

# **Annual Description of Comprehensive Compliance Program** <sup>[1]</sup>

## **Pursuant to California Health and Safety Codes §§ 119400-119402**

### **A. Introduction**

Our mission at Novartis is to discover, develop, and successfully market innovative products to prevent and cure diseases, ease suffering and enhance the quality of life.

We aspire to be the world's most respected and successful healthcare company. We can only realize this aspiration if we earn and maintain the trust and support of our key stakeholder groups: our patients, our associates, our shareholders, our healthcare partners, and society at large.

Our Code of Conduct reflects our commitments to meet the expectations of our stakeholders as a responsible corporate citizen and contains the fundamental principles and rules concerning ethical business conduct. We believe that how we achieve our business results is as important as the achievement itself.

The Novartis Code of Conduct forms an integral part of the terms of employment of all associates of the Novartis Group. Novartis insists on full compliance and will not tolerate any misconduct.

### **The Code of Conduct Outlines Our Five Core Principles**

- Patients - Patient benefit and safety is at the heart of everything we do
- Associates - We treat our associates fairly and respectfully
- Shareholders - We are committed to outstanding and sustainable performance with integrity
- Healthcare - We strive to be a trusted healthcare partner
- Society - We aspire to be a good corporate citizen

The current version of the Novartis Code of Conduct, which was approved by the Novartis AG Board of Directors on January 1, 2012, is applicable to all operations and associates of the Novartis Group.

### **Scope**

Novartis Pharmaceuticals Corporation (NPC) is committed to maintaining the highest

standards of ethical conduct and complying with all applicable laws, regulations, and codes.

NPC's Comprehensive Compliance Program (CCP) is consistent with the "Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the Office of Inspector General of the U.S. Department of Health and Human Services (the "OIG Guidance") on May 3, 2003, and the "code on Interactions with Healthcare Professionals" issued by the Pharmaceutical Research and Manufacturers of American ("PhRma Code") effective January 1, 2009.

On January 1, 2020, and in compliance with the annual declaration requirement under California Health and Safety Code §§119400 - 119402, NPC made its 2019 declaration for the twelve (12) month period covering January 1, 2019 through December 31, 2019.

Below is an overview of NPC's CCP. As described by the OIG Guidance, this program was designed to fit NPC's unique compliance needs. NPC continuously assesses the effectiveness of its CCP to enable it to implement necessary adjustments or refinements.

## **B. Overview of CCP**

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

a. Compliance Officer - NPC has a Chief Compliance Officer who is charged with the responsibility for developing, operating, and monitoring the compliance program. The Chief Compliance Officer reports directly to the President and Chief Executive Officer at NPC and has the authority to report to the Board of Directors. Our Compliance Officer has the ability to effectuate change within the organization and to exercise independent judgment.

b. Compliance Committee - NPC has a Compliance Committee that advises the Chief Compliance Officer on compliance-related activities and issues for the purposes of assessing compliance risks, helping to prevent compliance violations from occurring and, ensuring appropriate responses to compliance violations that may occur.

The members of the Compliance Committee are high-level personnel from multiple business units and functions across the company.

### **2. Written Standards and Closing.**

NPC has developed and distributed written compliance policies, procedures, and practices that guide the company and the conduct of our employees in day-to-day commercial operations. These policies and procedures have been developed under the direction and supervision of our Compliance Officer, Compliance Committee, Ethics and Compliance Department, Legal Counsel, and management from various functional areas.

The NPC Code of Conduct is a written statement of ethical and compliance principles, policies, and procedures that all NPC management, employees, and contractors are expected to follow. The Code of Conduct was designed to provide guidance on how to fulfill requirements of the Company's compliance program, resolve questions about the appropriateness of our conduct, and report possible violations of law or ethical principles. An employee's obligations under the Code of Conduct include strict observance of all laws and regulations applicable to our Company (e.g., laws and regulations governing the Federal

health care programs), ethical standards, and applicable NPC policies and procedures.

The OIG Guidance addresses several areas of potential risk for pharmaceutical manufacturers and suggests that companies develop compliance policies in these areas: data integrity pertaining to government reimbursement practices; kickbacks or other illegal remuneration; and distribution of drug samples. NPC has implemented written standards addressing each of these areas.

In addition, with respect to business activity in California, NPC has established "a specific annual dollar limit on educational items and promotional activities [NPC] may give or otherwise provide to an individual medical or healthcare professional." This annual dollar limit is \$2,500 and represents a maximum limit that takes into account a variety of factors, including our Company's specific situation with multiple field forces of representatives that present to medical or health professionals regarding a diverse portfolio or products as well as the capabilities of current information systems that capture promotional spend-related data.

NPC's relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Informational presentations and discussions by Company representatives and others speaking on behalf of NPC provide valuable scientific and educational benefits. In connection with such presentations or discussions, NPC may offer occasional meals and items designed primarily for the education of patients and healthcare professionals in accordance with the PhRMA Code.

The current spend limit will be in effect for the period of January 1, 2020 through December 31, 2020. NPC will evaluate this limit on an annual basis and make any necessary adjustments consistent with any operational or practical issues related to complying with this new requirement as well as any new legislative requirements.

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

NPC educates and trains employees on the facets of our compliance program through programs developed and conducted by compliance and legal professionals. Our education and training covers a variety of laws and regulations that impact the way we conduct business. Our live and computer-based programs include, but are not limited to, meaningful discussion of the application and consequences of the False Claims Act, Anti-Kickback Statute, OIG Guidance, PhRMA Code, as well as other applicable federal, state, and industry rules and guidelines. NPC regularly reviews and updates its training programs, and identified additional areas of training on an "as needed" basis.

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

NPC is committed to fostering dialogue between management and employees. Our goal is that all employees, whether seeking answers to questions or reporting potential instances of fraud and abuse, will know who to turn to for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted open-door, confidentiality, and non-retaliation policies. As part of its commitment to ethical and legal behavior, NPC requires its employees to report any actual or suspected violations of law or ethical standards so that they can be appropriately investigated and addressed. Employees can raise their concerns in a number of ways including with an appropriate member of management, through our Human Resources, Legal, Security, Business Practices Office, or Ethics and Compliance

Departments, or by calling our toll-free, 24-hour, anonymous Alert Line.

## 5. Auditing and Monitoring.

NPC's CCP includes activities to monitor, audit, and evaluate compliance with the Company's policies and procedures. NPC's approach includes targeted monitoring and auditing based on identified and prioritized risk areas. In accordance with the OIG Guidance, the nature of NPC's 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.

## 6. Responding to Potential Violations.

Adherence to the Code of Conduct is a condition of employment at NPC. Any violation of an employee's obligations under the Code of Conduct can subject an employee to serious disciplinary measures, including possible termination of employment. Although each situation is considered on a case-by-case basis, NPC undertakes significant efforts to ensure consistent and appropriate disciplinary action is taken in response to violations.

## 7. Corrective Action Procedures.

As part of our compliance program, NPC has established a comprehensive internal investigation and corrective action protocol to ensure that timely, complete, and objective investigations are conducted in response to allegations regarding the NPC Code of Conduct applicable policies. In accordance with the OIG Guidance, the exact nature and level or thoroughness of the internal investigation will vary according to the circumstances. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate.

NPC is dedicated to the maintenance and ongoing assessment required of an effective compliance program. As changes are made to either the OIG Guidance or the PhRMA Code, the NPC CCP must be updated with corresponding modifications within six months.

This Description is effective as of January 1, 2020. NPC will assess its CCP at least annually, for the purpose of declaring compliance with California Health and Safety Codes §§ 119400-119402.

A copy of this Declaration may be obtained by emailing:  
[ethicscompliance.support@novartis.com](mailto:ethicscompliance.support@novartis.com) [2].

### Accordion Type:

Collapsible

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