

# **Description of Comprehensive Compliance Program pursuant to the California Marketing Practices Act (California Health and Safety Code §§ 119400-119402)**

## **I. Introduction**

Idorsia Pharmaceuticals US Inc. and Idorsia Clinical Development US Inc. (together, “Idorsia” or “Company”) are committed to core principles of good corporate citizenship and integrity. A key component of this commitment – which is relevant to Idorsia’s relationships with the government, employees, and customers – is establishing and maintaining an effective compliance program. Idorsia has implemented a comprehensive compliance program (“CCP”), which puts Idorsia’s ethical principles into practice on a daily basis.

The CCP is intended to prevent and detect violations of law, regulation, or Idorsia policy. In the event that Idorsia becomes aware of violations of law, regulation, or policy, it will investigate the matter and, where appropriate, take disciplinary action and implement appropriate corrective measures to prevent future violations. Idorsia has tailored the CCP to fit the unique environment of Idorsia. Because a compliance program cannot be static, but rather must respond to evolving compliance needs, Idorsia will continually review, assess, and improve the CCP as necessary in light of the changing business and regulatory environment.

## **II. Comprehensive Compliance Program Overview**

### **1. Leadership and Structure**

- Idorsia maintains a Head of Compliance US and US Compliance Committee. Together, the Head of Compliance US and US Compliance Committee are responsible for providing oversight and guidance over Idorsia’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, promotion, educational, and research activities. Idorsia is committed to ensuring that the Head of Compliance US and the US 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.
- The Head of Compliance US is a Vice-President level role and charged with the responsibility of developing, operating, and monitoring the CCP. The Head of Compliance US shall function in an independent capacity and report directly to the General Manager/President of Idorsia with the ability to escalate compliance concerns to the Global Compliance Officer, the Idorsia Pharmaceuticals Ltd. Board of Directors and/or to the Idorsia Pharmaceuticals Ltd. audit committee chairperson. The Head of

Compliance US meets regularly with the US Compliance Committee and General Manager/President of Idorsia.

- Idorsia has established a US Compliance Committee, which supports the Head of Compliance US in implementing and operating Idorsia's Compliance Program. The US Compliance Committee consists of members of Idorsia's Leadership Team and is responsible for identifying and managing areas of risk and areas of critical focus for Idorsia and its Compliance Program. When necessary, the US Compliance Committee may establish a task force or sub-committee to address specific compliance concerns.

## 2. Written Standards

- Idorsia's CCP includes a system of written compliance policies, procedures and practices that guide Idorsia and the conduct of its employees in day-to-day operations. These policies and procedures have been developed under the direction and supervision of the Head of Compliance US, legal counsel, and management from the various functional areas. Idorsia's written standards include the following:
  - Idorsia's basic corporate policies are included in the Code of Business Conduct which requires all Idorsia employees to obey all laws, act in an ethical manner and make business decisions that are consistent with Idorsia policy. The Code of Business Conduct is available on the Company's website, including information regarding how to anonymously report a potential concern.
  - Idorsia has developed a wide range of policies, procedures and practices relating to sales and marketing practices and interactions with healthcare professionals and consumers, including, but not limited to, policies and procedures on appropriate promotional activities, providing ethically appropriate educational items to healthcare professionals, external funding requests (e.g., grants, charitable contributions), speaker training and speaker program execution, medical inquiries and adherence to federal and state disclosure laws.
  - With respect to business activity in California, Idorsia has established "a specific annual dollar limit on gifts, promotional materials, or items or activities that Idorsia may give or otherwise provide to an individual medical or healthcare professional." This annual dollar limit is \$2,000 and primarily reflects dollars expended in association with programs designed to inform prescribing medical and healthcare professionals about Idorsia products and the disease states these products help treat. Idorsia will evaluate this limit on an annual basis and make necessary adjustments consistent with any operational or practical issues related to compliance with California Law. 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 Idorsia may provide annually to a typical individual medical or healthcare professional. The average would be a lower amount.

Consistent with California law, Idorsia'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 to Idorsia by medical or healthcare 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).

Idorsia has adopted a calendar year cycle for purposes of tracking compliance with its gift limitation. When required by California law, annually, on or before August 1, Idorsia will make its declaration of compliance with its gift limitation for the 12-month period covering January 1 through December 31 of the preceding year.

### **3. Education and Training**

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

Relevant employees receive annual training that covers pertinent areas of Idorsia's CCP as the business evolves, 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. Idorsia also regularly reviews and revises its education and training programs, as well as identifies any new areas of education and training that may become necessary.

Newly-hired sales representatives and other relevant employees will receive special training on Idorsia's compliance policies. This will include 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 Interactions with Healthcare Professional, 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.

#### **4. Internal Lines of Communication**

- Idorsia 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 Idorsia's high standards. In most instances, employees should bring questions to their manager. Alternatively, any employee may request assistance and advice from various departments within Idorsia and may contact the Head of Compliance US directly or another member of the Compliance Department. Please refer to Idorsia's Code of Business Conduct for information on reporting compliance concerns. Idorsia'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.

#### **5. Auditing and Monitoring**

- Idorsia's Head of Compliance US, supported by the US Compliance Committee, is responsible for monitoring, auditing, and evaluating the elements of the CCP. 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, the changing needs of the business and other considerations.

#### **6. Responding to Potential Violations**

- Violation of applicable laws, any of the provisions of the CCP, or other Idorsia policy may result in disciplinary action pursuant to Idorsia policy. Upon identification of possible noncompliance, the Head of Compliance US 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, Idorsia will undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

#### **7. Corrective Action Procedures**

- A Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, Idorsia recognizes that even an effective Compliance Program may not prevent all violations. As such, it is Idorsia's policy to respond promptly to potential violations of law, regulation or Idorsia policy, take

appropriate disciplinary action, assess whether the violation is in part due to gaps in policies, practices or internal controls and, if so, to revise its policies, practices and internal controls to help prevent future violations.