

# **Collegium Pharmaceutical Compliance Program**

In April 2003, the Office of Inspector General (OIG), Department of Health and Human Services, developed the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. According to the OIG, "it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization." The OIG's guidance includes seven widely recognized and fundamental elements to an effective compliance program which are at the core of our Compliance Program here at Collegium Pharmaceutical.

## **Mission of the Compliance Program**

The purpose of the Collegium Pharmaceutical ("Collegium") Compliance Program is to: (a) prevent, detect, and correct violations of law and company policies and procedures; (b) assure the establishment of compliance-related policies and procedures for business operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures and standards; (d) implement a mechanism to evaluate the effectiveness of essential elements of the Compliance Program; (e) implement a mechanism for internal reporting of questionable or inappropriate activities to enable timely investigation and resolution; and (f) assure appropriate corrective action is taken to prevent recurrence of misconduct.

## **Elements of The Compliance Program**

### **A. Compliance Officer**

The Chief Compliance Officer ("CCO") is responsible for overseeing the administration and implementation of the Compliance Program and reports at least quarterly on Compliance Program operations to, among others, the Collegium Compliance Committee and the Collegium Board of Directors. The CCO is authorized to direct and implement compliance-related changes in the organization as necessary and to exercise independent judgment in assessing compliance-related matters. The CCO has authority to seek advice

from independent legal counsel or other outside experts when appropriate and is authorized to report issues of any kind directly to the Company Officers and/or the Board.

## B. Compliance Committee

Collegium has established a Compliance Committee which meets at least quarterly. The mission of the Compliance Committee includes ensuring the implementation and effectiveness of all components of the Compliance Program, which includes, among other things:

- Development and implementation of compliance-related policies, procedures, and guidelines in all areas of the U.S. business;
- Development and implementation of training and other programs designed to educate company employees and applicable contractors doing business on behalf of Collegium regarding applicable laws, rules, regulations, codes, policies, procedures, and guidelines (collectively, "Requirements");
- Development and implementation of auditing, monitoring, and other controls and processes designed to prevent, detect, and correct violations of applicable Requirements;
- Development and implementation of mechanisms for internal reporting of questionable or potentially inappropriate activities including the timely investigation and resolution of such instances; and
- Development and implementation of corrective and disciplinary action to address and prevent recurrence of misconduct or non-compliance.

The Compliance Committee also provides advice, counsel, and support to the CCO, who shall have day-to-day oversight responsibilities for the Compliance Program.

## C. Compliance Related Policies

As part of its commitment to the highest ethical standards of business conduct, Collegium has implemented Company policies and requirements that are consistent with operating as such every day and are specific to the company's operations and the evolving business and regulatory environment.

Collegium expects employees at all levels of the organization to comply with the Collegium Compliance Program, the standards set forth in the Collegium Code of Ethics (“the Code”), company policies and procedures, and all applicable laws and guidelines. Annually, all employees and applicable contractors must acknowledge their understanding of and commitment to follow these standards when conducting Collegium business and to report to management, Human Resources, Legal, or the Compliance Officer knowledge of any potential violation of these standards. Employees who violate these standards is subject to appropriate disciplinary action, up to and including termination. Collegium policy and the Code expressly prohibits retaliation or retribution against any employee for making any good faith report of suspected misconduct or improper behavior.

Collegium has policies and procedures designed to ensure that interactions with healthcare professionals (“HCPs”) are appropriate, ethical, and consistent with applicable laws, codes and guidelines, including (but not limited to) the April 2003 “Compliance Program Guidance for Pharmaceutical Manufacturers” issued by the U.S. Department of Health and Human Services Office of Inspector General (“OIG Guidance”) and the Pharmaceutical Research and Manufacturers of America (PhRMA) “Code on Interactions with Healthcare Professionals,” revised effective January 2009 (“PhRMA Code”). Furthermore, the Company has policies and procedures in place as part of its commitment to compliance with the PhRMA Code.

For a statement regarding compliance with the California Health & Safety Code § 119402, [click here](#).

## D. Training and Education

A critical component of the Compliance Program is the training and education of employees regarding their ethical obligations and their specific obligations to comply with Company policies and procedures and with all applicable laws and regulations. Collegium has implemented training programs to educate employees on the Code, on new and existing compliance policies, and on the policies and procedures applicable to their job functions. New employees receive compliance training as part of their initial training; employees receive on-going compliance training on a routine basis and as identified by ongoing monitoring activities and reports received

by the Collegium Compliance Helpline. Collegium also implements additional training for the entire company or particular departments and/or business units on an as-needed basis.

## E. Communicating Compliance Issues and Concerns

Collegium is committed to fostering an environment in which the open communication regarding questions about the Code or company policies and procedures or concerns about suspected improper business practices is encouraged. Any employee who has concerns about a particular activity that the employee feels potentially violates policies or the law is required to report such concerns. Reports may be made to their manager, HR, the CCO or to the Collegium Compliance Helpline by calling (1) 866-822-6517, emailing [Compliance@CollegiumPharma.com](mailto:Compliance@CollegiumPharma.com), or [COLL@openboard.info](mailto:COLL@openboard.info).

The Code and Company policy expressly prohibits retaliation or retribution against any employee for making any good faith report of suspected misconduct or improper behavior.

## F. Monitoring, Auditing, and Investigations

The Collegium Compliance Program includes activities designed to monitor and audit compliance with the company policies and procedures. The CCO oversees and/or coordinates systems for periodic monitoring and auditing. On a periodic basis, but not less than annually, the CCO develops an audit/monitoring plan, recognizing that the nature and frequency of reviews depends upon a variety of factors. A variety of internal and external auditing resources may be used to conduct periodic monitoring and auditing. The CCO works with relevant internal business functional experts and management to evaluate findings and ensure the implementation of any corrective action deemed necessary as the result of audits and routine monitoring activities.

The CCO (or designee) reviews and evaluates reports of activities that may be inconsistent with the Code, policies or procedures, or any provision of the Compliance Program or applicable laws and regulations or concerns of inappropriate behavior communicated to the Compliance Department to determine whether further investigation is required. The CCO may, as

required, request assistance from the members of the Compliance Committee, Human Resources or outside experts to conduct an investigation, depending on the nature of the alleged misconduct. Investigations shall be conducted confidentially to the greatest extent possible and with every effort to respect the rights of all concerned.

## G. Corrective Action and Discipline

If it is determined, after investigation, that noncompliant conduct occurred, the matter is forwarded to the appropriate parties for corrective and/or disciplinary action. Such response and disciplinary action may include (but is not limited to): providing additional training; revising guidelines, policies, and procedures or any function of the Compliance Program to prevent the reoccurrence of misconduct in the area; increasing auditing and monitoring procedures; disciplining supervisors in accordance with the facts for failure to supervise adequately and control the behavior of the employee(s); or other disciplinary actions up to and including termination of the employee(s) involved.

## H. Updating the Compliance Program

From time to time, the CCO may amend the Company's Compliance Program. The Compliance Committee reviews all changes suggested by the CCO prior to their implementation. The CCO is responsible for communicating changes in the Compliance Program to Company employees in a timely manner.