rights of patients, subjects and donors, including their rights to health and to access information directly.

Conflicts of Interest

Business partners shall take reasonable care to avoid and manage conflicts of interest. Business partners are expected to notify all affected parties if an actual, potential or perceived conflict of interest arises.

Clinical trials

Clinical trials must always be conducted by LEO Pharma, its partners and investigators in accordance with Good Clinical Practices and other applicable laws, regulations and international standards. Participation by study subjects is subject to a prior informed consent.

Responsible Sourcing of Minerals

Business partners shall ensure that any sourcing of minerals or metals (e.g. tin, tantalum, tungsten and gold) in their supply chain are from responsible and conflict-free sources only.

2. HUMAN RIGHTS

Business partners shall respect internationally recognized human rights as expressed in the *International Bill of Human Rights* and the principles concerning fundamental rights set out in the *International Labor Organization's Declaration on Fundamental Principles and Rights at Work.*

The United Nations Guiding Principles on Business and Human Rights (UNGPs) have been developed as a global reference point for understanding and upholding human rights. According to the UNGPs, companies should seek to prevent and mitigate the negative impacts on human rights that are linked to their operations, products and services by their business relationships, even if they have not contributed to those impacts.

In order to respect human rights, companies should have policies and procedures appropriate to size and circumstances, which include:

- Policy commitment
- Human rights due diligence process in order to identify, prevent, mitigate and account for how the company addresses impacts on human rights
- Processes to enable remediation of the negative impacts they cause or to which they contribute

The PSCI Principles specifically state that the PSCI supports the UNGPs and will offer and promote implementation guidance to members and the pharmaceutical sector to encourage their widest adoption. LEO Pharma encourages business partners to make use of this guidance which is available on the PSCI website.

As part of LEO Pharma's process for human rights due diligence, we may ask business partners to engage in assessment and evaluation activities.

3. LABOR

Labor rights are human rights that are of particular relevance to workers in supply chains. Business partners shall be committed to uphold the human and employment rights of workers and to treat them with dignity and respect. The Labor elements include:

Freely Chosen Employment

Business partners shall not use forced, bonded or indentured labor or involuntary prison labor. No worker shall pay for a job or be denied freedom of movement.

Child Labor and Young Workers

Business partners shall not use child labor. The employment of young workers below the age of 18 shall only occur in non-hazardous work and when young workers are above a country's legal age for employment or the age established for completing compulsory education.

Non-Discrimination

Business partners shall provide a workplace free from discrimination. There shall be no discrimination for reasons such as race, color, age, pregnancy, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status.

Fair Treatment

Business partners shall provide a workplace free of harassment, harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers and no threat of any such treatment.

Wages, Benefits and Working Hours

Business partners shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits.

Business partners shall communicate with the worker the basis on which they are being compensated in a timely manner. Business partners are also expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime. Overtime shall be consistent with applicable national and international standards.

Freedom of Association

Open communication and direct engagement with workers to resolve workplace and compensation issues is encouraged.

Business partners shall respect the rights of workers, as set forth in local laws, to associate freely, join or not join labor unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

4. HEALTH AND SAFETY

Business partners shall provide a safe and healthy working environment, including - where applicable - for any company-provided living quarters. Health and Safety measures shall extend to contractors and subcontractors on supplier sites. The Health and Safety elements include:

Health and Safety Authorizations and Reporting

Business partners shall comply with all local health and safety regulations, e.g. EU REACH. All required work permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

Worker Protection

Business partners shall protect workers from exposure to chemical, biological, physical hazards and physically demanding tasks in the workplace and in any company provided living quarters. Business partners shall ensure appropriate housekeeping and provide workers with access to potable water.

Process Safety

Business partners shall have management processes in place to identify the risks from chemical and biological processes and to prevent or respond to release of chemical or biological agents.

Emergency Preparedness and Response

Business partners shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

Hazard Information

Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

5. ENVIRONMENT

Business partners shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Business partners are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The Environmental elements include:

Environmental Authorizations and Reporting

Business partners shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained, and their operational and reporting requirements followed.

Waste and Emissions

Business partners shall have systems in place to ensure the safe handling, movement, storage, disposal, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment. This includes managing releases of active pharmaceuticals into the environment (PiE).

Spills and Releases

Business partners shall have systems in place to prevent and mitigate accidental spills and releases to the environment and adverse impacts on the local community.

Resource Use

Business partners shall take measures to improve efficiency and reduce the consumption of resources.

Sustainable Sourcing and Traceability

Business partners shall carry out due diligence on the source of critical raw materials to promote legal and sustainable sourcing.

6. MANAGEMENT SYSTEMS

Business partners shall use management systems to maintain business continuity, facilitate continual improvement and compliance with the expectations of these Standards. The Management System elements include:

Commitment and Accountability

Business partners shall demonstrate commitment to the concepts described in this document by allocating appropriate resources and identifying senior responsible personnel.

Legal and Customer Requirements

Business partners shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

Risk Management

Business partners shall have mechanisms to determine and manage risks in all areas addressed by these Standards.

Documentation

Business partners shall maintain documentation necessary to demonstrate conformance with these Standards and compliance with applicable regulations.

Training and Competency

Business partners shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address the expectations in these Standards.

Continual Improvement

Business partners are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, inspections, and management reviews.

Identification of Concerns

All workers shall be encouraged to report concerns, illegal activities or breaches of these Standards in the workplace without threat of or actual reprisal, intimidation or harassment. Business partners shall investigate and take corrective action if needed.

Communication

Business partners shall have effective systems to communicate these Standards to workers, contractors and suppliers.

As part of developing management systems, we expect and require business partners to require their suppliers of products and services to LEO Pharma (i.e. LEO Pharma's subcontractors) that they adhere to these Standards or their own similar expectations and requirements.

Sources

The Sustainability Standards for LEO Pharma business partners were formulated using the following external sources:

- The PSCI Principles for Responsible Supply Chain Management
  https://pscinitiative.org/home

- Sustainable Development Goals
  https://www.un.org/sustainabledevelopment/

- The Ten principles of the UN Global Compact
  www.unglobalcompact.org

- UN Guiding Principles on Business and Human Rights
  www.unglobalcompact.org/library/2

- Responsible Business Conduct - OECD Guidelines for Multinational Enterprises
  http://mneguidelines.oecd.org/

- International Labor Organization's Declaration on Fundamental Principles and Rights at Work
  http://www.ilo.org/declaration/lang--en/index.htm