

## **Compliance** <sup>[1]</sup>

As part of our commitment to deliver value to patients using our products, Novartis Pharmaceuticals Corporation has established and maintains an effective compliance program in accordance with federal, state, and industry regulations and guidelines.

### **I. Introduction**

Novartis Pharmaceuticals Corporation discovers, develops, and markets innovative products to cure diseases, to ease suffering, and to enhance the quality of life. As part of our commitment to deliver value to patients using our products, Novartis Pharmaceuticals Corporation has established and maintains an effective compliance program in accordance with federal, state, and industry regulations and guidelines including the "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. Department of Health and Human Services. We have dedicated significant time and resources to implementing a compliance program for Novartis Pharmaceuticals Corporation that includes a comprehensive framework of compliance controls throughout various segments of our commercial operations. Our compliance program is a representation of our commitment to the highest standards of corporate conduct.

Key elements of our Comprehensive Compliance Program include, but are not limited to:

- A Code of Employee Conduct that promotes the highest ethical and compliance principles that guide Novartis Pharmaceuticals Corporation operations;
- Extensive policies and procedures that address specific areas of government concern;
- Dedicated compliance oversight functions;
- Multi-faceted training and education programs;
- Multiple compliance communication mechanisms including an anonymous reporting system;
- Targeted monitoring and auditing;
- Well-publicized disciplinary guidelines; and
- A protocol for responding promptly to detected problems and implementing corrective action.

### **II. Overview of Novartis Pharmaceuticals Corporation Compliance Program**

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

Novartis Pharmaceuticals Corporation Compliance Officer is Bryant Aaron, Vice President,

Chief Compliance Officer and US Head, Ethics & Compliance, who is charged with the responsibility for developing, operating, and monitoring the compliance program. The Compliance Officer reports directly to the President and Chief Executive Officer of Novartis Pharmaceuticals Corporation 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.

## **2. Written Standards.**

Novartis Pharmaceuticals Corporation 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, Commercial Compliance Committee, Healthcare Compliance Department, Legal Counsel, and management from various functional areas.

**Code of Employee Conduct.** The Novartis Pharmaceuticals Corporation Code of Employee Conduct is a written statement of ethical and compliance principles, policies, and procedures that all Novartis Pharmaceuticals Corporation management, employees, and contractors are expected to follow. The Code of Employee 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 Employee 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 Novartis Pharmaceuticals Corporation policies and procedures. [Novartis Pharmaceuticals Corporation Code of Employee Conduct is attached for reference]

**Policies and Procedures.** Novartis Pharmaceuticals Corporation has established policies and procedures to address a variety of potential risk areas, including the potential risk of liability under several fraud and abuse statutes and regulations. These policies and procedures are part of a comprehensive framework of compliance controls that exist throughout various segments of our organization. In particular, Novartis Pharmaceuticals Corporation developed and implemented significant policies and procedures to reduce and eliminate the potential risks identified by the HHS Office of Inspector General in its Compliance Program Guidance for Pharmaceutical Manufacturers and addressed in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, including (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

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

Novartis Pharmaceuticals Corporation 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 Compliance Program Guidance, PhRMA Code on Interactions with Healthcare Professionals, as well as other applicable federal, state, and industry rules and guidelines. Novartis Pharmaceuticals Corporation regularly reviews and updates its

training programs, and identifies additional areas of training on an "as needed" basis.

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

Novartis Pharmaceuticals Corporation 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, Novartis Pharmaceuticals Corporation 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, or Ethics and Compliance Departments, or by calling our toll-free, 24-hour, anonymous AlertLine. Further information on our AlertLine and non-retaliation policies can be found in our Code of Employee Conduct.

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

Novartis Pharmaceuticals Corporation's compliance program includes activities to monitor, audit, and evaluate compliance with the Company's policies and procedures. Novartis Pharmaceuticals Corporation's approach includes targeted monitoring and auditing based on identified and prioritized risk areas. In accordance with the OIG Compliance Program Guidance, the nature of Novartis Pharmaceuticals Corporation'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. Enforcing Standards Through Discipline.**

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

#### **7. Responding to Detected Problems.**

As part of our compliance program, Novartis Pharmaceuticals Corporation has an 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 Novartis Pharmaceuticals Corporation Code of Employee Conduct and applicable policies. In accordance with the OIG Compliance Program Guidance, the exact nature and level of 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.

### **III. CLOSING**

Novartis Pharmaceuticals Corporation is dedicated to the maintenance and ongoing assessment required of an effective compliance program. Questions regarding Novartis Pharmaceuticals Corporation's comprehensive compliance program or Novartis Pharmaceuticals Corporation's Code of Employee Conduct can be directed to 1-800-524-0266.

**Accordion Type:**

Collapsible

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[1] <https://www.novartis.us/corporate-responsibility/business-conduct/compliance>