

## **ETHICS AND COMPLIANCE PROGRAM OVERVIEW**

### **STATE OF CALIFORNIA**

#### **A. 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.

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

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

AAA’s Ethics, Risk and Compliance Department (“ERC”) guides the company’s compliance program. The ERC has the ability to effectuate change within the organization as necessary, to exercise independent judgment and has free and unencumbered access to senior management.

AAA’s Compliance Associates are charged with the responsibility of assisting the ERC in developing, operating and monitoring the compliance program.

##### **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 the ERC and management from various functional areas.

**Code of Employee Conduct.** The Novartis Code of Conduct, 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 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. The Code of Conduct 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. AAA has excluded from its spending limit all items of nominal value (\$25 or less).

### **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 Conduct, 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 Conduct, ethics, or compliance. Questions may be emailed to the AAA U.S. Compliance Team or employees may call or simply stop by a Compliance employee's office.

AAA has established a Hotline ("SpeakUp," formerly known as BPO), 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 Conduct, or AAA's policies in an anonymous fashion and without fear of retaliation.

## **6. ENFORCING STANDARDS**

Adherence to the Code of Conduct is a condition of employment at AAA. Any violation of an employee's obligations under the Code of Conduct subjects an employee to serious disciplinary action, including possible termination. An employee's obligations under the Code of Conduct 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.

Copies of our comprehensive compliance program and Annual Declaration documents can be obtained by contacting the AAA U.S. Compliance Team.