Regional Business Compliance Program

Ljubljana, April 2025

TABLE OF CONTENTS

APPENDIX:

PURPOSE

The purpose of this document is to provide an overview of the Business Compliance and Ethics Program (in short "**Compliance Program**") for Lenis farmacevtika d.o.o. together with its daughter companies and contractors (hereinafter referred to as "**Lenis**") and set expectations related to business compliance.

For avoidance of doubt, this Compliance Program does not cover Regulatory Compliance, i.e. compliance with good manufacturing practice (GMP), good distribution practice (GDP) and other related pharmaceutical laws and guidelines, which are covered by departments of Quality, Medical Affairs, Regulatory Affairs and Pharmacovigilance in Lenis and governed by a separate set of Standard Operating Procedures (SOPs).

SCOPE

Lenis is committed to conducting its business ethically and maintaining and promoting culture that emphasizes integrity, individual and company acceptance of responsibility, effective self-policing, and transparency in the relationships between Lenis and its key stakeholders, including healthcare professionals (HCPs) and government officials. In furtherance of this commitment, Lenis has established a Compliance Program and abides by its requirements.

The Compliance Program is a dynamic program that provides a framework for adapting to the changing environment in which Lenis operates. It is continually evaluated by the compliance officer (CO) and the Managing Director to ensure that it functions as intended, serves the purpose for which it has been designed, and enables Lenis to meet its high standards and commitment to compliance.

This compliance program has six elements:

1. Policies & Procedures
2. Designated Compliance function
3. Training & Awareness
4. Audits & Monitoring
5. Whistleblowing
6. Investigations & Reporting

RESPONSIBILITIES

All employees are responsible for compliance with all applicable rules and standards.

The **Managing Director and Managers** are responsible for:

- exemplifying a culture of compliance and ethics throughout Lenis;
- setting the expectation for compliance and ethics as a core responsibility for all employees;
- promoting and maintaining a work environment where concerns can be raised, openly discussed, and reported without fear of retaliation;
- ensuring that the CO and Compliance Department have sufficient staffing, qualifications, resources, and financial support to perform their responsibilities;
- supporting the CO on compliance matters and supporting the effective operation of a robust, dynamic, and flexible Compliance Program;
- coordinating with the CO and Compliance Department to periodically evaluate the Compliance Program to ensure that it (i) functions as intended, (ii) serves the purposes for which it has been designed, and (iii) enables Lenis to meet its high standards and commitment to compliance and ethics;
- provide appropriate and timely responses to questions or concerns, in consultation with the Compliance Department, as needed;
- maintain communication with the Compliance Department about potential compliance and ethics concerns.

The **CO and its Deputies** are responsible for:

- designing, implementing, and overseeing an effective Compliance Program;
- leading the Business Compliance Department responsible for ensuring performance of the Compliance Program;
- keeping informed of developments and trends in healthcare compliance through regular education and training, and using such information to enhance the Compliance Program;
- keeping the Managing Director regularly informed of Compliance Program developments, as well as legal changes and industry best practices related to the Compliance Program;
- periodically assessing the effectiveness of the Compliance Program to determine that it (i) functions as intended; (ii) serves the purposes for which it has been designed; (iii) is reflective of current laws, developments, and industry best practices; and (iv) enables Lenis to meet its high standards and commitment to compliance.

Employees are responsible for:

- acting in compliance with the performance of their duties and in their conduct, and otherwise supporting the Compliance Program;
- reading, understanding, and complying with all policies and procedures;
- completing all required compliance and ethics training in a timely manner;
- reporting potential compliance issues to their supervisor, another member of the management team, the Compliance Department, the Managing Director, or the Whistleblowing channels;
- cooperating with the Compliance Department in the performance of compliance investigations, auditing and monitoring activities.

ELEMENTS OF COMPLIANCE PROGRAM

1. Policies & Procedures

Lenis has developed policies and procedures that capture its commitment to compliance and effectively address compliance obligations. The policies and procedures also account for specific areas of compliance and ethics risks relevant to HCPs, healthcare organizations (HCOs), non-governmental organizations (NGOs) and patient organizations (POs).

These policies and procedures will be periodically reviewed and revised (but not later than after 3 years) and made available to all employees.

Compliance with all applicable policies and procedures is a condition of employment and an element in evaluating and rewarding the performance of all employees.

Lenis' policies and procedures are:

- Regional Business Compliance Program* (this document)
- Regional Rulebooks on:
  - sponsorship and organization of an activity
  - commissioned lecture/expert opinion/article
  - attendance in a professional event
  - donation
  - advertising medicinal products and medical devices
  - the distribution of samples of medicinal products and medical devices
  - the transmission of advertising communications
  - collaboration between medical affairs and commercial department
  - interactions between medical affairs and other health-care stakeholders
- Checklist for activities
- Guidelines for booking flights
- Compliance Frequently asked questions (FAQ)
- Methodology on collection and publication of Transfers of Value (ToV)*
- ToV yearly reports*

- Guidelines for business partners*, including
  - Third Party Due Diligence Questionnaire and Declaration
- Conflict of Interest (COI) disclosure form
- Rulebook on the security of personal data processing (GDPR)
- Privacy Policy*
- Whistleblowing policy*

Documents marked with an asterisk (*) are also publicly available on the company website, under the section Our Policies.

2. Designated Compliance function

The **Compliance Officer (CO)** is an independent and objective function that reviews and evaluates compliance issues and concerns. Lenis has appointed a CO who is charged with operating and monitoring the Compliance Program. The CO has a direct reporting relationship to the Managing Director. The CO regularly informs the Managing Director and applicable stakeholders on the Compliance Program and compliance risks, concerns, issues, or violations that may come to their attention.

The CO **has Compliance Deputies** who support CO with operating and monitoring the Compliance Program.

Lenis encourages employees outside the Compliance department to become **Compliance Champions**, meaning that also employees take on the responsibility of promoting compliance practices within the organization, are knowledgeable about compliance requirements and company policies and proactively suggest improvements, and actively work to ensure that their colleagues understand and adhere to these standards.

3. Training & Awareness

Lenis organizes **regularly scheduled, comprehensive compliance training and education of its employees and business partners**. When necessary, compliance training and education is targeted by function and topic to maximize its effectiveness. Satisfactory participation in and completion of required compliance and ethics training is a condition of continued employment.

Lenis Compliance educational program consists of:

Type of training	Frequency	Target Audience
Business Compliance Training	Annually	Company-wide
Compliance Q&A meetings	Monthly	Initiators and approvers of activities and materials
One-day compliance workshops	Annually	Initiators and approvers of activities and materials
Onboarding Business Compliance training	As needed	New employees & returning employees after a prolonged leave (>6 months), Subdistributors
Training to inform about recent events in business compliance	As needed	As needed

List of all business compliance trainings, as well as materials from such trainings and training records (attendance logs), are maintained and regularly updated in the Business Compliance folder.

4. Audits & Monitoring

Risk Assessments

Lenis conducts regular **compliance risk assessments** to evaluate the compliance-related risks that have the potential for legal, financial, operational, and reputational damage and implements appropriate mitigation strategies as warranted. The output of these is the **internal compliance audit & monitoring plan**.

Approvals of activities and materials

Electronic application for **Activity Approvals**, serves for assessments based on which all interactions with HCPs, HCOs, NGOs and POs, and government officials are assessed and approved or declined. Procedure is based on assessment of proposed interaction, submitted by an initiator, and approvals of all relevant approvers in following order:

(I) Initiator
   a. Commercial/Medical/Public Affairs

(II) Approvers
   a. Commercial/Medical – depending on department of initiator
   b. Medical
   c. Compliance
   d. Managing Director/Commercial Director

More detailed instructions on the process of approval of activities are listed in Regional Rulebooks for each specific type of activity, as well as in the *Activity App Manual*.

Lenis uses another electronic application, called **Promotional and Informational Materials App**, for internal approval of all materials. Here, the compliance function is not an obligatory step in approval process, but based on the risk of materials, initiators can choose to voluntarily add compliance approver as an additional approver if needed. More detailed instructions on the process of approval of activities are listed in Regional Rulebook on advertising of medicinal products and medical devices, as well as in the *Promotional and Informational App Guide*.

Monitoring

Activity Approvals App and Promotional and Informational App also serve as a data and documents base for all relevant documentation for performed activities and prepared materials as a proof of compliance.

Compliance department periodically conducts monitoring of past activities and materials based on all relevant information and documents and proposes measures for improvement or risk mitigation if needed.

Third Party Assessment/Due Diligence

Lenis conducts third party due diligence on external stakeholders who conduct business on Lenis' behalf by assessing business and ethical practices:

- **Reputation check** - conduct background checks to assess the partner's reputation within the industry and marketplace; this can be done through industry reports, media searches, and feedback from other businesses. This is done through Appendix 1 of the Guidelines for Business Partners: the Third Party Due Diligence Questionnaire and Declaration.
- **Ethical policies and standards** - investigate the partner's ethical policies, practices, and any current and historical violations related to corporate governance, bribery or corruption. We ask the business partners to read our Guidelines for Business Partners, fill out the Third Party Due Diligence Questionnaire and sign the Declaration in Appendix 1.
- **Conflicts of interest** – check any potential conflicts of interest between Lenis or its employees and business partners, including any relationships that could affect impartiality in decision-making. This is done through the Conflict of Interest (COI) disclosure form or a disclosure by initiator of an activity in K2 phase of activity approval in the Activity App by checking the COI check box and providing the explanation in the provided text field for compliance to review.

Audits

Lenis periodically conducts audits and monitoring to support the prevention, detection, and correction of instances of noncompliance. This includes **internal audits** and **audits of Lenis' subdistributors**. Auditing and monitoring activities will be calibrated based on the results of compliance risk assessments, previous auditing and monitoring activities, and compliance investigations. The documentation regarding internal Audits is collated in the Internal Audits Log folder, and the outcomes are tracked in the Internal Audits Tracking Table.

Lenis is also **subject to external audits** performed by its principals. Compliance Department participates, supported by initiators and approvers of materials and activities, in providing information and relevant documents to auditors and executes proposed plans regarding compliance action if needed.

5. Whistleblowing procedure

Lenis has established and maintains a whistleblowing procedure that sets forth the duty of Lenis' employees to report potential compliance issues, including any identified concerns, issues, or questions regarding suspected or potential violations of policies and procedures, and/or applicable laws and regulations.

The Whistleblowing procedure emphasizes a strict nonretaliation policy. Lenis does not retaliate or take disciplinary action against any individual for reporting concerns in good faith. "In good faith" means the reporter believes that the information reported is true and correct to the best of their knowledge and ability.

The Whistleblowing procedure includes reporting channels that enable individuals to disclose potential compliance issues to the CO or some other person who is not in the disclosing individual's chain of command. The procedure is described in more detail in Lenis' Whistleblowing Policy, available on internal company channels and publicly on the company web page, under the section Our Policies.

6. Investigations & Reporting

Enforcement and corrective actions

Violations of the compliance program, failure to comply with applicable law, and other requirements, and other types of misconduct may threaten Lenis' status as a reliable, honest, and trustworthy partner, capable of participating in healthcare. Detected, but uncorrected, misconduct may seriously endanger the mission, reputation, and legal status of the Company.

Consequently, upon reports or reasonable indications of suspected noncompliance, the **CO initiates an investigation** to determine whether a material violation of applicable laws or requirements has occurred.

The steps in the internal investigation may include **interviews and a review of relevant documentation**. Records of the investigation should contain documentation of the alleged violation, a description of the investigative process, key documents, results of the investigation, and the corrective actions implemented. The documentation regarding each potential investigation is collated in the Case Log folder and the outcomes are tracked in the Case Log Tracking Table.

Lenis will take appropriate **disciplinary action** for established compliance violations and will identify corrective actions to help prevent the recurrence of similar violations. These may include, but are not limited to:

a. Addressing any gaps in policies, practices, and training and opining on any misinterpretation of policies, practices, or training that may have contributed to a violation

b. Imposing a range of disciplinary measures, up to and including termination of employment or contract termination for business partners.

Decisions regarding appropriate disciplinary action(s), if any, will be determined by the Human Resources department, Managing Director, and the relevant functional area.

Reporting

Within the scope of the Compliance Program, Lenis prepares the following reports:

- Transfer of Value Report (yearly until June 30th for the previous calendar year), prepared voluntarily based on the European Federation of Pharmaceutical Industries and Associations (EPFIA) Transparency code, in which Lenis discloses the scope and value of collaborative work with HCPs, HCOs and NGOs (e.g. payments, grants, donations, sponsorships, R&D funding) in order to prove fair compensation for any services provided to Lenis (e.g. consultancy fees) and to ensure transparency in other types of Transfers of Value (e.g. congress sponsorships, educational sponsorships). Compliance also reviews and evaluates interactions with HCPs.
- Record of distribution of promotional materials for medicinal products and medical devices
- Record of distribution of free samples
- Yearly Compliance report to the Managing Director, which includes revision of the previous year and the plan for the next period.

FINAL PROVISIONS

This Compliance Program can be amended in the same manner and according to the same procedure as it was adopted.