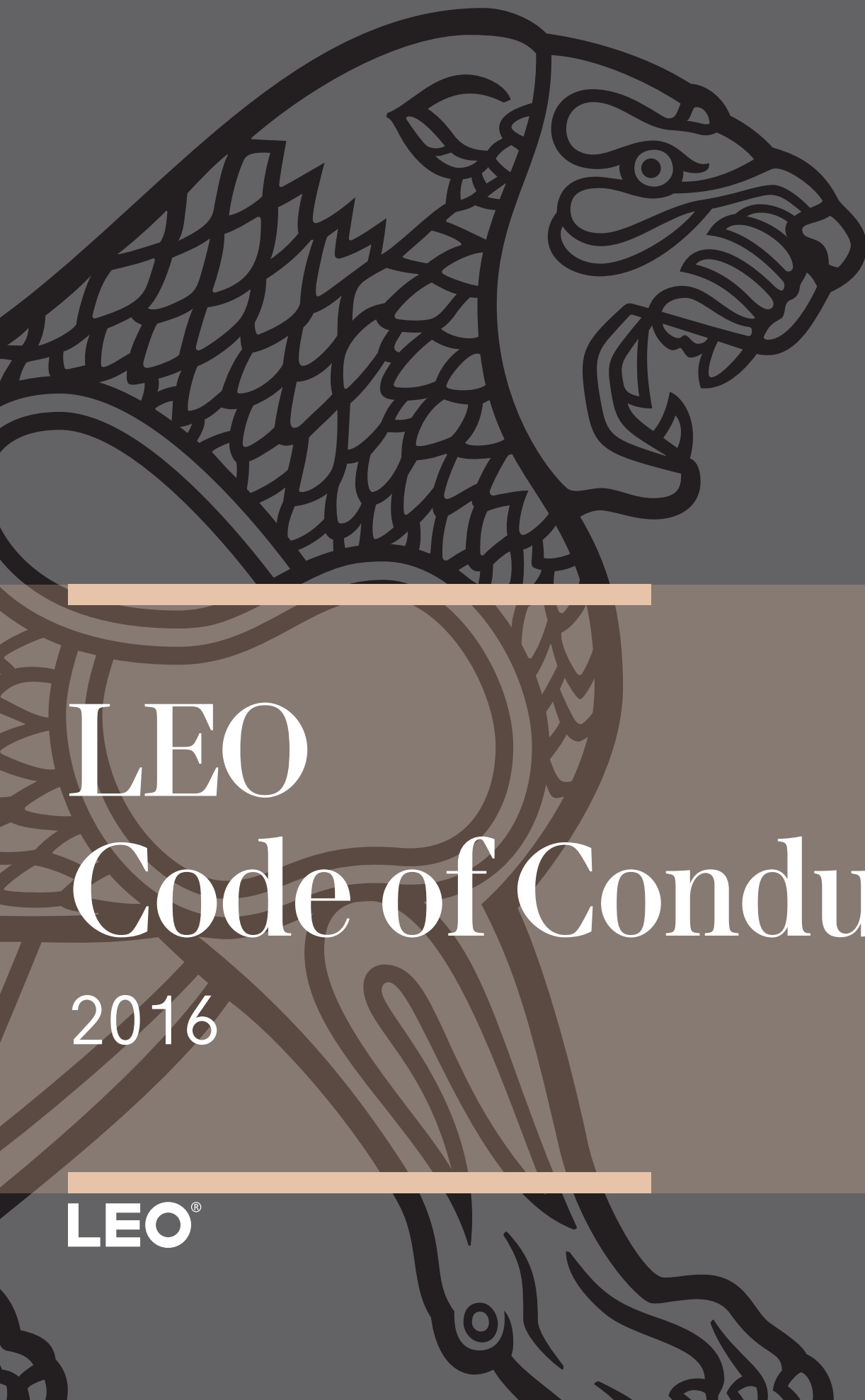


— we help people  
achieve healthy skin



LEO

# Code of Conduct

2016

LEO®







Dear LEO colleagues,

Since LEO Pharma introduced the first edition of the LEO Code of Conduct in 2011, our company and the industry in which we operate have seen significant changes. The compliance landscape for LEO Pharma is evolving, and the demands placed on us as a healthcare company are rapidly changing. Increased demands as a result of accessing new markets and launching new solutions mean that it is necessary to update the LEO Code of Conduct.

This updated version of the LEO Code of Conduct incorporates LEO policies and expresses what is expected of us as LEO people. Together with our guidelines, procedures, etc. it provides guidance for our behaviour based on our LEO values: Integrity – Customer focus – Innovation – Passion – Adaptability. It will help us translate our values into consistent actions by resolving ethics and compliance issues arising in our daily work, and protect one of our most valuable assets: our reputation – an asset which we all have an obligation to protect and strengthen to the benefit of patients.

We will only be able to maintain the trust of patients and other stakeholders, and protect our reputation as a responsible company, by living up to our values and high ethical standards. We do not compromise our commitment to integrity. Our performance is not only measured by the results we achieve. How we achieve these results is also crucial. What we do is important, but how we do it is equally important – and sometimes even more so.

We all have a commitment to doing things the right way, and we must all be motivated, empowered and supported to do so. This requires a workplace that encourages open and honest communication, and a culture of mutual trust. At LEO, we encourage the free exchange of views across borders – geographical as well as organisational. We believe that an open and honest working environment which promotes open dialogue and the active involvement of all LEO people is crucial for our success. We all can – and we are all expected to – make a difference.

We believe that high business standards play a significant role in ensuring our continued growth and success as well as in achieving our vision of becoming the preferred dermatology care partner improving people's lives around the world.

We in the Global Leadership Team, as well as our Board of Directors, have formally endorsed and fully support the implementation of this Code of Conduct, and kindly ask you to study the code carefully, implement it personally and live by its principles in all of your daily activities.

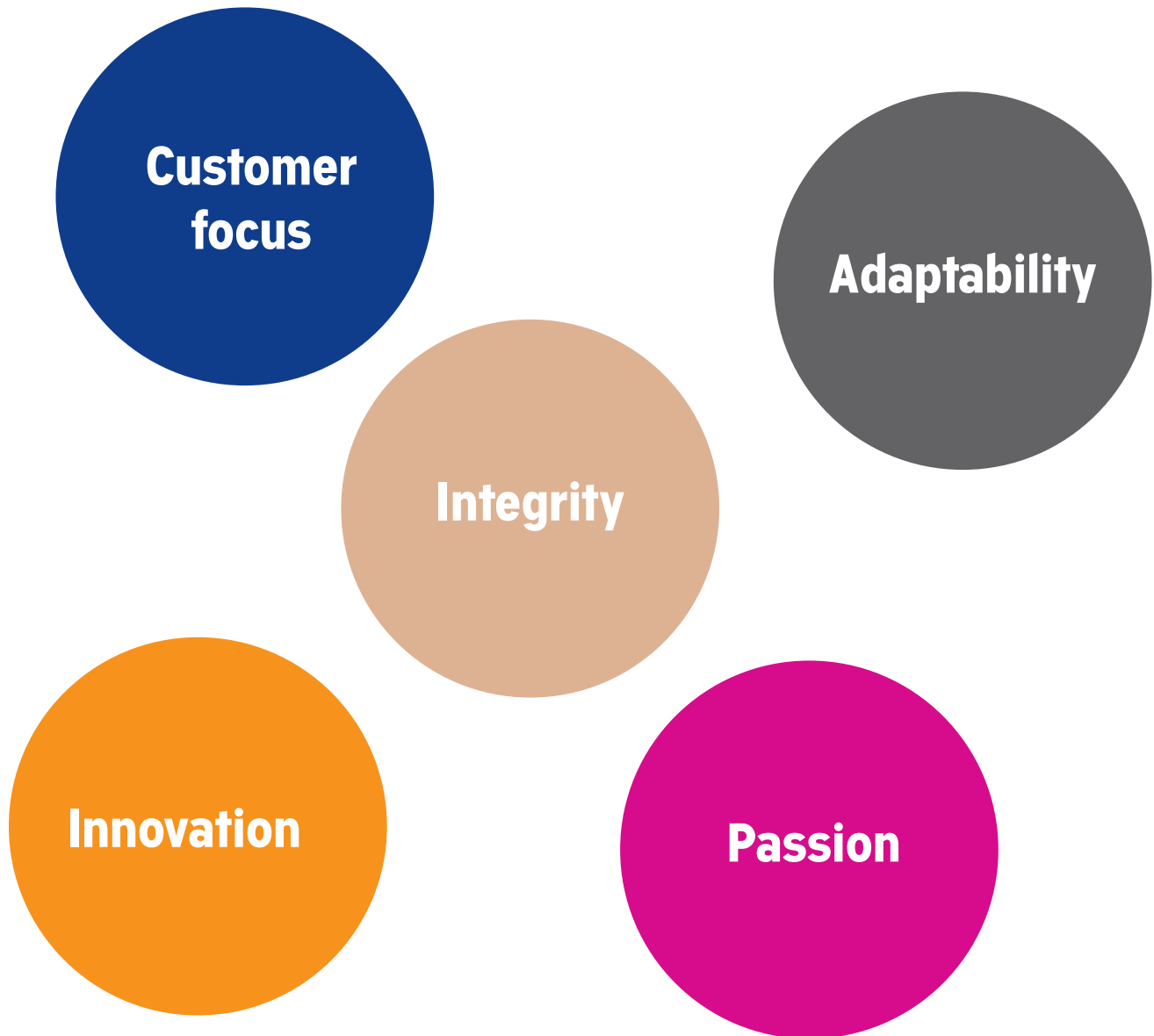
Compliance with the LEO Code of Conduct is mandatory for all LEO people.

Thank you for your support, on behalf of

THE GLOBAL LEADERSHIP TEAM,

Gitte P. Aabo

## LEO values



This Code of Conduct is a part of the terms of employment at LEO. Violations are not tolerated and any such violations can have serious consequences for LEO and for you as an employee. Any violations of this Code of Conduct may result in re-training or, depending on the circumstances and applicable law, disciplinary actions such as a formal warning or dismissal. Violations of the law can also result in the imposition of criminal and/or civil fines and other penalties, depending on applicable laws. Failure to report a breach may itself be a breach of this Code of Conduct.



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# Introduction

As a healthcare company with high ethical standards, we take responsibility for our actions.

This Code of Conduct will assist us in living up to this responsibility and help us to improve patients' quality of life. We focus on patient needs and take them into consideration in everything we do. Through this approach, we listen and respond to patients' challenges and needs. We believe that when we help people, business will follow.

Like any organisation, we face opportunities and risks from internal and external sources which may positively or adversely affect the achievement of our business objectives. Our approach to risk management is an integral part of all organisational projects and decision-making at LEO. We support and encourage formal processes for identifying and assessing risks, and develop plans to mitigate their impact.

As a sustainable company, Corporate Social Responsibility (CSR) is embedded in LEO Pharma's business and in the behaviour of LEO people. We have a business-driven CSR approach and acknowledge our economic, social and environmental responsibility in compliance with the principles of the United Nations Global Compact.

To ensure that we conduct our business in accordance with the LEO values and our business strategy, we must ensure compliance with this Code of Conduct regardless of location or the nature of the work.

The LEO Code of Conduct provides the framework for our behaviour and is supported by more detailed guidelines. We have an obligation to familiarise ourselves with and comply with all relevant guidelines in our daily work. When applicable laws, regulations or international requirements require higher standards than this code, these must also be followed.

The LEO Code of Conduct applies to all LEO people. Each of us is responsible for adhering to the values and standards set out in this code, and for raising questions if we are uncertain as to whether or not the standards are met.

No guidelines, no matter how detailed, can possibly anticipate all of the challenges we may face on the job. We are therefore always expected to use our judgement and common sense. Whenever we are in doubt about correct business behaviour or have a compliance concern, we should seek advice. We must always ask ourselves how our actions today would look if made public in tomorrow's news.

Throughout the LEO Code of Conduct, you will find 'Good attitudes' to help you determine the appropriate course of action.

If you become aware of, suspect or observe violations of this Code of Conduct and/or the supporting guidelines involving LEO, you must report it.

The LEO Code of Conduct will be reviewed on a regular basis.

# Anti-Corruption and -Bribery

**LEO people must refrain from and work against corruption and bribery globally. LEO people must comply with applicable laws, regulations, industry codes, international requirements and our supporting internal guidelines.**

**Corruption and bribery** are illegal and contrary to the LEO values and ethical standards. You must not act in a dishonest or deceptive manner, and you must never engage directly or indirectly in bribery, fraud, money laundering or any other corruptive actions with the aim of securing an improper advantage.

At LEO, we do not tolerate **facilitation payments**. Facilitation payments undermine our corporate anti-bribery procedures, contradict the anti-bribery message, nurture a culture of bribery and have the potential to escalate or otherwise be abused.

We do not pay **protection money** – also known as extortion money – in any country, to any person or entity.

We want to avoid **conflicts of interests** where our loyalty becomes compromised and personal interests may result in corruption or may be perceived as such.

**Business interactions** such as providing or receiving **hospitality, gifts, grants, sponsorships or donations**, or other remuneration can be perceived as having an undue influence on business decisions. You must never offer, provide or accept any of these in order to win or retain business in exchange for an improper advantage or in a manner or under conditions that might have an improper influence on the recipient. This applies even if it is customary and accepted practice in many business relationships.

You must take measures to prevent LEO becoming involved in cases of corruption or other financial crime. This includes taking measures to ensure the documentation and tracking of any financial transactions and other transfers of value.

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## Good attitudes

- Never engage in any type of bribery directly or indirectly, and contact your manager immediately if you are offered or asked to pay a bribe
  - Refuse to pay or receive any form of protection money or facilitation payment
  - Ensure that circumstances which might suggest a conflict of interests are transparent, even if there is no such conflict, and that associated business transactions are handled with the appropriate discretion and control
  - Do not engage in activities that could be perceived as improperly influencing any act or decision by an external party, including offering, giving or accepting gifts, hospitality, grants, sponsorships or donations
  - Remain alert to any suspicious circumstances that may signal corruptive activities or other financial crimes
-





## Anti-Corruption and -Bribery Policy

As a responsible company with high ethical standards, LEO Pharma is committed to operating with integrity and working against all forms of corruption.

LEO interacts with a variety of external parties, such as officials of domestic, foreign and international public agencies and organisations, policy-makers, healthcare professionals, healthcare organisations, patients and patient organisations, and other members of the public and private sector. We refrain from and work against corruption and bribery globally with regard to our interactions with external parties.

LEO people must comply with the following principles in order to refrain from and fight against corruption and bribery:

- **Bribery** is forbidden. This may include the receipt of any gift, fee, reward or advantage as an inducement to act in a way which is dishonest, illegal or in breach of trust. In order to differentiate between a bribe and a proper business condition, you must ensure that the appropriate level of authority is involved if a business transaction is conducted outside of normal terms and conditions.
- **Facilitation payments** are not permitted. When making a payment to an official body, for example, you should always ensure that the fee demanded is substantiated by publicly available information. When making a payment in general, always make sure that you receive and file a receipt.
- Payment of **protection money** must be avoided. Remain alert to any suspicious circumstances such as payments to bank accounts in suspicious locations or references to unsubstantiated legal or regulatory references.
- Circumstances which might suggest a **conflict of interests** must be avoided or, if unavoidable, they must be transparent and openly discussed with your manager.
- **Hospitality** at a reasonable level, such as meals, travel and entertainment, is permitted if it is in accordance with internal guidelines, local requirements, standards and common sense.
- **Gifts** may be offered to or received from third parties as long as they are modest in value, not offered/received in order to win or retain business or improperly influence any act or decision, and are in accordance with applicable laws and regulations. Anything of value exchanged in the course of our business, such as money, goods, services, tickets and prizes, may be considered a gift. However, cash and cash equivalents must never be offered or received.
- **Grants, donations and sponsorships** should never be offered or provided with an improper purpose, or in a manner or under conditions that could have an improper influence on the recipient. Contributions of any kind to political parties or individual politicians are prohibited.

At LEO, we find that our responsibility with respect to corruption and bribery extends beyond the boundaries of the legal entity. Furthermore, there is a risk that LEO may be held responsible for matters relating to the compliance of third parties working on behalf of LEO, for example hired sales forces, agents and distributors. Accordingly, before engaging – and while working – with third parties, it is important to conduct relevant due diligence procedures in order to assess their level of alignment with our values and Third Party Compliance Codex, and to prevent such third parties from bribing on our behalf.

# Communication

**LEO people protect our credibility and uphold our reputation when communicating and reporting. LEO people must comply with applicable laws, regulations, industry codes, international requirements and supporting internal guidelines.**

You are expected to always give honest and reliable information, and only to communicate and report on behalf of LEO if you are duly authorised to do so and only through approved communication channels.

When communicating, including when using social media, LEO people are expected to use common sense. Since people may form an opinion about LEO based on the behaviour of LEO people, LEO encourages LEO people to be polite and maintain a professional tone at all times.

When developing communication materials, you must follow applicable communication and branding guidelines at all times.

At LEO, we acknowledge the important role that patient organisations play in increasing patient understanding about disease and treatment. As a patient-centric company, we share their commitment to patients, and we join them in their efforts to improve patient support and healthcare.

Our relationships with patient organisations are strictly ethical, professional and non-promotional, and our collaboration must take place in an open and credible manner.

We also understand the importance of having open communication with policy-makers as a way of providing them with useful and timely information about medical conditions for the benefit of patients, and of ensuring industry participation in the political process. When involved in public affairs activities, LEO people are expected to conduct themselves in a transparent manner, avoiding any conflicts of interest.

Media enquiries about issues relating to the LEO Group must be directed to Group Communications. Media enquiries about local issues must be directed to your local communications manager or country manager (or similar).

At LEO, we are committed to disclosing and recording relevant funds and assets, and to providing our stakeholders with relevant financial information. Through relevant processes, we ensure that our books and records are accurate, sufficiently detailed and provide a truthful and transparent overview of our transactions and general operations.

## Good attitudes

- Never communicate or report on behalf of LEO unless you are duly authorised to do so
- When communicating or reporting, always give honest and reliable information
- Be aware of and ensure compliance with branding guidelines
- Make sure that any financial and non-financial information or report is true and not misleading
- In the event of media enquiries, consult Group Communications or your country manager (or similar)

## Within the context of your personal communications, including your private use of social media:

- If you make reference to any topic related to our business, please indicate that it is your own opinion
- Avoid making any statement about our pharmaceutical products that may be considered to be promotional
- Do not make any unauthorised disclosures, especially regarding confidential or sensitive information in relation to LEO
- Immediately report any possible adverse events or other experiences of LEO products that you might become aware of



## Use of Social Media Policy

Social media have extended people's communication outreach and have blurred the boundaries between private and public, and personal and professional communications. Private conversations held on social media by LEO people may be interpreted by the general public as communication on behalf of LEO, and an online reader could have difficulty distinguishing between their opinions and those of LEO.

### When speaking on behalf of LEO Pharma

Social media can be used at LEO as a way of engaging with patients, medical organisations, scientific researchers, future employees and other relevant stakeholders. To ensure that LEO social media originates from authorised sources and aligns with our LEO values, LEO social media must abide by the following principles:

- **Compliance:** LEO social media must adhere to applicable laws and regulations, codes of practice and internal guidelines.
- **Transparency:** Users shall be made aware of the identity of LEO as the social media owner.
- **Respect of confidentiality obligations and intellectual property rights:** Content on LEO social media must not provide any confidential or sensitive information, contain any copyright infringements or violate the intellectual property rights of others.

The set-up and management of LEO social media require explicit approval granted in accordance with applicable internal guidelines. Even if you are generally authorised to communicate on behalf of LEO due to your job description, this authorisation does not necessarily extend to social media without clear authorisation.

### When speaking about LEO

In your private use of social media, you must not portray yourself as a LEO spokesperson or otherwise act in a manner that is likely to be perceived by others as if you are communicating on behalf of LEO.

Even though information posted through your own private social media account is generally considered personal, the following principles must be followed:

- **Be transparent:** Separate your opinions from those of LEO, when referring to LEO/our business. You can do this by including remarks as “the views expressed here are my own, and do not necessarily reflect the views of LEO Pharma”.
- **Personal posts relating to LEO products:** In most countries, it is illegal for a pharmaceutical company or an individual to promote pharmaceutical products to the general public. Personal posts relating to our pharmaceutical products are strongly discouraged, and it is strictly prohibited to make any statement that implies any product benefit, efficacy, clinical trial, safety claim or other content that may be regarded as promotional or endorsing.
- **Unauthorised disclosures:** Within your personal communications, you must not disclose any sensitive or confidential information that you may obtain in the course of your work at LEO.
- **Adverse events (potential side effects) and other experiences** If you become aware of any possible adverse events or other experiences of LEO products, do not attempt to give an official response on behalf of LEO. Instead, report this immediately (see details in the Patient Safety section on page 24-25).
- **LEO Pharma's reputation:** You can contribute to protecting the public image of LEO by reporting any situations that could damage our reputation or that might require an official response.

Nothing in this policy shall be construed as limiting any rights protected by applicable local laws and/or regulations. In the event of a conflict between local legislation and this policy, local legislation shall apply.

# Competition and Export Controls

**LEO people must never enter into agreements, arrangements or understandings that prevent or hinder legitimate competition. LEO people must comply with applicable laws, regulations, industry codes, international requirements and supporting internal guidelines.**

Competition laws<sup>1</sup> are intended to stimulate free markets and enhance productivity, innovation and value for customers.

Anti-competitive practices are contrary to the LEO Code of Conduct, LEO values and our culture of patient centricity. Failure to comply with competition laws could have serious consequences for LEO and any individual LEO employee involved in a claim, such as damage to our reputation, large fines, exclusion from public contracts, lawsuits and imprisonment.

Cross-border interactions with competitors and business partners may result in anti-competitive conduct taking place in one country having harmful effects in other countries. LEO people must therefore take into account both the laws of the country in which they are operating and the laws of the country in which the effects of their conduct are likely to have an impact. This applies to a wide range of scenarios, such as attendance at trade association meetings and business meetings.

In many countries, governments have established domestic controls to prevent the spread and distribution of nuclear, chemical or biological weapons. Such controls may, for example, include the export of certain biological materials, genetically modified organisms, chemicals, biomedical and chemical-handling equipment used in the development or production of pharmaceuticals or medical devices, or the transfer of information or technology abroad for manufacturing, testing or engineering purposes. The controls may include the requirement to obtain an authorisation for the export of items which can be used for both civil and military purposes.

LEO people must always observe and respect applicable laws, regulations and internal procedures relating to export bans, export restrictions and other controls.

<sup>1</sup>Including antitrust and antimonopoly laws

## Good attitudes

- Do not engage in illegal arrangements that may damage competition
- Never disclose or exchange competitive sensitive material or engage in discussions that could be perceived as an attempt to illegally coordinate competitive behaviour
- Do not disclose information about pricing or information that may illegally affect pricing to competitors
- Bid for contracts and tenders independently from and without any agreements or arrangements with competitors
- During any investigation by the competition authorities, follow internal guidelines and never attempt to destroy any evidence or documents or otherwise obstruct the investigation





## Competition Policy

LEO Pharma engages in fair and open competition, in compliance with applicable competition laws.

In general, competition laws prohibit formal and informal agreements between competing companies that may have a negative impact on competition.

LEO people shall not take part in any illegal communication, negotiation or agreement with competitors, regardless of whether it takes place in a formal or informal setting, verbally or in writing, which involves or may be considered to involve:

- Price fixing agreements with competitors to raise, lower or stabilise prices, or to fix the terms and conditions of sale.
- Agreements between LEO and competitors where the parties agree to divide or allocate product markets, sales territories or buyers between them.

- Bid-rigging practices between LEO and competitors, by them joining together in advance to rig bids to provide goods or services.

- Agreements with competitors with regard to the total amount, quality or type of products that are to be manufactured or offered by LEO and/or the competitor.

Under most competition laws, it is not illegal for a company to be or strive to be in a dominant position, as this can be achieved by legitimate means. However, abuse of such dominance is a violation of competition laws.

Competition authorities in many countries have the right to conduct an investigation if they suspect a violation of competition laws. In the event of an investigation by the competition authorities, you must follow the internal guidelines and cooperate with the competition authorities in good faith.

# Confidential Information and Intellectual Property Rights

**LEO people must protect our confidential information, interests and intellectual property rights, and those of others. LEO people must never engage in industrial espionage and are expected to comply with applicable laws, regulations, industry codes, international requirements and our supporting internal guidelines.**

Confidential information and intellectual property rights, such as business-sensitive information, know-how, patents, the LEO logo, trademarks, designs, domain names, copyright, slogans, etc., are important assets for LEO.

You must only share confidential information with people who have a legitimate business need – and never with any third party<sup>2</sup> without a prior confidentiality agreement and without marking confidential information as such. This applies to sensitive information about LEO Pharma's business, including information about our solutions, potential acquisitions and alliances, research activities, clinical trials, patents, commercial strategies, corporate transactions, legal matters and investigations, and personal information about colleagues obtained through your position at LEO, business partners or applicants for a vacant position at LEO.

You must never use or disclose confidential information in an improper way. Confidentiality obligations apply both during and after your employment at LEO.

LEO people must take the necessary measures to ensure the confidentiality, integrity and availability of information as required by applicable laws and regulations, and internal procedures, including rules for protection of personal data and data retention periods.

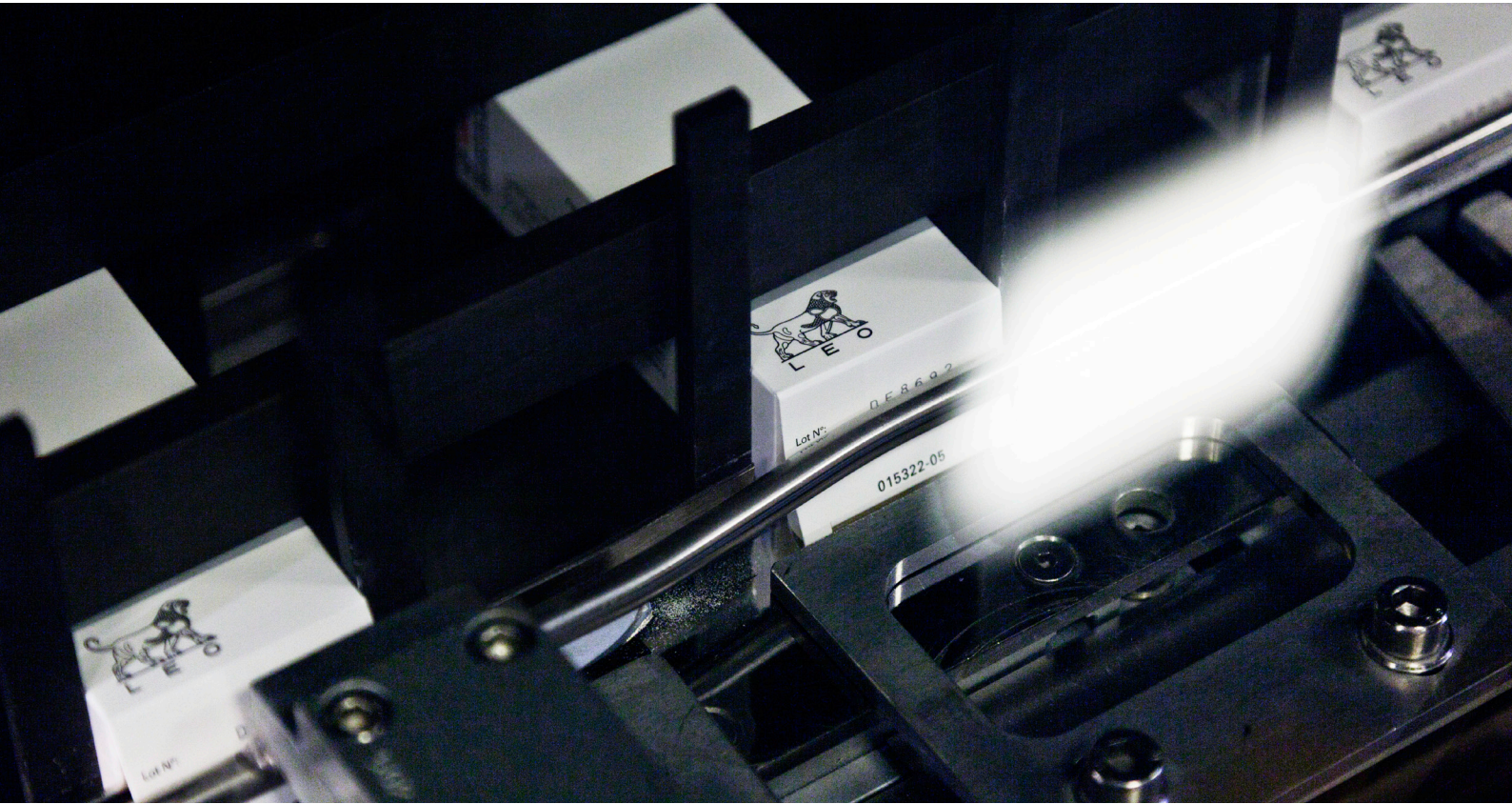
<sup>2</sup>Regulatory and other governmental bodies may be excluded due to local obligations to disclose confidential information.

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## Good attitudes

- Always consider whether information is confidential before disclosing it
  - Always ensure the proper use and protection of confidential information
  - Ensure that a confidentiality agreement is signed when relevant
  - Uphold your confidentiality obligation both during and after your employment with LEO
  - Ensure that information is encrypted when relevant
  - Consider how you handle confidential information, for example when printing and copying
-





## Information Security Policy

LEO is committed to ensuring the security of all aspects of information, whether it is spoken, written, printed, electronic or transferred to any other media, regardless of whether it is being created, viewed, transported, stored or destroyed.

Physical security and people security is fundamental to all information security efforts at LEO. Without adequate physical security controls, all other information security measures are considerably more difficult, if not impossible, to implement. Physical security requires that equipment and infrastructure be safeguarded in a way that minimises the risk of theft, destruction or tampering.

People security refers to measures which help manage the risk of LEO people and other trusted insiders using their legitimate access to LEO people, facilities, systems or assets, for example, to cause harm – whether intentionally or inadvertently.

All LEO information and information entrusted to LEO by third parties must be managed and protected accordingly.

LEO people must ensure compliance with the security-related handling of LEO information and documentation, and ensure the protection of the confidential information, interests and intellectual property rights of LEO and others.



# Conflicts of Interests

**LEO people must act in the interests of LEO Pharma. LEO people must make decisions based solely on objective criteria and professional judgement, and must never be improperly influenced by personal interests or relationships. LEO people must comply with applicable laws, regulations, industry codes, international requirements and our supporting internal guidelines.**

A conflict of interest occurs when personal, financial or other interests outside LEO may improperly influence or may be seen to improperly influence our professional duties and decision-making as LEO people.

Always strive to avoid situations where your loyalty may become compromised and your personal interests conflict or may conflict with the interests of LEO.

Never misuse your position or role at LEO for personal benefits or for the benefit of relatives or close internal or external acquaintances.

You can never accept money, gifts, services or hospitality that may compromise your independence or professional judgement. You must always refrain from engaging in activities that have the potential to be misinterpreted if publicly disclosed.

In circumstances which might suggest a conflict of interests, even if there is no such conflict, you must ensure transparency and that associated business transactions are handled with the appropriate discretion, control and documentation.

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## Good attitudes

- Use common sense and strive to avoid engaging in relationships that could create a potential conflict of interest
  - Do not misuse your position at LEO for your personal benefit or for the benefit of relatives or close internal or external acquaintances
  - If in doubt, discuss with your manager any situation that may entail a conflict of interest, and act in a way that ensures transparency and the appropriate documentation
-



# Environment, Climate and Energy

**LEO people must conduct business in a manner that protects the environment, prevents pollution and promotes efficient energy use. LEO people must comply with applicable laws, regulations and industry codes, international requirements as well as our supporting internal guidelines.**

LEO aims to protect the environment, prevent pollution and promote efficient use of energy, materials and water. We aim to minimise our environmental impact through programmes focusing on continuous improvement.

When economically reasonable to contribute towards limiting global warming, we focus on climate-friendly energy sources and seek to minimise emissions of substances that affect the climate by implementing energy-efficient solutions.

LEO manufacturing sites are certified according to the ISO 14001 standard (Environmental Management Systems) in order to continuously reduce our environmental and climate impact.

We define specific environmental and energy goals, and make all LEO people aware of these goals.

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## Good attitudes

- Consider the environmental risks before starting a task
  - Ensure that you have the proper training before starting a task
  - Always follow applicable procedures regarding environmental affairs
  - Look for opportunities to minimise the environmental impact
  - Report dangerous situations to your Environmental, Health and Safety (EHS) representative, manager or the EHS department
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## Environment Climate and Energy Policy

As a LEO employee, you must take personal responsibility for the environment, climate and energy, and integrate environmental considerations into your daily work. You must ensure that you understand and follow environmental procedures applicable to your work at LEO.

When new projects are initiated, LEO people must consider using technology which is beneficial for environmental and energy performance.

LEO adheres to international conventions and applicable laws and regulations related to biodiversity.

You must report actual or potential environmental issues related to our business immediately to your Environmental, Health and Safety (EHS) representative, manager or the EHS department.



# Health and Safety

**LEO people must comply with applicable laws, regulations and industry codes, international requirements as well as our supporting internal guidelines, and integrate occupational health and safety considerations into their work.**

LEO provides a safe and healthy work environment for LEO people and visitors, in accordance with applicable laws and international standards. We define specific health and safety goals and make LEO people aware of these goals.

A healthy and safe work environment is characterised as a workplace which prevents and manages physical and psychological injuries. It is characterised by cooperation, based on respect and trust, and by individual and organisational competence in preventing and reducing work-related stress. This supports our ambition to be an innovative, adaptable organisation with a high level of integrity that delivers patient-centric solutions on time.

By implementing an Occupational Health and Safety Management System (OHS) in accordance with applicable laws and international standards, our focus is to continuously improve our health and safety performance at LEO.

We use the results of regular surveys on the work environment and on employee engagement to define activities that improve health, safety and engagement.

## Good attitudes

- Consider health and safety before starting a task
- Ensure that you have the proper training before starting a task
- Always follow safety procedures and support your colleagues in doing the same
- Look for continuous improvements in health and safety for you and your colleagues
- Challenge your colleagues if you see that they are behaving in a way that is unsafe
- Act if you experience or witness psychological health issues for you or your colleagues
- Report dangerous situations to your EHS representative, manager or the EHS department
- Keep your workstation neat and tidy
- Always use pedestrian lanes in production areas
- Always use the personal protective equipment and technical aids specified for the task



## Occupational Health and Safety Policy

LEO people must comply with current legislation on occupational health and safety, and any agreements made with organisations regarding OHS requirements.

LEO people must take personal responsibility for understanding and following occupational health and safety procedures.

You must always look for continuous improvements in health and safety for you and your colleagues, and challenge behaviour that threatens health and safety for you and your colleagues.

You must report actual or potential health and safety issues related to LEO Pharma's business immediately to your Environmental, Health and Safety (EHS) representative, manager or the EHS department.

# Human and Labour Rights

**LEO supports and respects the protection of internationally adopted human and labour rights, including the Universal Declaration of Human Rights and fundamental workers' rights espoused by the International Labour Organisation. LEO people must comply with applicable laws, regulations and industry codes, international requirements as well as our supporting internal guidelines.**

LEO people form the basis for the success of our company. We must ensure that we respect each employee's integrity and always treat others with respect and decency.

At LEO, we do not engage in or in any way support the use of child labour.

LEO aims for high standards with regard to performance management, compensation and rewards, training and development.

We ensure that LEO people receive adequate job training and that the standards for specific skill sets in a given job are met. We ensure that we have competent and skilful people, and we focus on knowledge management, including sharing of information.

---

## Good attitudes

- Treat other LEO people and stakeholders with respect and decency
  - Never engage in or support physical, psychological, verbal or any other form of harassment
  - Contribute to upholding a working environment free from discrimination
  - Respect opinions and customs that are different from your own
  - Ensure that LEO people receive adequate job training and that the standards for specific skill sets in a given job are met
-



## Human and Labour Rights Policy

You must integrate human and labour rights considerations into your daily work and ensure that you meet applicable requirements regarding industrial and labour relations.

Discrimination is prohibited, including when recruiting, selecting, promoting or downgrading LEO people, on the basis of privacy, race, colour, sex, language, religion, political or other opinion, caste, national or social background, property, citizenship, ethnicity, birth, union affiliation, sexual orientation, health status, family responsibilities, age, disability or any other distinguishing characteristics.

LEO people respect freedom of association and the effective recognition of the right to collective bargaining, applicable laws regarding wages, benefits and working hours as well as the promotion of the fair treatment of LEO people, by making the company a pleasant and rewarding place to work.

We take all allegations of harassment or bullying seriously, and address them promptly and objectively. Any investigation will be conducted with the greatest degree of confidentiality consistent with completing a fair and thorough investigation.



# Patient Safety

**As LEO people, we are aware of our responsibility in ensuring patient safety. We develop and supply safe, innovative, high-quality products and solutions to patients worldwide. LEO people must comply with applicable laws, regulations, industry codes and international requirements as well as supporting internal guidelines.**

Patient safety is a high priority for LEO. We take on the responsibility of keeping patients safe by pre-empting and preventing unexpected and unintended events related to our products and services. We are committed to and focused on providing safety and comfort to the millions of patients receiving our products and services every day.

**LEO people** involved in the lifecycle of the products are responsible for conducting work in compliance with all applicable procedures related to their job function, thereby helping to ensure that the product received by the patient is fit for its intended use and meets the appropriate level of safety, quality, efficacy and performance.

LEO people shall report **complaints, adverse events**<sup>3</sup> (potential side effects) or **other experiences**<sup>4</sup> (e.g. use during pregnancy, misuse, lack of efficacy, suspected counterfeit medicine) with LEO medicinal products – thereby contributing to the protection of patients. For medical devices, LEO people shall report complaints and **adverse device events**<sup>5</sup>.

If you receive information about any adverse event or other experience with LEO medicinal products, you **must report this within 24 hours** to the relevant local safety contact person or, if you work at LEO Headquarters, to [drug.safety@leo-pharma.com](mailto:drug.safety@leo-pharma.com). Every effort must be made to obtain information about at least the four minimum criteria (product, patient, event/experience and reporter), but case reports with missing information must also be forwarded immediately.

**People managers** involved in the lifecycle of the products are fully responsible for professional competences in their department, and for compliance with applicable regulatory requirements and with the GxP Quality Management System, as applicable, for work performed within their business area. This responsibility also includes outsourced activities.

LEO has appointed a **Qualified Person Responsible for Pharmacovigilance (QPPV)** and a deputy QPPV, who oversee all safety-related issues globally for LEO medicinal products.

The purpose of **Pharmacovigilance** (regular surveillance of product safety) is to promote the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals, the public and the authorities.

In accordance with legal requirements, LEO Pharma has established and maintains a **Pharmacovigilance System Master File (PSMF)** – a document which describes the overall **global Pharmacovigilance System**. Relevant departments within LEO must contribute to the PSMF.

## Good attitudes

- Support the development and supply of safe, innovative and high-quality products and solutions
- Always inform the QPPV of any potential safety issues
- Immediately report any adverse events or other experiences or complaints about LEO medicinal products
- Immediately report any counterfeit or suspected counterfeit medicine
- Ensure that the high expectations regarding the safety, quality, efficacy and performance of our products are met

<sup>3,4,5</sup> See glossary

# GxP Quality Policy

## Quality objectives

LEO Pharma will, at all times, develop, produce and market medicinal products, drug device combination products and medical devices that are fit for their intended use, comply with applicable regulatory requirements, including the requirements of the Marketing Authorisation or Clinical Trial Authorisation as appropriate, and will not place patients at risk due to inadequate safety, quality, efficacy or performance.

**The Executive Leadership Team** is committed to quality, and acknowledges that it is ultimately responsible for ensuring that the conditions and resources needed to satisfy the quality objectives are present and that we have effective management involvement and oversight in our quality systems.

We believe that embedding continuous improvement and innovative concepts into our quality systems and mindset are critical for patients and for the future success of our company.

The Vice President of Global Quality is the appointed **management representative** with responsibility for the LEO GxP Quality Management System, has the authority to enforce GxP compliance and has the final say in quality disputes after the issue has been duly escalated through the organisational levels. The management representative has the authority to escalate quality issues to the CEO & President if relevant.

To meet the quality objectives, LEO operates and maintains a well-designed and properly implemented **GxP Quality Management System**. When relevant this Quality Management System applies throughout the lifecycle of the products, ensuring strong integration between the various functions responsible for the overall lifecycle of the products.

Furthermore, the Quality Management System supports continual improvement – including maintenance of the **effectiveness and continual improvement** of the Quality Management System – change management, risk management, and the timely and effective communication and escalation of appropriate quality issues.

LEO operates and maintains **premises, equipment and utilities** suitable for the operations to be carried out, with a design and layout devised to minimise any potential risk to the quality of the product.

The successful operation of the Quality Management System is achieved by **competent and skilful personnel, knowledge management and information-sharing**.

**Quality standards** at LEO are in written form, and LEO people must understand and comply with these standards in their daily work.

To ensure the control of **outsourced activities**, the quality of **purchased materials** and in order to meet the quality objectives, the Quality Management System includes evaluation, approval and oversight of suppliers, collaborators and distributors, with a strong emphasis on the effectiveness of and controls for these processes.

A **GxP Quality Management Review** is performed at specified intervals in order to monitor and ensure the suitability, adequacy and effectiveness of the GxP Quality Management System, identify opportunities for continual improvement, ensure that the Quality Management System satisfies the quality policy and the quality objectives, and monitor the performance of products and processes.

# Protection of Personal Data

**LEO people must protect personal data and the privacy of individuals with due care in all areas of our business. LEO people must comply with applicable laws, regulations, industry codes, international requirements and supporting internal guidelines.**

As part of our business activities, LEO Pharma may process personal data, including those about LEO people, contractors, suppliers' staff, healthcare professionals and clinical study participants. LEO may also process sensitive personal information in the course of its business.

To ensure a high standard of protection of personal data worldwide, all collection and processing of personal data, including sensitive data, must be in accordance with applicable laws, regulations and internal guidelines.

Compliance with the above is highly important and must be an integral part of our internal business processes. Violation of such laws, regulations and applicable internal procedures could have serious consequences, both for the people whose data are collected and processed by LEO, and for LEO.

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## Good attitudes

- Be aware that certain data may constitute personal data and must be treated with due care. This may include human biological samples used for research, patient information from clinical trials, employee records kept in connection with HR management and data regarding healthcare professionals
  - If legally required, remember to obtain the explicit and documented consent of the person whose personal data are being collected and/or processed
  - Never store personal data for longer than necessary, and ensure that only authorised people have access to it on a need-to-have basis
  - Consider whether the information being collected and/or processed is personal data and/or sensitive personal data before deciding where and how to store it
-





## Protection of Personal Data Policy

At LEO, we must protect and respect the rights of the people whose data LEO collects and processes in relation to our activities.

LEO people must comply with the following principles in order to ensure the protection of personal data:

- **Approval from authorities:** You should be aware that in order to collect certain personal data (e.g. research data), a specific authorisation from the relevant data protection authorities may be required.
- **Purpose:** You may only process personal data, including sensitive data, for specific, explicit and legitimate purposes relevant for the business of LEO.
- **Need-to-have requirement:** Personal data shall only be collected on a need-to-have basis. The personal data collected must be adequate, relevant and not excessive in relation to the purposes for which they are collected and processed.
- **Transparency:** Where legally required, you must inform the individual about the purpose of processing their personal data, their right to have their personal data rectified, deleted or blocked, and the identity of the company responsible for the collection and processing of their personal data.
- **Consent:** Where legally required, you must obtain the explicit, clear and documented consent of the individual to the collection and processing of his or her personal data. Such consent is always required when collecting and processing sensitive personal data.
- **Accuracy:** To ensure that the personal data being processed are always accurate, you must ensure that personal data are reviewed and updated at regular intervals, where appropriate.
- **Security:** When processing personal data, it is important that these are safeguarded by adequate security measures to minimise risks such as loss of data, unauthorised access, destruction and unintended/accidental disclosure.
- **Retention and deletion:** Personal data must only be stored for the length of time required to fulfil the purpose, or as prescribed by law.
- **Cross-border transfer of data:** Transfers of personal data from one country to another may be subject to approval from or notification to the relevant data protection agencies. You must ensure compliance with applicable legal requirements.

# Research and Development Ethics

**LEO people only engage in research and development which is scientifically justified and conducted in accordance with high ethical standards. LEO people must comply with applicable laws, regulations, industry codes, international requirements and our supporting internal guidelines.**

We are committed to compliance with the relevant laws and regulations, international guidelines and standards, such as:

- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- Ethical standards that meet international requirements
- Requirements for the development of medical devices, for example ISO 13485

Medical research by LEO involving humans must be consistent with the principles of the Declaration of Helsinki by the World Medical Association and applicable ethical standards, laws and regulations. When engaging in clinical trials with patients or volunteers, you should always ensure that the rights, safety and integrity of all trial participants are protected, and that data are reliable and robust.

LEO considers transparency of data from clinical trials to be a scientific, ethical and moral responsibility. When working on the public registration of clinical trials, you must follow the applicable laws, regulations and internal guidelines.

LEO is committed to communicating scientific data from our clinical trials. When scientific, medical and technical publications are involved, you must follow internal procedures.

When the use of animals for scientific purposes is involved, we follow the principles of the 3Rs: Replace, Reduce and Refine. All animal testing and care performed internally and through third parties must, as a minimum, comply with the standards set by EU legislation.

Any non-compliance with the above-mentioned requirements or any unethical research and/or development activities should be reported immediately.

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## Good attitudes

- Only work on research and clinical trials if you are trained and authorised to do so
  - Always ensure that the rights, safety and integrity of the study subjects are protected
  - Always strive to replace, reduce and refine the use of animals for scientific purposes
  - Report any unethical research and/or development activities to your manager immediately
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# Sales and Marketing Ethics

**LEO people must comply with applicable laws, regulations, industry codes, international requirements and internal guidelines in connection with sales and marketing activities and interactions with patients, healthcare professionals, organisations, public authorities and other stakeholders.**

When sales and marketing activities are involved, you must take measures to provide accurate, verifiable and clear information about LEO products and services. You must not engage in any practices that are deceptive, fraudulent, dishonest, misleading or unfair.

The main purpose of interactions with healthcare professionals is to ensure patient care and safety. You must always interact with healthcare professionals ensuring integrity and high ethical standards. You must carefully consider whether or not you are interacting with a healthcare professional under the applicable laws and regulations, and circumstances. Should more than one definition of a healthcare professional apply, you must always comply with the strictest rule in the specific situation.

We must never offer, give or take money or gifts, and never provide or accept services or hospitality to/from patients, healthcare professionals or any other stakeholders in order to obtain improper advantages.

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## Good attitudes

- Never engage in any sales and marketing practices that are deceptive, fraudulent, dishonest, misleading or unfair
  - Always ensure that promotional materials are duly reviewed and approved
  - Always determine whether the person you are interacting with is to be considered a healthcare professional under the applicable laws and regulations, and behave according to the relevant rules
  - Never offer, give or take money, provide or accept services or any benefit in kind to/from a healthcare professional in order to obtain improper advantages
  - Always make sure the legitimate business need for the engagement of a healthcare professional and the selection criteria used are documented
-



## Interaction with Healthcare Professionals in relation to Pharmaceuticals Policy

At LEO, we interact with healthcare professionals in order to provide or obtain scientific or educational information and knowledge, or to support medical research. Such interaction must be conducted in a truthful manner, avoiding deceptive practices and potential conflicts of interests.

### **LEO people must comply with the following principles when communicating with healthcare professionals:**

- Only appropriately trained LEO people may communicate with healthcare professionals on behalf of LEO.
- LEO material used in a promotional setting, regardless of its form and media, targeted at healthcare professionals must be duly approved.
- Off-label promotion or promotion of pharmaceutical products which have not yet obtained a marketing authorisation is strictly forbidden.<sup>6</sup>
- Gifts, donations, grants and sponsorships may only be provided to the extent allowed by applicable laws, regulations, codes and internal procedures, and must not constitute an inducement to obtain improper commercial advantages. They must also be approved and documented internally.

- Events and meetings may be organised or sponsored by LEO only for the purpose of gaining or providing scientific or educational information, and must be held at an appropriate venue.

- Hospitality, such as travel arrangements, meals and accommodation, may only be provided to healthcare professionals if appropriate and allowed by the applicable laws and regulations.

- Entertainment activities or other leisure or social activities are not permitted.

### **LEO people must comply with the following principles when engaging the services of healthcare professionals:**

- There must always be a legitimate business need for the service and a written contract must be in place before the services commence.

- The selection criteria for the healthcare professional must be transparent and documented.

- Remuneration for the services must be reasonable and reflect fair market value.

- Any notification and reporting requirements must be observed.

<sup>6</sup> Scientific Affairs employees may upon unsolicited request respond to off-label usage in a scientific and balanced manner. Appropriate communication about off-label use and non-approved products in a clinical/research setting is not considered as promotion.



## Supporting and Monitoring Compliance

All LEO people have a shared responsibility to ensure compliance at LEO. You must understand and follow the guidelines applicable to your role, and be attentive to areas which may require improvement.

LEO managers must ensure that these standards are followed at all times.

Competent authorities inspect LEO as part of their governance, to ensure that LEO complies with relevant laws and regulations. LEO Management has likewise established an audit programme to ensure compliance.

LEO people must support ongoing compliance at LEO Pharma by assisting in the proper conduct of audits and inspections, and by collaborating with third parties that meet our requirements and ethical standards.

Internal and external audits and inspections may be performed in order to identify issues in a timely manner, take corrective and preventive action, and ensure compliance with relevant requirements. Our Internal Audit department helps provide assurance that effective systems of control exist and that risks have been properly identified and assessed.

It is the responsibility of LEO people to be prepared for inspections at all times. If notified of an inspection or an audit, you must immediately contact the person responsible overall for the inspection. During audits and inspections at LEO, you must be available for questioning by the inspectors, and answer any questions truthfully and to the best of your knowledge. Documentation of internal audits should be maintained.

LEO acknowledges the importance of partnerships and collaborations. When engaging with third parties, you must seek to enter into relationships with third parties who are able to meet our requirements, and strive to develop business relationships built on trust, mutual respect and shared values.

LEO people collaborating with third parties must take measures to ensure their compliance with the LEO Third Party Compliance Codex, relevant guidelines and applicable laws and regulations, and to uphold high-quality and ethical standards. Before entering into new business engagements as well as during ongoing relationships with third parties, LEO may perform evaluation and monitoring activities to confirm that the third parties comply with the required standards.





## WhistleBlower Hotline

If any actual or potential serious concerns within LEO are detected, LEO people must report them, in order for us to continuously improve. Reporting of misconduct is in line with LEO values and the LEO Code of Conduct.

The LEO WhistleBlower Hotline has been introduced as an alternative to other communication channels to make it possible to come forward and disclose unethical behaviour within LEO in a secure and confidential way. The LEO WhistleBlower Hotline only covers legally described serious concerns. Other concerns are still very important for LEO to know about, but they have to be reported through ordinary communication channels such as HR or to your immediate manager.

The LEO WhistleBlower Hotline is operated through an external supplier's IT system. Only a very limited number of people have access to the concerns reported to the LEO WhistleBlower Hotline. An internal process has been established to protect the reporter of the concern as well as the subject of the report.

### What can be reported?

Only serious concerns or suspicions that could have an impact on the LEO Group or matters that could have a vital impact on an individual's life, health and/or environment can be reported, meaning:

- Serious economic crimes such as bribery, fraud, money laundering, serious irregularities related to accounting/internal audit, forgery or any other corruptive actions.
- Serious breach concerning environmental, health and/or safety issues that could have a vital impact on an individual's life, health and/or environment.
- Serious offences directed towards an employee, such as actual or threatened violence or sexual abuse.

The above list is not exhaustive.

### Who can report concerns and who can be the subject of a report?

- All LEO people, board members, customers, suppliers, collaborators, business partners and others related to LEO can report concerns.
- All LEO people and board members can be the subject of a report.

Reporting through the LEO WhistleBlower Hotline is possible in a variety of languages 24 hours a day, 365 days a year, from anywhere in the world – including anonymous reporting (when legally possible). Reporting is possible by phone and via the Internet. For further information, see Pulse or [www.leo-pharma.com](http://www.leo-pharma.com).



# Glossary

## Adverse device event

is any untoward medical occurrence, unintended disease or injury, or any untoward clinical sign (e.g. an abnormal laboratory finding) in subjects, users or other people related to the use of a medical device. This includes any adverse device event resulting from insufficiencies or inadequacies in the instructions for use, deployment, implantation, installation, operation or any malfunction of the medical device as well as any event that is a result of a use error or intentional misuse.

## Adverse event

is any untoward medicinal occurrence in a patient or clinical trial subject to whom a medicinal product has been administered that does not necessarily have a causal relationship with this treatment.

An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not it is considered to be related to the medicinal product.

Synonym: Adverse experience.

## Bribery

is offering, promising or giving a financial or other advantage to a person and/or entity to encourage said person and/or entity to perform their functions or activities improperly or to reward that person and/or entity for having already done so.

## Collection of personal data

means any kind of systematic or individual data gathered by LEO whether electronically, physically (e.g. human biological samples) or on paper. This includes personal data stored in a database, a spreadsheet, an e-mail or a physical paper list.

## Consent

in relation to personal data means any freely given specific and informed indication of a person's wishes by which the person whose personal data will be processed signifies his/her agreement to personal data relating to him/her being processed. In relation to GCP, a consent is an agreement to take part in a clinical study and an agreement to the use and processing of data.

**Counterfeit** refers to products that are falsified, or a product manufactured or sold with the intent to deceptively represent its origin, authenticity or effectiveness, or a product that is deliberately and fraudulently mislabelled.

## Facilitation payment

can be a payment made explicitly to ensure or expedite the performance by officials of a routine action to which you are already entitled, such as procuring permits, licences or work orders, receiving power and water supply, police protection, loading and unloading cargoes and customs clearance.

## GxP

at LEO is understood to be requirements within GMP (Good Manufacturing Practice), GDP (Good Distribution Practice), RA (Good Regulatory Practice), GPvP (Good Pharmacovigilance Practice), GCP (Good Clinical Practice) and GLP (Good Laboratory Practice). GxP is applicable for investigational medicinal products, medicinal products, drug device combination products, medical devices and cosmetics. Processes covered by these regulations must be included in the QMS.

## LEO Social media

refers to all web-based, digital and mobile technologies that provide an opportunity for user-generated content and two-way instant interactive communications between users, which could be one-to-one, one-to-many or many-to-many, and which are owned, paid for or managed by LEO, where LEO has authority over the content and LEO people communicate on social media on behalf of the company. Some examples of social media are social networks such as Facebook and LinkedIn, microblogs such as Twitter, image- and video-sharing channels such as YouTube, Wikipedia and other "Wikis", virtual worlds, weblogs and video blogs, Internet fora, chat rooms and health portals.

## Other Experience (OE)

are considered 'non events' which describe the circumstances around the use of a drug which potentially could cause drug related problems or which could potentially give positive knowledge of a drug. These may or may not be associated with adverse events. These cases include but are not limited to:

- Unintended beneficial effects
- The risk that an unborn child has been exposed to a LEO product in utero or via maternal or paternal exposure before or during pregnancy
- The risk that a breast fed child has been exposed to a LEO product via breast milk
- Occupational exposure
- Drug overdose or abuse



- Drug misuse or medication error
- Off label use/unapproved use
- Lack of efficacy
- Drug and food interaction
- Any suspicion of counterfeit product

### **Personal data**

are defined as any information relating to an identified or identifiable natural person. Personal data are, for example, names, birth dates, addresses, telephone numbers, social security numbers, photographs, e-mail addresses, blood samples and tissue samples. They include both personal data that are connected to an individual acting as a private person and data connected to a person acting as a professional, for example a business contact. Consequently, personal data include, but are not limited to, personal data about LEO people (including employee records in HR), contractors, suppliers' staff, healthcare professionals and clinical study participants.

### **Pharmacovigilance System Master File (PSMF)**

is a detailed description of the global pharmacovigilance system used by the marketing authorisation holder with respect to the data concerning one or more authorised medicinal products. The document is legally required in the EU according to Directive 2001/83/EC Article 1(28e). The document must be updated and maintained continuously, and must be made available to all authorities upon request. The PSMF contains important information from many parts of the LEO organisation, for example overviews of studies and market research, information about due training of staff, timely handling of reports on adverse events and other experiences, findings from authority inspections, and internal audits within pharmacovigilance.

### **Processing of personal data**

is any operation or set of operations that is performed on personal data by computer or manually, for example collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

### **Protection money**

can be sums extracted from a person or entity by a criminal, gang leader or government official to "protect" the person or entity, for example from other criminals or regulatory agencies.

### **Sensitive personal data**

are data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, or concerning health (such as medical records and human biological samples) or sexual orientation.

### **Third party**

is any company or individual that is engaged to provide products or services to LEO or to act on behalf of LEO (i.e. vendor or service provider) and/or enters a business partnership with LEO (i.e. business partners).

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## Contact

You can find information about who to contact on Pulse:

- If you have questions regarding LEO Code of Conduct.
- If you need guidance about the issues covered by the LEO Code of Conduct.

