NOVARTIS

Compliance program

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

Novartis and its US entities/affiliates (including AAA and Novartis Gene Therapies) discover, develop, manufacture, market and sell innovative pharmaceutical products and cell and gene therapies to treat or cure diseases, to ease suffering, and to enhance patients' quality of life. As part of our commitment to patients using our products, Novartis 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 (OIG), U.S. Department of Health and Human Services and the Pharmaceutical Research and Manufacturers of America's (PhRMA) "Code on Interactions with Healthcare Professionals". We have dedicated significant time and resources to implementing a compliance program for Novartis that includes a comprehensive framework of compliance controls throughout various segments across our 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 Country-level Compliance Officer
- A Country-level Compliance Committee, as well as Compliance Committees within each affiliate
- A Chief Compliance Officer for each affiliate
- A Code of Ethics that serves as a guide for decision-making to help associates navigate situations that are complex or unclear. It is designed to drive meaningful conversations around ethics and most importantly, to help associates do what is right
- Extensive policies and procedures that address specific areas of government concern
- Dedicated compliance oversight functions
- Multi-faceted training and education programs
- Compliance communication mechanisms including an anonymous reporting system
- Risk based monitoring and auditing activities
- Well-publicized disciplinary guidelines
- A protocol for responding promptly to detected problems and implementing corrective action.

Leadership and Structure

Novartis' Chief Compliance Officer (CCO) is charged with the responsibility for developing, operating, and monitoring the compliance program. The CCO reports directly to the President of Novartis, Head Pharma North America 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.

Written Standards

Novartis has developed and distributed written compliance policies, procedures, and practices that guide the Company and the conduct of our employees in day-to-day operations. These policies and procedures have

been developed under the direction and supervision of our Compliance Officer, Compliance Committee, Ethics, Risk and Compliance Department, Legal Counsel, and management from various business and functional areas.

Code of Ethics. The Novartis Code of Ethics provides a clear framework for ethical decision making; a guide that helps associates navigate complex situations. The Code of Ethics is principles-based, resulting in a collection of commitments that the Company makes to doing what's right for patients, and for society. The principles outline the standards of behavior that are expected and encouraged, and the commitments are supported by an ethical decision-making framework and resource materials that equip associates with the tools and confidence to make the best possible ethical decisions and do what's right.

Policies and Procedures. Novartis has established policies and procedures to address a variety of potential risk areas associated with Federal Healthcare Programs. These policies and procedures are part of a comprehensive framework of compliance controls that exist throughout various segments of our organization. In particular, Novartis developed and implemented significant policies and procedures to be consistent with guidance from the HHS Office of Inspector General and addressed in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals.

Education and Training

We educate and train employees on our compliance program and in accordance with CIA requirements. Our education and training covers a variety of laws and regulations that impact the way we conduct business. Our live and e-learning 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. We regularly review and update our training offerings, and identify additional areas of focus on an ongoing basis.

Internal Lines of Communication

Novartis 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 in place strong confidentiality and non-retaliation policies.

As part of its commitment to ethical and legal behavior, Novartis 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 the SpeakUp Office, an appropriate member of management, through our People and Organization, Legal, Security, or Ethics, Risk and Compliance Departments, or by calling our toll-free, 24-hour, anonymous AlertLine (888-436-7001).

Risk Assessment, Auditing, Monitoring and Data Analytics

The Ethics, Risk and Compliance Risk Management Oversight function annually develops and implements a centralized Healthcare Compliance Risk Assessment that incorporates key elements of an effective ethics and compliance program.

The primary objective of the centralized, annual Healthcare Compliance Risk Assessment is to identify and address risks associated with each Government Reimbursed Product, including risks related to the covered activities in the CIA, in the areas associated with the sales, marketing, and promotion of such products.

Furthermore, current and emerging U.S. regulatory and industry guidance is considered in designing the annual risk assessment to proactively identify, assess, and mitigate potential novel risks to the organization.

The results of the annual Healthcare Compliance Risk Assessment are proactively leveraged to enhance the control environment and advance the organization’s Compliance Program. The findings are used to make risk-based decisions based on available cross-functional data, which may incorporate mitigation plans that reflect relevant lessons learned from such analysis.

The Ethics, Risk and Compliance Risk Management Oversight function annually develops and implements an auditing, monitoring and data analytics plan, which incorporates our Corporate Integrity Agreement obligations and other business activities identified through the Healthcare Compliance Risk Assessment as potentially higher risk. The primary objective is to help the organization manage certain healthcare compliance risks by evaluating and improving the effectiveness of our policies, procedures and controls. Following the completion of each review, the Ethics, Risk and Compliance Risk Management Oversight function works together with the relevant risk owners to identify the root cause(s) and to consider corrective action(s) to help manage the risk.

Enforcing Standards Through Discipline

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

Responding to Detected Problems

As part of our compliance program, Novartis 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 Code of Ethics, policies and procedures, and its CIA. 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.

Novartis is dedicated to the maintenance, continual review and ongoing assessment required of an effective Comprehensive Compliance Program. Questions regarding Novartis’ Comprehensive Compliance Program or Novartis’ Code of Ethics can be directed to 1-888-NOW-NOVA (1-888-669-6682).

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