

California Declaration of Comprehensive Compliance Program

Astellas US 2024

Declaration of Compliance with Comprehensive Compliance Program

DECLARATION

Astellas US, LLC and Astellas Pharma US, Inc. (collectively, "Astellas US" or the "Company"), are headquartered in Northbrook, Illinois, and are wholly owned subsidiaries of Astellas Pharma Inc., which is headquartered in Tokyo, Japan.

Astellas US is in compliance with its Comprehensive Compliance Program (CCP) and Cal. Health & Safety Code §§ 119400-119402. Our CCP, which is described in further detail below, contains the elements of an effective compliance program 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 ("HHS-OIG Guidance"). In addition, Astellas US has adopted the "Code on Interactions with Healthcare Professionals" published by The Pharmaceutical Research and Manufacturers of America (the "PhRMA Code") and has policies, procedures and processes designed to help ensure compliance with the PhRMA Code.

COMPREHENSIVE COMPLIANCE PROGRAM DESCRIPTION

I. INTRODUCTION

Astellas US is committed to conducting its business in accordance with the highest ethical and compliance standards. A key component of this commitment is our establishment and maintenance of a CCP in accordance with the HHS-OIG Guidance. We expect our employees to comply with our CCP, and we investigate and appropriately resolve potential violations of the CCP, applicable laws, regulations, industry codes and other Company policies. Where appropriate, we take disciplinary action, up to and including termination, and implement corrective measures to prevent future violations.

Our CCP is an evolving and flexible program that is designed to account for growth and other changes in the Company, as well as changes in our legal, regulatory or industry obligations. We reevaluate our CCP on a regular basis for opportunities to further enhance its reach and effectiveness. The fundamental elements of our CCP are described below.

II. COMPLIANCE PROGRAM OVERVIEW

A. Leadership and Structure

- **Compliance Officer.** The Vice President, Head of Ethics & Compliance US, Development and Innovation, is charged with developing, operating and monitoring the CCP. This individual reports directly to our Senior Vice President, Head of Ethics & Compliance, interacts routinely with senior management, reports on the CCP to our Board of Directors on at least an annual basis and provides regular reports to the Senior Vice President, Head of Ethics & Compliance, as well as senior management.
- **Compliance Committee.** Astellas US has established a Compliance Committee to advise the Vice President, Head of Ethics & Compliance US, Development and Innovation and to assist in the implementation of the CCP at the Company. The Compliance Committee is comprised of senior members of functional units across the Company, including sales, marketing, research and development, medical affairs, legal, regulatory, finance and human resources. The Committee meets on a regular basis to monitor Company activities and compliance developments.

B. Written standards

- Astellas US has established its commitment to compliance through a number of Company policies, including the Astellas Group Code of Conduct, which is global. The standards in these policies apply to all Astellas US employees, and adherence to them is a condition of employment. The Company expects all officers and managers to review applicable policies, including those supporting our CCP, with their employees and to make every effort to ensure their adherence to these policies and with all applicable laws, regulations and industry codes.
- The Company has developed and implemented restrictions on items of value that may be provided to healthcare providers ("HCPs") that conform to the PhRMA Code.
- Astellas US has also established a total annual dollar limit on items of value (including meals) that the Company may provide to California HCPs in accordance with Cal. Health & Safety Code §§ 119400-119402. The Company's established annual aggregate limit per California HCP is \$1,200. This annual limit may be revised by the Company from time to time. Per Cal. Health & Safety Code §§ 119400-119402, the annual aggregate limit does not apply to drug samples provided

to HCPs that are intended for free distribution to patients and payments for legitimate professional services provided by an HCP.

C. Education and Training

We regularly provide compliance training to all Astellas US employees, including at new hire orientation. We train employees on our CCP, Company policies, and on all applicable laws, regulations and industry codes.

D. Internal Lines of Communication

We employ a variety of internal communication tools to communicate with employees about compliance issues and concerns. These include an intranet website for the Ethics & Compliance Department and regularly distributed newsletter. In addition, we routinely respond to compliance questions from individual employees and regularly respond to compliance inquiries and address compliance issues at company meetings and through regular compliance communications. We instruct employees on their obligation to report actual or potential compliance violations, and we provide them with various resources including an independent, third-party operated Compliance Hotline by which they can anonymously, if they wish to do so, report compliance questions, concerns or violations.

E. Auditing and Monitoring

Astellas US performs annual compliance risk assessments, routine compliance monitoring and compliance audits. Reports of these activities are made to the Vice President, Head of Ethics & Compliance US, Development and Innovation, Senior Vice President, Head of Ethics & Compliance, the Compliance Committee, and senior management. Identified issues and opportunities for enhancement are addressed, and education, training and corrective action are taken when necessary.

F. Responding to Potential Violations

Our CCP requires that the Company respond promptly to potential violations of law, regulation, industry codes or Company policies. Potential violations are investigated and evaluated on a case-by-case basis. Disciplinary action, up to and including termination, is taken when deemed appropriate.

G. Corrective Action Procedures

After investigation of a reported or detected compliance issue, the Company assesses whether additional corrective action is appropriate. The assessment includes a determination as to whether a violation is due, in part, to any gaps in our policies, training or internal controls. If a gap is identified, the Company will take action to correct it.

To request a copy of the Astellas US Declaration and Comprehensive Compliance Program description, please call 1-800-888-7704.