

# AstraZeneca US Compliance Program

## Key Objectives

AstraZeneca's US Compliance Program is focused on two equally important objectives:

- Exercising due diligence to prevent, detect and correct unlawful conduct
- Promoting an organizational culture that encourages ethical conduct and compliance with law.

## Fundamental Elements

These objectives are accomplished through the coordinated implementation of the fundamental elements of the US Compliance Program:

- **Leadership and Structure** that is responsible and accountable for the development, operation and oversight of the Compliance Program;
- **Employing the Right People** who possess a strong and unwavering degree of integrity and commitment to ethical behavior;
- **Written Policies and Procedures** to assist employees to comply with laws and regulations and to serve as a tool to identify instances of noncompliance;
- **Training and Education** to ensure employees are aware of company policies and procedures and appropriate behavior;
- **Lines of Communication** to enable employees to report actual and suspected policy violations or request guidance.
- **Auditing and Monitoring** to ensure the program is operating effectively;
- **Investigation of Violations and Enforcement of Policy** for those who either engage in misconduct or fail to take reasonable steps to prevent or detect compliance and ethics violations
- **Corrective Action** to address any identified shortcomings in the program.

## A Risk-based Approach

In addition to these fundamental elements, the Compliance Program is founded on a risk-based approach. The Compliance Officer, with input from affected functional areas, identifies key risk areas for our business and tailors compliance efforts to mitigate risk in those areas.

## **Leadership and Structure**

The Compliance & Ethics Department is headed by the US Compliance Officer who is also a member of the Business Integrity and Assurance Team.

### **Business Integrity and Assurance Team (BIAT)**

The BIAT is charged with leading the US Business in setting standards for ethical business practices and policies and serves as both the conscience of the organization, focusing on “how” we deliver our business value, and the caretaker of its license to operate.

### **US Compliance Officer**

The US Compliance Officer is charged with responsibility for operation of the US Compliance Program and makes periodic reports on compliance matters to the US Leadership Team.

### **Board of Directors**

AstraZeneca’s Board of Directors fully supports the US Compliance Program and takes an active leadership role with respect to the content and operation of AstraZeneca’s corporate ethics and compliance programs. Board members are periodically updated on the status of the Compliance Program and provide an extra level of oversight.

### **Designated Individuals**

To assist the Compliance Officer in the development, implementation and oversight of the Compliance Program, the Compliance Officer oversees a staff with appropriate resources and authority.

## ***Employing the Right People***

AstraZeneca is committed to conducting business with the highest standards of integrity, trust and respect for the law. The success of this commitment depends on those who conduct the business. Accordingly, AstraZeneca engages in a rigorous process to ensure that it employs only those individuals who possess an equally strong and unwavering degree of integrity and commitment to ethical behavior. As part of the overall hiring process, AstraZeneca screens all candidates for employment to determine if they are currently excluded from participating in federally funded healthcare programs, or have been convicted of a criminal offense related to the provision of healthcare items or services or otherwise related to the responsibilities of the job. It is AstraZeneca practice not to hire any of these individuals.

Additionally, AstraZeneca annually screens all current employees to assure that they have not been excluded from participation in federally funded healthcare programs. Employees' compliance with law, policy and ethical standards is also taken into account in performance reviews, compensation programs, and other personnel decisions.

## Written Policies and Procedures

AstraZeneca has developed written policies and procedures to address the many compliance challenges that AstraZeneca faces as a heavily regulated company.

These policies and procedures are organized by risk area to reflect the distinct legal and regulatory issues presented by our business. In terms of the US Policies, the Office of Inspector General (OIG) has identified three primary potential risk areas for pharmaceutical manufacturers in its Compliance Program Guidance:

- Integrity of data used by state and federal governments to establish payment amounts (e.g. government price reporting);
- Kickbacks and other illegal remuneration; and
- Compliance with laws regulating drug samples.

AstraZeneca has adopted policies and procedures designed to address the specific areas identified by the OIG, areas discussed in the PhRMA Code on Interactions with Healthcare Professionals, and other risk areas identified by AstraZeneca as the external and internal environments evolve.

**Code of Conduct.** The AstraZeneca Code of Conduct is a written statement of ethics and compliance principles, policies, and procedures that all AstraZeneca managers, employees, and designated contractors are expected to follow. It is one of the most important documents in the US Compliance Program.

## Training and Education

A central component of the Compliance Program is the development and implementation of a comprehensive training program covering the risk areas within the scope of the program. AstraZeneca requires that personnel at all levels, including executives and the Board of Directors, are educated about the substance of relevant areas of compliance. The Compliance Officer is responsible for ensuring that training and education plans, materials and resources are developed and delivered. Furthermore, the Compliance Department is responsible for answering any questions an employee may have during or after formal training. AstraZeneca takes compliance training and education very seriously. Training is an important part of every employee's career development and individual growth. Participation in training programs is a condition of continued employment and failure to comply with training requirements may result in disciplinary action up to and including termination of employment.

## Lines of Communication

AstraZeneca cannot meet its commitment to doing business with the highest ethical standards and respect for the law if individuals do not come forward when they should. Each AstraZeneca employee shares in the responsibility for ensuring that our policies are followed and our standards of conduct are met.

AstraZeneca strives to create an environment of openness, responsible conduct and mutual respect. Open communication is the single most effective way to deal with issues when - or ideally before - they arise. In every case, it is critically important for employees to ask any questions or raise any concerns they may have. To help employees uphold their responsibilities, AstraZeneca has provided several options for seeking guidance or raising concerns. Regardless of the method used, AstraZeneca enforces a no retaliation policy so that employees can come forward without fear of retaliation or retribution of any kind for raising a concern in good faith by honestly presenting information believed to be true. Raising a concern does not, of course, excuse an employee from the ongoing responsibility to meet the performance and policy standards that apply generally to AstraZeneca employees.

### Seeking Guidance

**Code of Conduct Helpline.** If employees are unsure about whether a particular activity they are considering engaging in is consistent with AstraZeneca's standards for compliance and ethics, they may address the matter with their manager or through an appropriate Human Resources, Compliance, or Legal Department contact. They may also call the Code of Conduct Helpline or send a question or concern to a third-party web site, anonymously if desired. Both avenues of communication are operated 24 hours a day/seven days a week for employees' convenience. Questions or reports are reported to AstraZeneca.

### Raising Concerns

- **Line Manager.** In general, each employee should first start with his or her manager. AstraZeneca expects all managers to maintain an open door policy that allows for free and open communication with employees; an employee who feels comfortable seeking guidance from or reporting a suspected violation to his or her manager is encouraged to do so.

If employees are uncomfortable seeking guidance from or raising concerns to their immediate managers, AstraZeneca encourages employees to use the following alternative mechanisms:

- **The US Compliance Officer**
- **Their Human Resources Partner**
- **The US Legal Department**
- **Code of Conduct Helpline.**

## **Auditing and Monitoring**

AstraZeneca is committed to a program of rigorous auditing and monitoring to provide independent and objective review and assessment of the Company's compliance efforts. The audit plan is designed to focus on those risk areas of special significance and to ensure adequate reporting and follow-through. In addition to formalized compliance audit procedures, AstraZeneca conducts compliance assessments focused on specific risk areas.

The Compliance Program's auditing is divided into two types: (1) auditing focused on risk areas identified in the Compliance Program; and (2) review of the Compliance Program itself. For each risk area, the audit generally reviews the following subjects:

- Adherence to written policies and procedures;
- Adequacy of publication and dissemination of policies and procedures;
- Adherence to certification requirements, where applicable;
- Adherence to record keeping and documentation requirements;
- Adequacy of employee education, including new hire, HQ and field training, record keeping and certification; and
- Systems review.

In addition to AstraZeneca's formalized compliance audit procedures, AstraZeneca conducts compliance assessments focused on specific risk areas to assess whether company policies and procedures are being followed. The nature, frequency and extent of these reviews may vary according to factors such as internal risk assessments, new regulatory requirements, and changes in AstraZeneca's business practices. Monitoring may be conducted by line management in the area being assessed or by Compliance Department personnel.

## **Investigation of Violations and Enforcement of Policy**

Employees are expected to comply with the Code of Conduct, company policies and procedures, and applicable law. The Code of Conduct and AstraZeneca's Policy on Discipline specify that, when an employee's conduct or behavior violates the standards and expectations set by AstraZeneca, appropriate disciplinary action, up to and including dismissal, may be required. Although each reported violation is handled on a case-by-case basis in light of the specific facts presented, AstraZeneca consistently undertakes disciplinary action to address inappropriate conduct and deter future misconduct.

The Company takes steps to protect the confidentiality of the information relating to a reported violation and informs employees and managers of details relating to a report or an investigation on a need-to-know basis only. The Compliance Department records the violation in a detailed log that chronicles alleged violations of compliance policies, including the nature of any investigation, its results, and any remedial action taken. The individual who made the report will be advised generally of the results of the investigation.

When policies have been violated, line management, in consultation with Human Resources, legal counsel and the Compliance Department as needed, determine the appropriate disciplinary action to be taken.

While discipline is administered fairly, in all instances, each situation is judged on its own individual merits.

## Corrective Action

A critical attribute of the Compliance Program is the need to ensure that reasonable steps are taken to respond to policy violations and to implement corrective action designed to prevent further violations. Corrective action collectively may consist of discipline of the individuals involved and/or broader remedial action. Examples of remedial action include policy revisions, revisions to training programs, or dissemination of compliance-related guidance, such as frequently asked questions (FAQs).

In addition to investigating all suspected policy violations and administering individual discipline where appropriate, AstraZeneca undertakes review and root cause analysis necessary to identify and correct any programmatic compliance-related issues, including those identified through auditing and monitoring activities.

The Business Integrity and Assurance Team (BIAT) supports the Compliance Officer and other senior managers in these efforts. BIAT is provided with periodic reports on the status of policy compliance, audit findings and review of the adequacy of company controls in compliance risk areas. Ultimately, the BIAT endeavors to guarantee that adequate processes and safeguards are in place to mitigate risk and assure AstraZeneca's ongoing compliance with legal obligations and ethical responsibilities.

## California Compliance Program Law

For purposes of compliance with the requirements of California Health and Safety Code, §§ 119400-119402 (effective July 1, 2005) (hereinafter "California Compliance Program Law"), AstraZeneca has established, as part of its comprehensive compliance program, an annual dollar limit concerning appropriate items covered by the California law ("Covered Items") that are provided to individual California medical and healthcare professionals as part of AstraZeneca's interactions with these professionals to enhance the practice of medicine and benefit patient care. Some examples of these Covered Items include educational items, such as medical textbooks, or modest meals provided in connection with AstraZeneca's efforts to advance the professionals' understanding of the efficacy, safety, and benefits of AstraZeneca's products. AstraZeneca's annual dollar limit is \$1800 per individual healthcare professional.

This limit is a maximum amount; it is not an average. Because this limit is a part of AstraZeneca's compliance program, and because AstraZeneca's compliance program, by its very nature, must remain dynamic in order to be effective, this annual limit may be revised based on a variety of factors. This limit reflects the breadth of products that AstraZeneca offers and the broad range of healthcare professionals with whom AstraZeneca representatives may interact. AstraZeneca markets various products for treatment options in these diverse therapeutic areas: (1) Cardiovascular; (2) Gastrointestinal; (3) Neuroscience; (4) Oncology; (5) Respiratory; and (6) Infection. Because some healthcare professionals may treat different patients with a variety of conditions in the therapeutic areas listed above, situations may arise in which certain healthcare professionals interact with multiple company personnel.

Consistent with AstraZeneca's good faith understanding of the California Compliance Program law, AstraZeneca excludes certain items and payments from its coverage. AstraZeneca's annual dollar limit, as of July 1, 2009 does not include the value of:

- Drug samples provided to individual healthcare professionals intended for free distribution to patients.
- Financial support of independent education, including continuing medical educational forums.
- Financial support for health education scholarships.
- Payments for legitimate professional services, including professional speaking, advising, consulting, training or market research services, that are based on the fair market value of the services provided.
- Educational items provided to physicians to give to their patients to enhance patients' understanding or management of a disease state or disorder (items such as patient educational brochures, instruction sheets, and patient self-assessment tools to track medical information).

**Annual Declaration for Purposes of California Health & Safety Code, §§ 119400-119402**

AstraZeneca declares, to the best of its knowledge and based upon a good faith understanding of the applicable statutory requirements, that it has established a Comprehensive Compliance Program that encompasses the compliance program requirements stated in California Health & Safety Code, §§ 119400-119402. As of July 1, 2009, AstraZeneca declares that it is, in all material respects, in compliance with the Comprehensive Compliance Program as described above and California Health & Safety Code, §§ 119400-119402. Because compliance is a dynamic concept, AstraZeneca will assess the overall effectiveness of the elements of its Comprehensive Compliance Program at least annually, and, as part of its assessment, AstraZeneca may modify aspects of its program to enhance the program's effectiveness. By declaring that it is in compliance with its Comprehensive Compliance Program, AstraZeneca is asserting that its program is reasonably designed to prevent or detect and address misconduct. Copies of this summary of the U.S. Compliance Program and declaration may be obtained by contacting AstraZeneca at the following toll-free number: 800-236-9933.