

**THERAVANCE BIOPHARMA, INC.**  
**DECLARATION AND COMPREHENSIVE COMPLIANCE PROGRAM**

Updated: July 1, 2019

**DECLARATION**

As part of our continuing commitment to corporate compliance, Theravance Biopharma, Inc. or any of its affiliates (individually and collectively referred to herein as “Theravance Biopharma”) declares that, to the best of its knowledge, based on a good faith understanding of the statutory requirements of California Health and Safety Code sections 119400 - 119402, that Theravance Biopharma has established a Comprehensive Compliance Program (“CCP”) as mandated by California law. As of the date of this declaration, Theravance Biopharma believes that it is in compliance with its CCP in all material respects.

The CCP, described in further detail below, contains policies, procedures and processes to address risk areas identified in the “Compliance Program Guidance for Pharmaceutical Manufacturers” published by the Office of the Inspector General, U.S. Department of Health and Human Services (“OIG Guidance”) and the Pharmaceutical Research and Manufacturers of America voluntary Code on Interactions with Healthcare Professionals (the “PhRMA Code”). We cannot completely eliminate the possibility that an employee, through inadvertence or otherwise, will fail to comply with some aspect of the CCP. However, we train covered employees on the various elements of our CCP and have established processes for identifying potential violations and disciplining employees, if necessary.

**COMPREHENSIVE COMPLIANCE PROGRAM DESCRIPTION**

**I. INTRODUCTION**

Theravance Biopharma is committed to conducting its global business based on high ethical standards. In the United States, a key component of this commitment is the establishment and maintenance of a compliance program in accordance with the OIG Guidance. The purpose of our CCP is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is our expectation that employees will comply with the PhRMA Code, the Theravance Biopharma Code of Business Conduct, the Theravance Biopharma Healthcare Compliance Policy, as well as with other company policies. In the event that Theravance Biopharma becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, implement corrective measures to prevent future violations.

Our program is scalable to address the size, organizational structure, and resources of our company and will continue to evolve accordingly. We periodically monitor and reassess the program in order to improve it. Described below are the fundamental elements of the Theravance Biopharma Comprehensive Compliance Program.

## **II. COMPLIANCE PROGRAM OVERVIEW**

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

- **Compliance Officer.** The Executive Vice President and General Counsel serves as the Compliance Officer. This individual is charged with developing, operating and monitoring the Compliance Program, and is advised regularly by the Compliance Committee. This individual serves as the company's Chief Compliance Officer with direct access to the CEO, Board of Directors, and senior management. This individual provides a report on the Compliance Program to the Theravance Biopharma senior management team both annually and on an as-needed basis.
- **Compliance Committee.** Theravance Biopharma has a Senior Leadership Group that serves as the Compliance Committee to advise the Compliance Officer and assist in the implementation of the Compliance Program. The Committee is comprised of heads of functional units across the company. It meets on a regular basis to monitor company activities and compliance developments.

### **2. Written standards.**

- The Theravance Biopharma Code of Business Conduct, the Theravance Biopharma Healthcare Compliance Policy and complimentary policies outline the company's commitment to compliance and corporate accountability. The standards set forth in the policies apply to all Theravance Biopharma employees, and adherence to company policies is a condition of employment. The company expects all officers and managers to review policies with their employees and to ensure adherence to policies, procedures, laws, guidances and regulations.
- Our CCP limits meals with healthcare professionals and applies standards for the use of healthcare professional consultants and promotional materials to conform with the PhRMA Code.
- Theravance Biopharma has established spending parameters that include an annual upper dollar limit of \$1,500 on promotional spending directed toward individual California healthcare professionals. On rare occasions, management has the authority to authorize additional spending based on circumstances such as the revision or expansion of product labeling, the

launch of a new product, or the availability of new scientific information relating to existing products.

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

All covered employees receive general compliance training applicable to their job function and responsibilities, which includes training on the Theravance Biopharma CCP. Specialized training occurs in specific departments where a need for additional training has been identified. Employees are trained on how to report compliance concerns through internal channels, including anonymously through the Compliance Hotline.

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

A variety of internal communications tools exist for communicating compliance issues and concerns, including an intranet site. We have communicated to all Theravance Biopharma employees that the company maintains a toll-free Compliance Hotline for reporting compliance concerns and that they may use the hotline anonymously if they wish.

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

The Theravance Biopharma compliance auditing and monitoring plan includes various monitoring activities. The nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. Results are reported to the Compliance Committee and to appropriate managers.

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

Enforcement action for CCP violations is addressed in Theravance Biopharma company policies. We have a progressive disciplinary process, up to and including termination, depending upon the severity of the violation.

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

Our CCP requires that the company respond promptly to potential violations of law or company policy. After investigation of a reported or detected issue, the company will assess whether disciplinary action is appropriate, and whether a violation is in part due to gaps in our policies, practices, training, or internal controls, and take action to prevent future violations.

*To request a copy of the Theravance Biopharma Declaration or Comprehensive Compliance Program description, please call 1-866-806-2637.*