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**COMPREHENSIVE COMPLIANCE PROGRAM**

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## **COMPREHENSIVE COMPLIANCE PROGRAM**

Orexo U.S., Inc. (“Orexo US”) is committed to core principles of good corporate citizenship and integrity. A key component of this commitment—which is relevant to Orexo US’s relationships with the government, employees, and customers—is establishing and maintaining an effective compliance program.

The “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “OIG Guidance”) outlines seven key elements of an effective compliance program. Based on these elements, Orexo US has implemented a comprehensive compliance program (“CCP”), which puts Orexo US’s ethical principles into practice on a daily basis.

The CCP is intended to prevent and detect violations of law or Orexo US policy. While the OIG Guidance recognizes that the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated, it is Orexo US’s expectation that employees will comply with the policies established in support of the CCP. In the event that Orexo US becomes aware of violations of law or Orexo US policy, it will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

In accordance with the OIG Guidance, Orexo US has tailored the CCP to fit the unique environment of the Orexo US. Because a compliance program cannot be static, but rather must respond to evolving compliance needs, Orexo US will continually review, assess and improve the CCP as necessary in light of the changing business and regulatory environment.

The fundamental elements of the current CCP are described below.

### **LEADERSHIP AND STRUCTURE**

Orexo US maintains a Compliance Officer and Compliance Committee. Together, the Compliance Officer and Compliance Committee are responsible for overseeing Orexo US’s program for complying with the applicable federal and state healthcare laws and regulations, and for adhering to the highest ethical standards in its marketing, promotional, educational, and research activities. Orexo US is committed to ensuring that the Compliance Officer and Compliance Committee have the resources and authority to exercise independent judgment and to effectuate change within the organization as necessary to establish and maintain the CCP.

**Compliance Officer.** Orexo US’s legal counsel currently serves as the Compliance Officer. The Compliance Officer is charged with the responsibility of developing, operating and monitoring the CCP. The Compliance Officer reports semi-annually, and on an as-needed basis to the Compliance Committee of Orexo AB’s Board of Directors, and meets regularly with Orexo US’s Compliance Committee.

**Compliance Committee.** Orexo US has established a Compliance Committee, which supports the Compliance Officer in implementing and operating Orexo US’s

Compliance Program. The Compliance Committee consists of members of Orexo US's senior management and operating divisions, and is responsible for identifying and managing areas of risk and areas of critical focus for the Orexo US and its compliance program. When necessary, the Compliance Committee may establish a task force to address specific compliance concerns.

## **WRITTEN STANDARDS**

Orexo US's CCP includes a system of written compliance policies, procedures and practices that guide the Orexo US and the conduct of its employees in day-to-day operations. These policies and procedures have been developed under the direction and supervision of Orexo US's Compliance Officer, legal counsel, and management from various functional areas. Orexo US's written standards include the following:

**Code of Business Conduct and Ethics.** Orexo US's basic corporate policies are included in the "Code of Business Conduct and Ethics," which requires all Orexo US employees to obey all laws, act in an ethical manner and make business decisions that are consistent with Orexo US policy. The Code of Business Ethics is available at [www.orexo-us.com](http://www.orexo-us.com), together with more specific policies regarding whistle-blowing and insider trading.

**Commercial Compliance Policies.** Orexo US has developed a wide range of policies, procedures and practices relating to sales and marketing practices and interactions with healthcare professionals and consumers, including, among other things, policies and procedures relating to PhRMA Code compliance, providing medically and ethically appropriate items to healthcare professionals, charitable contributions, grants, investigator-initiated studies, promotional activities, direct-to-consumer education, outreach, and communication, speaker programs, operating commercial booths and medical inquiries.

**PDMA Policies.** Orexo US currently does not require policies and operating procedures relating to the distribution of product samples pursuant to the Prescription Drug Marketing Act because it is not distributing product samples.

**Annual Gift Limitation.** With respect to business activity in California, Orexo US has established "a specific annual dollar limit on gifts, promotional materials, meals, or items or activities that Orexo US may give or otherwise provide to an individual medical or health care professional." This annual dollar limit is \$1500 and primarily reflects dollars expended in association with programs designed to inform prescribing medical and healthcare professionals about Orexo US products and the disease states these products help treat. Orexo US will evaluate this limit on an annual basis and make any necessary adjustments consistent with any operational or practical issues related to compliance with the statute. It is important to note that this annual dollar limit is an upper limit. It is not an accurate representation of the average value of gifts, promotional materials, items or activities that Orexo US may provide annually to a typical individual medical or healthcare professional. That average would be a lower amount.

Consistent with California law, Orexo US's annual dollar limit does not include drug samples given to physicians and healthcare professionals intended for free distribution to patients, financial support for continuing medical education forums, financial support for health educational scholarships and fair market value payments for legitimate professional services provided by health care or medical professionals. In addition, the dollar limit does not include reprints, printed advertising or promotional materials, and other items provided for distribution to patients (e.g. patient oriented health and disease management information).

Orexo US has adopted a calendar year cycle for purposes of tracking compliance with the \$1500 gift and meal limitation. Annually, on or before June 1, Orexo US, pursuant to California Health and Safety Code §§ 119400-119402, will make its declaration of compliance with the \$1500 gift and meal limitation for the 12-month period covering January 1 through December 31 of the preceding year.

## **EDUCATION AND TRAINING**

The education and training of Orexo US's employees regarding their legal and ethical obligations under applicable laws, including federal healthcare programs, is a critical element of Orexo US's CCP.

Relevant employees receive annual training that covers pertinent areas of Orexo US's CCP, including healthcare compliance policies and procedures and the relevant legal requirements. Training takes a variety of forms, including live training and written materials. Employees must certify completion of training and/or complete a testing regimen. Orexo US also regularly reviews and revises its education and training programs, as well as identifies any new areas of education and training that may have become necessary.

Relevant employees receive special training on Orexo US's Commercial Compliance policies. Newly-hired sales representatives and other relevant employees of third-party service providers receive training on Orexo's commercial compliance policies. This includes training to ensure compliance with the federal laws and regulations that relate to pharmaceutical sales and marketing such as the anti-kickback statute, the PhRMA Code on Healthcare Professional Interactions, and FDA drug promotion regulations. After this initial training, there is periodic training aimed at re-certifying sales representatives on relevant policies. Sales representatives and other relevant personnel based in geographies with state or other region-specific regulatory requirements also receive training specific to the local requirements.

## **INTERNAL LINES OF COMMUNICATION**

Orexo US is committed to fostering dialogue between management and employees. Employees may seek guidance when uncertain as to the appropriate course of conduct in adhering to Orexo US's high standards. In most instances, employees should bring questions to their supervisor. Alternatively, any employee may request assistance and advice from various departments within the Orexo US and may contact the Compliance

Officer directly. Finally, Orexo US maintains the following website address and phone hotline for the reporting of compliance concerns: [www.orexo.ethicspoint.com](http://www.orexo.ethicspoint.com) and +1-844-251-4251. Orexo US's goal is that all employees, when seeking answers to questions or reporting potential violations, should know who to turn to for a meaningful response and should be able to do so without fear of retribution.

## **AUDITING AND MONITORING**

Orexo US's Compliance Officer, supported by the Compliance Committee, is responsible for monitoring, auditing and evaluating the CCP. In accordance with the OIG Guidance, the nature, extent and frequency of compliance monitoring and auditing varies according to a number of factors, including new regulatory requirements, changes in business practices and other considerations.

## **RESPONDING TO POTENTIAL VIOLATIONS**

Violation of applicable laws, any of the provisions of the CCP, or other Orexo US policy may result in disciplinary action pursuant to Orexo US policy. Upon identification of possible noncompliance, the Compliance Officer is responsible for commencing an investigation to determine whether there has been a violation and the materiality of any such violation. Although each situation is considered on a case-by-case basis, Orexo US will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

## **CORRECTIVE ACTION PROCEDURES**

A Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, it is Orexo US's policy to respond promptly to potential violations of law, regulation or Orexo US policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in policies, practices or internal controls and, if so, that it revise its policies, practices and internal controls to help prevent future violations.

## **QUESTIONS**

Questions about this CCP should be directed to the Compliance Officer.