



SUN PHARMACEUTICAL INDUSTRIES, INC. U.S. COMPREHENSIVE COMPLIANCE PROGRAM

I. Introduction

Sun Pharmaceutical Industries, Inc. ("Sun Pharma") is committed to conducting business with a high degree of ethics and integrity and in compliance with all applicable legal and regulatory requirements. Through our Healthcare Compliance North America ("HCNA") Group we have established a healthcare compliance framework to promote adherence to the laws, regulations and requirements applicable to our business activities.

The purpose of our Comprehensive Compliance Program (the "Compliance Program") is to promote compliance with the laws, regulations, and guidances that govern our interactions with healthcare professionals and healthcare institutions as well as communications about our products. The compliance program has been developed in accordance with the principles set forth in the U.S. Department of Health and Human Services *Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers* dated May 5, 2003 (the "OIG Compliance Guidance") and the standards set forth in the *Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals* (the "PhRMA Code"), as well as other relevant industry guidance.

The foundational components of Sun Pharma's Compliance Program are set forth below in Section II. Sun Pharma through HCNA will review and update its Compliance Program from time to time to promote an organizational culture of integrity, ethical conduct, principled decision-making, openness and trust. Sun Pharma strives to foster an environment where Sun Colleagues operate in compliance with U.S. healthcare laws, regulations, and guidance.

II. Overview of the U.S. Healthcare Compliance Program

1. Leadership and Structure

Sun Pharma has established a foundational structure to support its commitment to compliance. This structure is continuously evolving to ensure the Compliance Program is responsive to Sun Pharma's business and activities.

Sun Pharma has established the HCNA Group and a dedicated Compliance Officer to support the company's culture of compliance for its branded U.S. sales and marketing activities. The Compliance Officer has overall responsibility for developing and implementing policies, procedures, and practices designed to ensure compliance with applicable healthcare program requirements.

2. Written Standards

The development and distribution of written standards of conduct, policies, procedures, and guiding principles is integral to the Compliance Program. The Sun Pharmaceutical Industries, Limited Global Code of Conduct ("Global Code of Conduct") describes our organizational principles





and values. Additionally, the Global Code of Conduct provides policy and standards for conducting business and sets forth the expectations for reporting instances of possible noncompliance.

In addition to the Global Code of Conduct, Sun Pharma has written policies and procedures governing our general business activities as well as those activities related to the marketing and sales of our products and our interactions with healthcare professionals and healthcare institutions. These written standards are designed to ensure compliance with the provisions of the OIG Compliance Guidance and PhRMA Code as well as address potential risk areas such as those identified in the OIG Compliance Guidance. Sun Pharma's approach to policy drafting has been to address key areas such as: meals, venues, and educational items to facilitate interactions with healthcare professionals; scientific exchange activities; and the provision of prescription drug samples, by way of example.

3. Compliance Committee

The Compliance Committee consists of members of HCNA and senior management. It provides a forum for discussion on compliance-related topics including policy development and promotional activities. The Compliance Officer leads the Compliance Committee.

4. <u>Training</u>

Another critical element to our Compliance Program is the education and annual training of our field-based and home office employees regarding healthcare compliance related topics. Our Compliance Program incorporates training on Sun Pharma's policies as well as laws, regulations, and guidelines that govern pharmaceutical marketing and selling activities in the U.S.

Sun Pharma provides periodic training for employees including refresher training on topics related to anti-kickback, fraud and abuse laws, drug samples, drug promotion, the PhRMA Code, and Sun Pharma codes, policies and procedures.

5. Auditing and Monitoring

Sun Pharma's Compliance Program includes monitoring, auditing, and ongoing evaluation to ensure compliance with the company's policies and procedures. The extent and frequency of auditing and monitoring activities varies according to a variety of factors including changes in business activities, changes in regulatory requirements, and other considerations. The results of monitoring and/or auditing reviews may be used as a basis for improving upon existing policies/procedures or adopting new ones and for the development or modification of training or business practices.

6. Procedures for Reporting Violations

Sun Pharma encourages open communication amongst our colleagues and emphasizes a continual dialogue. We encourage reporting of potential instances of noncompliance and have a policy of non-retaliation. Our Global Code of Conduct and policies require employees to report any known or suspected violations of law, regulations, company policies or procedures. To support this effort, Sun Pharma has established several vehicles for reporting including an external reporting hotline to facilitate confidential, anonymous reporting. Additionally, Sun Pharma investigates all reports and prohibits retaliation against any person who, in good faith, reports known or suspected





compliance issues. Sun Pharma has established a toll-free telephone number, 1-877-208-3015, for reporting of such violations or possible violations.

7. Investigations, Corrective Actions and Sanctions

In the event that Sun Pharma becomes aware of any suspected violations of law, regulation, policy or procedure, we investigate the circumstances surrounding the suspected noncompliance to determine whether a violation has occurred. If a violation is found, Sun Pharma takes appropriate corrective action, which may involve disciplinary action up to and including termination of employment.

8. <u>Annual Dollar Limit on Gifts or Incentives Provided to Medical or Health Professionals in</u> California

As required by, and in accordance with the definitions set forth in, California SB 1765, Sun Pharma has established an annual dollar limit on gifts, promotional materials, or items or activities that the company may give or otherwise provide to an individual medical or healthcare professional in California. This annual dollar limit is \$1,500 per such individual and may be revised by Sun Pharma from time to time. Sun Pharma follows a calendar year reporting cycle for purposes of making its annual declarations under California Health and Safety Code Sections 119400 - 119402. The annual declaration is made on or around July 1 each year for covered activities occurring in the preceding calendar year.

9. Obtaining Copies of the U.S. Comprehensive Compliance Program and the Annual Declaration of Compliance

Copies of this document and the Annual Declaration of Compliance can be obtained by calling our toll-free number, 1-844-786-4262; by emailing HCNA.Help@sunpharma.com or visiting www.sunpharma.com/usa/us-compliance-program.