— we help people achieve healthy sk



# LEO Pharma Third Party Compliance Code



## LEO values

Integrity
Customer focus
Innovation
Passion
Adaptability

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## Introduction

LEO Pharma Third Party Compliance Code (hereinafter referred to as "this Compliance Code") outlines LEO Pharma's requirements and expectations towards Third Parties (as defined immediately hereafter) in relation to business ethics, human rights, labour rights, health and safety, environment, subcontractors and management systems for these areas.

"Third Party" (or "Third Parties" in plural, as appropriate) shall mean any individual or legal entity with whom LEO Pharma is collaborating, in whichever way, and/or who is acting on behalf of LEO Pharma, including, without limitation, suppliers, contractors, manufacturers, vendors, consignments stock holders, consultants, customers, distributors, agents, intermediaries, business partners, public and private clinics, hospitals, universities and institutions, as well as nongovernmental organisations.

Notwithstanding anything to the contrary herein, "Third Party" shall not include any individual patients or healthcare professionals.



### **Corporate Social Responsibility at LEO Pharma**

Integrity is our core value at LEO Pharma. We are a responsible company and keep our promises. We want to act and communicate in an open, honest and trustworthy way. This is reflected in our strategy for Corporate Social Responsibility (CSR). At LEO Pharma, we work with CSR e.g. as outlined in our internal LEO Code of Conduct and through our anti-corruption and -bribery programme. Furthermore we have obtained ISO 14001 and OHSAS 18001 certification of all LEO Pharma production sites.

### **Our commitment to Third Parties**

LEO Pharma will focus on four areas when implementing this Compliance Code:

• Prioritise: We will make our assessments and evaluations based on a risk based approach and focus on where negative impact in our supply chain and third party collaborations are most likely to occur or where the consequences are most severe.

• **Respect**: We will conduct our business with Third Parties in a fair, objective, transparent and professional manner.

• **Communicate and train**: We will ensure that our employees are aware of this Compliance Code and that those who are responsible for collaborating with Third Parties are appropriately trained.

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

### LEO Pharma Third Party Compliance Code

LEO Pharma expects and requires all Third Parties to operate in full compliance with all applicable laws, rules and regulations as well as to work with high quality and ethical standards, and in accordance with any special instructions or requirements from LEO Pharma.

This Compliance Code is largely based on Pharmaceutical Industru Principles for Responsible Supply Chain Management<sup>1</sup> . LEO Pharma is aware of differences in culture and the challenges associated with interpreting and applying this Compliance Code globally. This Compliance Code is universal, but we understand that the methods for meeting the requirements and expectations may be different and must be consistent with the laws. values and cultural expectations of the different countries and societies of the world. Furthermore, the size, sector and the operational context of the Third Party will influence the methods used for living up to this Compliance Code. We believe that this Compliance Code is best implemented through a continuous improvement approach that advances Third Party performance over time

Third Parties are expected and required to willingly cooperate on assessment and monitoring activities. These activities may include self-assessment, 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 Third Party, if:

- there is reluctance or no willingness to cooperate on assessment and evaluation in relation to this Compliance Code, or

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

- a Third Party (or its subcontractors, as applicable) fails to comply with this Compliance Code.

#### **COMPLIANCE AREAS**

#### 1. Business ethics

Third Parties shall conduct their business in an ethical manner and act with integrity. The ethics elements include the following aspects:

## •Business integrity and fair competition

All corruption, extortion and embezzlement are prohibited. Third Parties shall not pay or accept bribes or facilitation payments or participate in other illegal inducements in business or government relationships. Third Parties shall conduct their business consistent with fair and vigorous competition and in compliance with all applicable anti-trust laws, export control regulations and trade embargoes. Third Parties shall employ fair business practices including accurate and truthful advertising.

#### Identification of concerns

All workers should be encouraged to report concerns or illegal activities in the workplace without threat of reprisals, intimidation or harassment. Third Parties shall investigate and take corrective action if needed.

#### Animal welfare

Third Parties shall treat animals humanely and minimise pain and stress. Animal testing should be performed after consideration to replace animals, to reduce the numbers of animals used, or to refine procedures to minimise distress. Alternatives should be used wherever these are scientifically valid and acceptable to regulators.

As a minimum requirement, all animal testing and care must be in compliance with the standards set by EU legislation, regardless of where the use of animals is taking place.

## • Privacy, confidentiality and intellectual property rights

Third Parties shall safeguard and make only proper and legal use of non-public information to ensure that company, worker, and patient privacy rights are respected and protected in accordance with any applicable local legislation. Similarly, Third Parties shall ensure that no confidential information belonging to LEO Pharma or any other companies or individuals becomes disseminated or unduly disclosed due to the acts or omissions of Third Parties. Finally. Third Parties shall fully respect and abstain from infringement or violation of any intellectual property rights belonging to LEO Pharma or any other companies or individuals

#### Clinical trials

When conducting clinical trials this must always be done by Third Parties in accordance with applicable laws, regulations and international standards including Good Laboratory Practice, Good Clinical Practice and Good Pharmacovigilance Practice as well as the right to free, prior and informed consent to medical or scientific experimentation.

#### Conflict minerals

Third Parties must ensure that products delivered to LEO Pharma do not contain metals derived from minerals or their derivatives originated from conflict regions that directly or indirectly finance or benefit armed groups.

#### Conflict of interests

Third Parties shall ensure that their workers always strive to avoid situations where their loyalty may become compromised and personal interests conflict or may conflict with their professional duties and interests.

#### 2. Human rights

Third Parties shall respect internationally recognised human rights as expressed in the *International Bill* of Human Rights and the principles concerning fundamental rights set out in the *International Labour Organization's Declaration on Fundamental Principles and Rights at Work.* 

United Nations Guiding Principles on Business and Human Rights have been developed as a global reference point for understanding how to respect human rights. According to the Guiding Principles on Business and Human Rights the responsibility to respect human rights requires that companies avoid causing or contributing to negative human rights impacts through their activities, and companies should seek to prevent and mitigate the negative impacts that are linked to their operations e.g. via Third Parties

In order to respect human rights companies should have in place 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

This process is similar to the expectations and requirements in relation to management systems also set forth in section 7. As part of LEO Pharma's process for human rights due diligence, we may ask Third Parties to engage in assessment and evaluation activities.

#### 3. Labour rights

Third Parties shall uphold the human rights of their workers. As stated above in relation to human rights, we therefore expect and require Third Parties to respect the rights set out in the International Labour Organization's Declaration on Fundamental Principles and Rights at Work.

More specifically this means the following:

#### • Freely chosen employment

Third Parties shall not use forced, bonded or indentured labour or involuntary prison labour.

#### • Child labour and young workers

Third Parties shall not use child labour. 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

Third Parties shall provide a workplace free of harassment and discrimination. Discrimination for reasons such as race, colour, age, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status is not condoned.

#### • Fair treatment

Third Parties shall provide a workplace free of 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

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

Third Parties shall communicate with their workers the basis on which they are being compensated in a timely manner. Third Parties are also expected and required to communicate with their workers whether overtime is required and the wages are to be paid for overtime.

#### • Freedom of association

Open communication and direct engagement with workers to resolve workplace and compensation issues is encouraged. Third Parties shall respect the rights of workers, as set forth in local laws, to associate freely, join or not join labour unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisals, intimidation or harassment.

#### 4. Health and safety

Third Parties shall provide a safe and healthy working environment, including for any company provided living quarters.

LEO Pharma expects and requires Third Parties to understand the applicable health and safety standards for its products or services and to extend this Compliance Code, as necessary.

The health safety elements include:

#### Worker protection

Third Parties shall protect workers from over exposure to chemical, biological, physical hazards and physically demanding tasks in the work place and in any company provided living quarters.

#### • Process safety

Third Parties shall have programmes in place to prevent or mitigate catastrophic releases of chemicals.

## • Emergency preparedness and response

Third Parties shall identify and assess emergency situations in the workplace and any company provided living quarters, and minimise 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

Third Parties shall operate in an environmentally responsible and efficient manner to minimise adverse impacts on the environment. Third Parties 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 authorisations

Third Parties shall comply with all applicable environmental regulations. All required environmental permits, licences, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

#### • Waste and emissions

Third Parties shall have systems in place to ensure the safe handling, movement, storage, 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.

#### Spills and releases

Third Parties shall have systems in place to prevent and mitigate accidental spills and releases to the environment.

#### 6. Subcontractors

LEO Pharma expects and requires Third Parties to support and adhere to this Compliance Code or develop their own codes which include principles similar to ours. As part of developing management systems we expect and require Third Parties to demand from their suppliers of products and services to LEO Pharma (i.e. LEO Pharma's subcontractors) that they adhere to this Compliance Code or their own similar expectations and requirements.

#### 7. Management systems

Third Parties shall use management systems to facilitate continual improvement and compliance with this Compliance Code. The management system elements include:

#### • Commitment and accountability:

Third Parties shall demonstrate commitment to the concepts described in this Compliance Code by allocating appropriate resources and developing relevant policies.

#### • Legal and customer requirements

Third Parties shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

#### Risk management

Third Parties shall have mechanisms to determine and manage risks in all areas addressed by this document.

#### Documentation

Third Parties shall maintain documentation necessary to demonstrate conformance with these expectations and requirements and compliance with applicable regulations.

#### Training and competency

Third Parties shall have a training programme in place that achieves an appropriate level of knowledge, skills and abilities in management and workers to address these expectations and requirements.

#### • Continual improvement

Third Parties are expected and required 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.

### References

The following sources were used in formulating this present LEO Pharma Third Party Compliance Code. Additional information can be found through these references:

#### **External sources**

Pharmaceutical Industry Principles for Responsible Supply Chain Management https://pscinitiative.org/home

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

#### Internal sources

Business Ethics http://www.leo-pharma.com/Home/LEO-Pharma/Business-Ethics.aspx

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