

## **HELINN THERAPEUTICS (U.S.) INC. COMPREHENSIVE COMPLIANCE PROGRAM**

### **A. Introduction**

Helsinn Therapeutics (U.S.) Inc. (Helsinn) is committed to establishing and maintaining a comprehensive and effective compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the Office of Inspector General, U.S. Department of Health and Human Services on May 5, 2003 (the "OIG Guidance") and with the Pharmaceutical Research and Manufacturers of America "Code of Interactions with Health Care Professionals," effective January 2022 (the "PhRMA Code"). Originally published in 2002, the PhRMA Code was updated in 2009, 2019 and January 2022.

Our Compliance Program is one of the key components of our commitment to the highest standards of ethical business conduct. As acknowledged by the OIG Guidance, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. It is Helsinn's expectation that our employees will comply with The Helsinn Code of Business Conduct and Ethics, the Compliance and Quality Manual and other relevant policies. In the event that Helsinn becomes aware of violations of law, regulations or Company policy, we will investigate the matter and, as appropriate, take disciplinary action and implement corrective measures to prevent future violations.

The fundamental elements of our Compliance Program are described below. Consistent with the OIG's recommendation, Helsinn's Compliance Program has been established consistent with the unique environment that exists at Helsinn. Further, our Compliance Program is dynamic; we periodically engage in a review of our Compliance Program to meet our evolving compliance needs on an ongoing basis.

### **B. Summary of Compliance Program**

#### 1. Leadership and Structure

Helsinn has a Group Compliance Officer (GCO) and U.S. Compliance Officer. The Compliance Officer is responsible for implementing, operating and monitoring the Compliance Program. The Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate, and has access to, and is authorized to, report concerns or issues of any kind directly to Helsinn Board of Directors.

The Compliance Program is fully supported by Helsinn's Board of Directors and senior management team.

## 2. Written Standards

The Helsinn Code of Business Conduct and Ethics, the Compliance and Quality Manual and other policy documents are our statement of ethics and compliance principles that guide our daily operations. These policies establish our expectation that management, employees and agents of the Company act in accordance with all relevant laws, regulations and Company policies.

The OIG Guidance identified several key risk areas for pharmaceutical manufacturers and called on companies to develop compliance policies in these risk areas. These risk areas include (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; (3) sales, marketing and promotional practices; and (4) compliance with laws regulating prescription drug sampling activities. Helsinn has accordingly established policies that address interactions with health care professionals (including promotional practices and kickbacks), data integrity, and sampling activity.

Helsinn has also established an annual spending limit of \$2,000 per health care professional as per the California Business and Professional Code §119402. This amount is an upper limit and addresses spending on health care professionals for occasional meals and snacks, meals provided in connection with a Company speaker program, and any gifts, such as medically related textbooks or journals. This amount does not include the value of pharmaceutical drug samples, grants for medical education, medical scholarships, professional service or consulting fees, patient education materials, and approved scientific reprints. This limit may also be subject to other state or federal laws addressing interactions with government employees and health care professionals.

## 3. Training and Communication

A key element of the Compliance Program is education and training so Helsinn employees understand their legal and ethical obligations and specific requirements that impact their daily job responsibilities. Helsinn is committed to taking the steps necessary to effectively communicate our standards and procedures to all of our personnel. In addition, Helsinn will regularly review and update our training program and identify additional areas of training as needed.

## 4. Lines of Communication

Helsinn employees are encouraged to reach out to their Supervisor, HR, Legal, or Compliance to report suspected violations to our Code, policies, or legal obligations. Helsinn also maintains a Compliance hotline (Compline), which can be accessed 24 hours a day, seven days a week, where employees can report suspected violations anonymously. The Compline can be reached by dialing 1(855) 409-0016 or at [www.ethicspoint.com](http://www.ethicspoint.com).

Helsinn has a strict non-retaliation policy and no employee will be punished or disciplined for reporting a suspected violation in good faith. Confidentiality is a priority and every effort will be made to protect complainant's identity.

## 5. Auditing and Monitoring

Helsinn engages in auditing and monitoring of various business practices to ensure compliance with the Company's written standards, laws, regulations and codes. The nature of these activities as well as the

extent and frequency of our audit and monitoring activities is dependent upon many factors, including changing regulatory requirements, changes in business practices, and other considerations. The auditing and monitoring program is reviewed periodically to ensure that it is focused on the right business activities and risks.

#### 6. Responding to Detected Violations

Helsinn has established compliance standards and policies for which employees are accountable. Consequences of violating the law or Company policy include discipline up to and including termination.

#### 7. Corrective Actions

Consistent with the OIG's comments, Helsinn recognizes that even an effective Compliance Program may not prevent all violations. Helsinn's Compliance Program requires that the Company respond promptly to all potential violations of law or Company policy, take appropriate disciplinary action, perform an assessment of the violation to ascertain if the violation reveals a gap in our policies, practices, or internal controls and take appropriate action to prevent future violations.

For a copy of this Compliance Program, please email [HTUCompliance@helsinn.com](mailto:HTUCompliance@helsinn.com)