



**Aurobindo Pharma USA, Inc.
Ethics and Compliance Program
Branded Products**

I. Introduction



Aurobindo's successful business operations and reputation is built upon the principles of fair dealing and ethical conduct of all employees. The Company's reputation for integrity and excellence requires careful observance of the spirit and letter of all applicable laws and regulations, as well as scrupulous regard for the highest standards of conduct and personal integrity. Aurobindo's continued success is dependent upon customer trust, and Aurobindo is dedicated to preserving that trust.

The Company insists employees maintain the highest possible ethical standards in their dealings with customers, third parties, suppliers, competitors, co-workers, and the public, in general. The integrity, reputation, and profitability of the Company ultimately depend upon the individual actions of each employee. Employees, in all jobs and at all levels, must strive to conduct the Company's business in a fair, ethical, forthright, and lawful manner.

In interacting with the medical community, Aurobindo is committed to following the highest ethical standards as well as all legal requirements. Our interactions with healthcare professionals ("HCPs") are not to be perceived as inappropriate by patients, the government, or the public at large. All HCP interactions must be professional exchanges designed to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about products, providing scientific and educational information, and supporting medical education. Aurobindo abides by the principle that a HCP's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the HCP's medical knowledge and experience.

II. Ethics and Compliance Program



At Aurobindo, we foster a culture that promotes the prevention, detection, and resolution of problems. The primary manner we do this is by maintaining the Company's Ethics and Compliance Program, which is a set of internal standards and controls that promote adherence to pharmaceutical industry statutes, regulations, and requirements of federal healthcare programs with respect to the development, manufacturing, marketing, and selling of Aurobindo products.

The Program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing HCP operational functions; improving the quality of healthcare services; and reducing the cost of healthcare. Attaining these goals provides positive results to Aurobindo, the government, and individual citizens alike.

Although implementation of an Ethics and Compliance Program may not eliminate improper conduct, a good faith effort to comply with applicable statutes and regulations as well as federal healthcare program requirements, demonstrated by an effective program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior

In terms of HCP interactions, all communications must 1) be accurate and not misleading; 2) make claims about a product only when properly substantiated; 3) reflect the balance between risks and benefits; 4) be consistent with all other Food and Drug Administration (“FDA”) requirements governing such communications.

The benefits of the Ethics and Compliance Program include:

- A concrete demonstration to employees and the community at large of Aurobindo’s commitment to honest and responsible corporate conduct;
- An increased likelihood of preventing, or at least identifying, and correcting unlawful and unethical behavior at an early stage;
- A mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action; and
- Through early detection and reporting, minimizing any financial loss to the government and any corresponding financial loss to the Company.

A. Commitment

The Aurobindo Executive Leadership Team are in support of and are committed to an ethical culture facilitated by the Ethics and Compliance Program. It is an expectation of the Executive Leadership Team that the commitment should filter down through management to every employee and agent of the Company. Managers are expected to be champions for ethics and compliance with their work teams.

B. Governance

The Aurobindo Ethics and Compliance Program is overseen and managed by the following officers and committees:

1. Chief Compliance Officer

The Chief Compliance Officer manages the creation, development, implementation, operation, monitoring, and enforcement of the Company’s Ethics and Compliance Program, and the day-to-day administration of the Ethics and Compliance Department. The roles and responsibilities of the Chief Compliance Officer are set forth in the job description, as reviewed and approved by the Executive Leadership Team, including the Vice President and General Counsel.

The Chief Compliance Officer is responsible for:

a. Guidance and Reporting to Management

- (1) Providing guidance and advice to Executive Leadership, including the Vice President and General Counsel, and other company personnel related to the Company’s Ethics and Compliance Program.

- (2) Developing metrics, reports, and dashboards to measure the effectiveness of the Ethics and Compliance Program, and providing regular reports and updates to Executive Leadership, including the Vice President and General Counsel, and Compliance Committee (discussed in Section IIC3).

b. Implement Written Standards, Policies, and Procedures

- (1) Ensuring written standards, policies, and procedures correspond to applicable legal and regulatory requirements, reflect the Company's values, and are available and easily accessible to Aurobindo employees.
- (2) Overseeing the maintenance, distribution, and revision, as necessary, of the Company's Code of Ethics and Business Conduct, and the approval of Executive Leadership.
- (3) Overseeing the development, maintenance, distribution, and revision, as necessary, of written compliance policies, procedures, and guidances, and the approval of the Compliance Committee.

c. Ensure Effective Communication, Education, and Training

- (1) Providing updates and training on applicable federal, state, and local laws, including enforcement updates related to such laws, Office of Inspector General ("OIG") guidance, and industry guidance (e.g., PhRMA Code), as well as the policies and procedures associated with the Company's Ethics and Compliance Program, to all Company employees, including Executive Leadership and the Compliance Committee.
- (2) Ensuring tailored training activities for high risk personnel and agents of the Company.
- (3) Overseeing the dissemination of relevant and appropriate communications to Aurobindo employees and third parties that represent and serve as role models for the Company's Ethics and Compliance Program.
- (4) Ensuring complete and accurate training records are maintained and archived.

d. Monitoring, Auditing, and Internal Reporting Systems

- (1) Initiating and overseeing periodic Ethics and Compliance Program risk assessments and benchmarking.
- (2) Ensuring adequate mechanisms are in place for employees to ask ethics- and compliance-related questions or to report ethics and compliance concerns or suspected violations through EthicsPoint.

e. Investigations and Corrective Actions

- (1) Overseeing all internal and external investigations into actual or suspected violations of the Company's Ethics and Compliance Program.
- (2) Recommending consistent and appropriate disciplinary action(s) and corrective actions to the Compliance Committee when non-compliance is substantiated.
- (3) In conjunction with the Legal Department, cooperating with and managing federal and state inquiries and investigations into potential violations of applicable laws.

2. Compliance Committee

The Compliance Committee evaluates the effectiveness of the Company's Ethics and Compliance Program through the review and approval of the Company's Code of Ethics and Business Conduct and related policies, procedures, and internal controls reasonably designed to comply with applicable laws and regulations. The membership, structure, and roles and responsibilities of the Compliance Committee are set forth in the Company's Compliance Committee Charter, as reviewed and approved by Executive Leadership, including the Vice President and General Counsel.

The Compliance Committee is composed of senior members of management, representing certain core departments and functions across the Company. Each member must be of sufficient seniority to represent his or her respective department's views, and support the Ethics and Compliance Program as needed. The Committee is chaired by the Chief Compliance Officer and comprised of at least five members from the following departments:

- Legal
- Finance and Accounting
- Commercial and Operations
- Clinical and Medical
- Human Resources

The Compliance Committee is responsible for:

- Reviewing and evaluating the design, development, and operation of the Company's Ethics and Compliance Program, including its policies and procedures and related internal controls, which are designed to ensure compliance with the Company's Code of Ethics and Business Conduct and applicable laws.
- Considering and providing guidance on matters reported by the Chief Compliance Officer and providing support and assistance to the Chief Compliance Officer and Ethics and Compliance Department, as necessary, with the administration of the Ethics and Compliance Program.

- Reviewing and approving any changes to the Company's Code of Ethics and Business Conduct.
- Reviewing and approving any changes to policies, procedures, or internal controls related to the Company's Ethics and Compliance Program.
- Reviewing and approving measures that require Committee approval pursuant to any policies related to the Company's Ethics and Compliance Program.
- Reviewing and providing recommendations related to the Chief Compliance Officer's annual Ethics and Compliance Department work plan.
- Reviewing and providing recommendations related to the Chief Compliance Officer's annual monitoring and auditing work plan.
- Developing metrics to measure the effectiveness of the Ethics and Compliance Program and approving reports and dashboards that help management evaluate the effectiveness of the Ethics and Compliance Program.
- Authorizing periodic enterprise risk assessments.
- Receiving regular training and updates from the Chief Compliance Officer related to applicable laws and regulations, OIG guidance, industry guidance, and Company policies.
- Obtaining periodic reports from the Chief Compliance Officer related to ethics violations reported to EthicsPoint, and investigations into actual or suspected non-compliance with the Company's Ethics and Compliance Program, as well as corrective actions.
- In consultation with the Human Resources and Legal Departments, issuing disciplinary measures and approving corrective actions when non-compliance is substantiated.

3. Funding and Support Request Review Committee

The Funding and Support Request Review Committee reviews and approves funding and support requests from outside individuals and organizations against a series of rules and guidelines. The membership, structure, and roles and responsibilities of the Funding and Support Request Review Committee are set forth in the Company's Funding and Support Request Review Committee Charter, as reviewed and approved by the Company's Compliance Committee.

The Funding and Support Request Review Committee is chaired by the Chief Compliance Officer and supported by the Vice President, Medical Affairs Operations and comprised of at least three individuals from the following departments:

- Medical Affairs

- Legal
- Clinical
- Regulatory

The committee is responsible for:

- Reviewing and either approving, modifying, or denying any external funding request submitted to Aurobindo in the form of grants, sponsorships, exhibits, investigator-initiated studies, corporate memberships, charitable contributions, business donations, and requests for expanded access of investigational products, as defined in the Company's Ethics and Compliance Program and associated policies and procedures.
- Review and approve measures that require committee approval pursuant to any policies related to the Company's Ethics and Compliance Program.
- Reporting its activities, including all approved funding and support requests, to the Compliance Committee on a quarterly basis.

4. Vice President and General Counsel

The Vice President and General Counsel advises the Company on the legal and regulatory risks and counsels management on applicable laws and regulations that govern, relate to, or impact the Company's day-to-day operations and strategy. The Vice President and General Counsel also manages the day-to-day function and administration of the Legal Department. The roles and responsibilities of the Vice President and General Counsel are set forth in the job description, as reviewed and approved by the Chief Executive Officer.

C. Elements of the Ethics and Compliance Program

1. Written Standards

Aurobindo is committed to developing and distributing written standards of conduct, as well as written policies and procedures that verbalize the Company's commitment to ethics and compliance and addressing specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to federal healthcare programs and sales and marketing practices.

a. Code of Ethics and Business Conduct

Aurobindo abides by the following core principles:

- We will use all ethical and lawful means possible to bring our therapy options to the right patients, in the right way.
- We will be personally responsible to understand and adhere to the spirit and letter of all laws and Company policies that pertain to our daily business.
- We will only collaborate with HCPs, suppliers, and other business partners who share our commitment to understand and uphold the laws and regulations that apply to our operations.
- We will respect and protect the dignity and privacy of patients, HCPs and their staffs, business partners, competitors, and our fellow employees.
- We will promptly and cooperatively report, without fear of retaliation, any behavior contrary to these principles to management, the Ethics and Compliance Department, or EthicsPoint.

Aurobindo's foundation is built on strong ethical practices and values that reflect our commitment to conducting business with honest, fairness, and integrity; whereby, we avoid doing anything that could even suggest impropriety in any of our dealings.

b. Policies and Procedures

Policies address an organization's guiding principles, whereas procedures address a sequence of steps to be followed, in a consistent manner, that help us comply with policies.

At Aurobindo, organizational expectations are documented to ensure employees understand the Company's culture and requirements. All employees are required to read, understand, and acknowledge all policies and procedures applicable to their roles and responsibilities.

2. Education and Training

Aurobindo is committed to developing and implementing regular, effective education and training programs for all employees and third parties.

At Aurobindo, education and training enable individuals to recognize their obligations to comply with the organization's policies and procedures and identify high risk areas, which reduces the probability of unethical and non-compliant conduct.

3. Communications

Aurobindo is committed to creating and maintaining an effective line of communication between the Chief Compliance Officer and all employees, including a process to receive complaints or questions (e.g., EthicsPoint) and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation.

a. Duty to Report

At Aurobindo, all employees have a duty to report any known or suspected violation of laws, rules, or regulations that apply to the Company. All reports are handled with sensitivity and discretion. The identity of the individual who reports any information will be protected, to the extent possible, consistent with applicable laws and Aurobindo's need to investigate an allegation.

There are many resources at Aurobindo that can be leveraged to ask questions or report any suspected instances of misconduct including Supervisors, Ethics and Compliance, Human Resources, and Legal. Additionally, employees can call EthicsPoint if they prefer to remain anonymous:

Phone: **(844) 744-9516**

Website: <http://aurobindousa.ethicspoint.com>

b. Protection from Retaliation

Aurobindo prohibits retaliation against an employee who, in good faith, seeks help or reports known or suspected violations, including participating in an investigation or opposing any unlawful or discriminatory practices.

4. Risk Assessments, Auditing, and Monitoring

Aurobindo is committed to using audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems.

a. Risk Assessment

Ethics and Compliance risk is the threat posed to a company's financial, organizational, or reputational standing resulting from violations of laws, regulations, codes of conduct, or organizational standards of practice.

Aurobindo proactively conducts risk assessments to determine which risks have the greatest potential for legal, financial, operational, or reputational damage, and thereby allocates resources to manage and mitigate those risks.

b. Auditing and Monitoring

Ethics and Compliance auditing is a retrospective assessment of activities to determine if behaviors were consistent with policies and procedures. Compliance monitoring is an observation of real-time activities.

Aurobindo proactively conducts routine auditing and monitoring of business processes in accordance with the annual Ethics and Compliance monitoring and auditing work plan that is approved by the Compliance Committee. Additionally, Aurobindo conducts for-cause audits in the event they are deemed necessary.

5. Third Party Screening

Aurobindo is committed to the screening of third parties that we hire to conduct business on our behalf. If Aurobindo determines that a third party has been excluded or debarred from federal healthcare programs or government contracts, Aurobindo will not contract with them.

In addition, third parties must be suitable to do business with from an anti-bribery perspective. We expect third parties with whom we work to comply with bribery and corruption laws and to observe our requirements concerning anti-bribery.

6. Investigations

Aurobindo is committed to developing policies and procedures for the investigation of identified instances of non-compliance or misconduct. These include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

At Aurobindo, the facts and circumstances of each particular situation undergo a thorough review and violations are addressed in an appropriate manner.

7. Transparency and Disclosure

Aurobindo is committed to reporting all transactions that constitute a payment or transfer of value to a HCP or healthcare organization (HCO) to the Centers for Medicare and Medicaid Services (“CMS”).

At Aurobindo, it is the responsibility of each employee to track all applicable transactions. Individual employees may be held financially responsible for any Company penalties incurred as a result of the individual employee failing to report or inaccurately reporting a transaction to the Company. If an individual is ever in doubt as to whether a payment or transfer of value should be reported, they should err on the side of reporting.