



## **COMPREHENSIVE COMPLIANCE PROGRAM**

### **I. INTRODUCTION**

LEO Pharma Inc. ("LEO" or the "Company"), a wholly owned U.S. subsidiary of LEO Pharma A/S, is a pharmaceutical company focused on developing and commercializing products for the treatment of patients living with skin diseases.

LEO conducts its activities in accordance with all applicable laws and regulations and is committed to establishing a corporate culture of legal and ethical compliance.

LEO has established and maintains a comprehensive compliance program ("Compliance Program") that has been developed in accordance with the United States Department of Health and Human Services, Office of Inspector General "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Guidance") published in April 2003.

As recommended in the OIG Guidance, the LEO Compliance Program has been designed to fit the specific compliance needs of the Company. LEO will continue to regularly review the effectiveness of its Compliance Program and refine it to meet the Company's on-going compliance needs, as well as any changes in applicable federal or state laws.

### **II. OVERVIEW OF COMPREHENSIVE COMPLIANCE PROGRAM**

#### **A. Compliance Officer and Compliance Committee**

LEO has designated a Compliance Officer who is charged with the responsibility of developing, maintaining, operating, and monitoring the LEO Compliance Program. The Compliance Officer has the authority to effectuate change and exercise independent judgment within the Company. Additionally, the Compliance Officer has the authority to report directly to the President & CEO.

LEO has also established a Compliance Committee comprised of senior management personnel from a variety of business units. The Compliance Committee advises and assists the Compliance Officer in the creation, updating, and implementation of the Compliance Program.

## **B. Written Policies and Procedures**

As part of its Compliance Program, LEO has established a code of conduct consistent with the OIG Guidance, which provides instruction on the principles to which all LEO directors, officers, employees, independent contractors, and agents must adhere. In addition, LEO has adopted policies, procedures, and guidelines consistent with the Pharmaceutical Research and Manufacturers of America "Code on Interactions with Healthcare Professionals" (the "PhRMA Code") effective January 2009. These policies reflect the Company's commitment to compliance with federal and state law. LEO reviews its policies and procedures on a routine basis and revises them as necessary to meet the changing requirements imposed by law.

## **C. Effective Training and Education**

Training and education are critical components of the LEO Compliance Program. LEO requires regular compliance training for all applicable directors, officers, employees, independent contractors, and agents on LEO policies and procedures. LEO regularly reviews and updates its training program to ensure the program reflects the most current and meaningful education on Company policies and procedures and applicable federal and state laws.

## **D. Effective Lines of Communication**

LEO maintains an open-door policy to encourage open dialogue about compliance questions and concerns. LEO personnel may discuss issues, concerns, problems, and suggestions with their immediate supervisor or with the Compliance Officer. In addition, LEO personnel may also report questions and concerns anonymously via the LEO Hotline, which is available 24 hours a day, 7 days a week, 365 days per year. Individuals may make good faith reports of known or suspected violations without fear of reprisal. Retaliation against any individual who makes a good faith report of a known or suspected violation is strictly prohibited under Company policy.

## **E. Monitoring and Auditing**

Internal monitoring and auditing techniques are vital parts of the LEO Compliance Program. Effective monitoring can provide LEO with the ability to detect and prevent deviations that can potentially affect Company compliance goals. Accordingly, LEO routinely monitors its policies and procedures to evaluate whether they adequately address risk areas and personnel compliance with Company policies and procedures and federal and state law. Additionally, LEO personnel, at all levels, are responsible for reporting potential compliance issues of which they become aware.

## **F. Disciplinary Guidelines**

The LEO Compliance Program supports prompt response and appropriate corrective action for any detected compliance violations. It is expected that any compliance concerns received by the Compliance Officer or LEO management will be reviewed carefully, investigated in a timely manner, and result in appropriate corrective action and preventive measures to ensure the integrity of the Compliance Program. In addition, when appropriate, a compliance report may be provided to the relevant authorities.

Personnel who violate LEO policies and procedures, applicable state and federal laws, or both, may be subject to disciplinary action, up to and including termination, as determined on a case-by-case basis.

### **III. STATEMENT OF ANNUAL AGGREGATED LIMIT**

In accordance with the requirements of California Health & Safety Code § 119402, LEO has set a specific annual dollar limit on “gifts, promotional items or activities” that may be provided to medical or health professionals within California. LEO has determined that the annual aggregate limit on covered promotional expenditures is \$2000 per covered medical or health professional per year.

This figure represents an upper limit, not a spending goal. Not included in the internal spending limit are any items that are exempt as provided by California law. In setting this limit, LEO has taken into account the size of the Company and product portfolio. As the size of the Company and product portfolio changes, LEO may revise its annual aggregate limit.

### **IV. DECLARATION OF COMPLIANCE**

Based on its good faith understanding of the California requirements, as of the date of this declaration, LEO declares that to the best of its knowledge, information, and belief it is in compliance with its Compliance Program and the California Health & Safety Code §§ 119400-119402.

LEO also declares that the structure of its Compliance Program and the guidelines enunciated in LEO policies regarding applicable interactions with medical or health professionals incorporate the principles articulated in the OIG Guidance and the updated PhRMA Code effective January 2009.

LEO has developed and implemented elements of its Compliance Program to address certain unique issues raised by the California law and will continue to refine these compliance elements as necessary. As appropriate and in accordance with the law, LEO will amend and update its policies, guidelines, and procedures and this statement to assure compliance.

Copies of this Summary of Comprehensive Compliance Program and the declaration of Compliance may be obtained upon request by contacting LEO Pharma Inc. toll free at **(877)494-4536**.