Taiho Oncology, Inc. Comprehensive Compliance Program (U.S.)

Introduction

Taiho Oncology, Inc. has implemented a Corporate Compliance Program based on the seven elements of an effective compliance program as outlined in the Office of Inspector General (OIG) “Compliance Program Guidance for Pharmaceutical Manufacturers.” Taiho’s program is consistent not only with the OIG guidance, but also with the provisions of the Code of Interactions with Healthcare Professionals created by the Pharmaceutical Research and Manufacturers Association (PhRMA). Taiho is committed to maintaining a program that promotes prevention, detection, and resolution of potential violations of the law, the PhRMA Code and Taiho’s code of conduct and policies.

The key elements of Taiho’s compliance program related to commercial activities are outlined below. Taiho’s program is one of ongoing improvement. Throughout the year, modifications to the program may be made in the spirit of this continuous improvement.

Compliance Program

A. Compliance Leadership and Governance

Taiho has a Vice President of Compliance who serves as the organization’s Compliance Officer and who has responsibility for developing, implementing, and overseeing the organizations compliance program. The company has a Compliance Committee made up of Senior Leaders, which assists the Compliance Officer in overseeing the operation of the Compliance Program for the organization.

B. Written Standards

Taiho has a Healthcare Compliance Code of Conduct, which specifically addresses the company’s standards for interactions with healthcare professionals based on the healthcare laws, the OIG industry guidance, and the PhRMA Code. The Code applies to employees, contractors, and third parties and sets forth the expectation to act in accordance with laws, regulations, and industry codes. In addition to the Healthcare Compliance Code of Conduct, Taiho has written guidance and procedures to direct our daily activities.

C. Education and Training

Taiho is committed to education and training of employees. The company has mandatory New Hire training, which covers fundamental compliance expectations. In addition, depending on the employee’s role, there are additional training requirements which are role specific. The Company has a system to ensure regular review and acknowledgement of key guidance and procedures.

D. Internal Lines of Communication

Taiho believes in open communication within the organization and clearly communicates the many avenues through which employees can get questions answered and concerns addressed. In addition to encouraging employees to bring concerns to their manager, senior management, HR, Legal or Compliance, the company has established an Anonymous Hotline for reporting concerns or complaints. The hotline is managed by an outside vendor who intakes complaints and forwards them to the Compliance Officer to investigate and remediate, as appropriate. The hotline allows reporting via an 800 number or an online report option. Taiho does not tolerate retaliation against anyone who brings forth a compliant in good faith.

E. Auditing and Monitoring

Taiho reviews and assesses the execution of business activities for compliance with company guidance, procedures, and the law and regulations. Many activities are managed with systems which have built in controls which allow for
ongoing monitoring. When issues present, the company actively initiates remediation and builds in corrective actions, as needed including clarification of policy and/or additional training.

F. Disciplinary Action

Taiho investigates allegations of misconduct or findings from auditing or monitoring activities and institutes appropriate discipline in line with the violation. Discipline may take the form of coaching, warning letters, or termination depending on the severity of the violation.

G. Corrective Action

Taiho responds appropriately to address issues that are identified or reported. Corrective action will take the form of appropriate discipline for the employee as well as an ongoing assessment of the Compliance Program to identify if policies need to be clarified, additional training is required, or if controls need to be reevaluated.

California Health & Safety Code §§ 119400 – 119402

Taiho Oncology, Inc. as established an annual dollar limit of $2,500.00 for educational or practice-related items, items of minimal value, and meals associated with informational presentations or discussions provided to licensed medical or health professionals in California as defined in the California Health & Safety Code §§ 119400 – 119402. This dollar limit represents a spending maximum and not an average or goal. Taiho reserves the right to change this limit at any time.

For a copy of our Corporate Compliance Program and/or annual written declaration of compliance with California Health & Safety Code §§ 119400 – 119402, please call 844-US TAIHO (844-878-2446) and select the operator and ask to speak with the Vice President of Compliance.

September 22, 2015 (Time of First Product Approval)
Declaration of Compliance with California Health & Safety Code §§ 119400 – 119402

To our knowledge, and based on our good faith understanding of the statutory requirements, Taiho Oncology declares that it is in compliance in all material respects with our Corporate Compliance Program and the requirements of California Health & Safety Code §§ 119400 – 119402.