



# **ETHICS, RISK AND COMPLIANCE PROGRAM OVERVIEW – STATE OF CALIFORNIA**

## **I. INTRODUCTION**

Advanced Accelerator Applications USA, Inc. (“AAA”) is firmly committed to compliance with the letter and spirit of the laws that govern our operations. Our vision is not just to have a compliance program, built of policies and procedures, but to foster a culture of compliance. To be a company where people do the right thing not because a policy requires it, but because they value ethics and recognize the critical importance of compliance to the success of our business. By weaving compliance into the fabric of our corporate DNA, we safeguard our most precious assets, from our reputation to the trust of the patients who rely on us. We are ever mindful that failures in compliance jeopardize the very assets upon which our success depends, and often also lead to recalls, litigation, whistleblower actions and government investigations, all of which threaten our corporate health. It is only through a bona fide culture of compliance, in which ethics are a fundamental part of how we do business, that we guarantee our success in the long run.

Our Compliance Program is dynamic, involving not only multiple policies and procedures, but also the commitment of senior management and the support of all employees to make the program effective. The Program is designed to prevent, detect, and correct illegal or improper activity and to promote compliance with federal, state, and local laws.

This summarizes our efforts to comply with federal and state laws, industry standards, and the guidance set forth by the Office of the Inspector General in the Compliance Program Guidance for Pharmaceutical Manufacturers (the “OIG Guidance”). As discussed in the OIG Guidance, AAA has tailored its compliance program based on the nature of its business model, its size, organizational structure and resources.

## **II. OVERVIEW OF AAA COMPLIANCE PROGRAM**

### **1. LEADERSHIP AND STRUCTURE**

**Head of Ethics, Risk and Compliance.** AAA has a Head of Ethics, Risk and Compliance (“ERC”) who is responsible for developing, operating, and monitoring the compliance program. Our Head of ERC has the ability to effectuate change within the organization and to exercise independent judgment.

ERC guides the company’s compliance program.

**Compliance Committee.** AAA has a Compliance Committee that advises the AAA US Executive Leadership Team 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 the business units and functions across the company.

## **2. WRITTEN POLICIES AND PROCEDURES**

AAA 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 ERC and management from various functional areas.

**Code of Employee Conduct / Ethics.** The Novartis Code of Ethics, which has been fully adopted by AAA, is a written statement of ethical and legal principles, policies, and procedures that all AAA employees and management are required to follow. The Code of Ethics 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. The Code of Ethics is based on the laws and regulations applicable to our Company and prevailing ethical standards.

**Policies and Procedures.** AAA has established policies and procedures to address a variety of potential risk areas. These policies and procedures are part of a framework of compliance controls that exist throughout our organization. In particular, AAA's policies and procedures 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 data integrity pertaining to government reimbursement practices and kickbacks and other illegal remuneration.

**California Annual Spend Limit.** AAA'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 AAA provide valuable scientific and educational benefits. In connection with such presentations or discussions, AAA may offer occasional meals and items designed primarily for the education of patients and healthcare professionals. AAA has established a specific annual dollar limit of \$2,500 per medical or health professional in California on educational items and promotional activities in accordance with Cal. Health & Safety Code §119402. AAA will evaluate this limit on an annual basis and make any necessary adjustments consistent with any operational or practical issues related to compliance with the California statute. It is important to note that this annual dollar limit is an upper limit and not a spending goal.

## **3. TRAINING AND EDUCATION**

Training and education are key to our vision of a compliance culture of shared values and responsibilities. To that end, AAA educates and trains employees on all aspects of our compliance program through programs developed and conducted by compliance and legal professionals. Our live and computer-based training programs include, but are not limited to, meaningful discussions of our Code of Ethics, 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. AAA regularly reviews and updates its training programs and identifies additional areas of training on an “as needed” basis.

#### **4. AUDITING AND MONITORING**

AAA’s compliance program includes activities to monitor, audit, and evaluate compliance with the Company’s policies and procedures. AAA’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 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.

#### **5. OPEN LINES OF COMMUNICATION**

AAA offers open lines of communication to all employees seeking answers to questions about the Code of Ethics, ethical decisionmaking, or compliance. Questions may be emailed to the AAA U.S. ERC Team or employees may call or simply stop by an ERC associate’s office.

AAA has established a Hotline (“SpeakUp”), which is available to employees 24 hours a day, 7 days a week. This hotline allows employees to report suspected violations of the law, AAA’s Code of Ethics, or AAA’s policies in an anonymous fashion and without fear of retaliation.

#### **6. ENFORCING STANDARDS**

Adherence to the Code of Ethics is a condition of employment at AAA. Any violation of an employee’s obligations under the Code of Ethics subjects an employee to serious disciplinary action, including possible termination. An employee’s obligations under the Code of Ethics include strict observance of all laws and regulations applicable to our Company.

#### **7. RESPONDING TO VIOLATIONS**

AAA takes very seriously and investigates all suspected compliance violations. Although each situation is considered on a case-by-case basis, AAA consistently takes appropriate disciplinary action to address inappropriate conduct and deter future violations. Additionally, where the investigation reveals gaps in AAA’s compliance infrastructure, remedial action is taken to prevent further violations from occurring.

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

Copies of our comprehensive compliance program and Annual Declaration documents can be obtained by contacting [npc.ethicsandcompliance@novartis.com](mailto:npc.ethicsandcompliance@novartis.com) or by calling 888-669-6682.