# Aurobindo Pharma USA, Inc. Code of Ethics and Business Conduct Branded Products

### Why do we have a Code of Ethics and Business Conduct?

Dear Colleague,

Aurobindo's foundation is built on strong ethical principles and values which reflect our commitment to conducting our business with honesty, fairness, and integrity.

In addition to fully complying with all applicable laws, we should avoid doing anything that could even suggest impropriety in any of our dealings.

This Code of Ethics and Business Conduct, Branded Products, reflects the Company's core principles. Please read and follow it completely. All employees are required to comply with these standards by behaving ethically and compliantly with our stakeholders at all times, including:

- Patients
- Healthcare Professionals (HCPs)
- Government Officials
- Supply Chain Partners
- Other employees
- Society at large

We have an open-door policy and encourage you to ask questions about topics addressed in this Code. Please feel free to speak with:

- Your supervisor
- Ethics and Compliance
- Legal
- Human Resources
- Any officer of Aurobindo Pharma USA

If you wish to report an ethics violation, please contact EthicsPoint:

Phone: (844) 744-9516

#### Website: http://aurobindousa.ethicspoint.com

Thank you, in advance, for adhering to the principles outlined in this Code.

Hunter Murdock Vice President and General Counsel Aurobindo Pharma USA, Inc.

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	EthicsPoint.



# Core Principle 1:

We will use all ethical and lawful means possible to bring our therapy options to the right patients in the right way.

#### "Ethical and lawful means" - what does this mean for you and your job?

	Something may be technically lawful, but it's still not the right thing to do. Use
•	common sense in accordance with the highest ethical standards.
	You are expected to follow laws and regulations, Office of Inspector General
v	("OIG") guidance, the PhRMA Code, and Aurobindo policies.
	Product promotion is one of our biggest risk areas. There is no excuse for
v	engaging in "off-label" promotion or attempting to influence HCP decision-
	making with economic incentives.

#### Our patients, healthcare partners, and the future of Aurobindo depend on you!

We are committed to more than simply complying with all applicable laws and regulations. Beyond complying, we strive to conduct our business in accordance with the highest of ethical standards. This Code of Ethics and Business Conduct reflects Aurobindo's values and business practices that support this commitment.

We expect every officer, manager, employee, and certain business partners to read and understand this Code and abide by it in performance of his or her business responsibilities. When we refer to our employees in this Code, we mean our directors, officers, and all employees of Aurobindo Pharma USA, Inc. and its subsidiaries ("Aurobindo" or "the Company"), unless we specify or the context implies otherwise.

This Code addresses conduct that is particularly important to proper dealings with the people and companies with whom we interact, but reflects only a part of our commitment. From time to time, we may adopt additional policies or procedures with which our employees are expected to comply. The Code is just one part of Aurobindo's overall program to ensure that all employees follow the appropriate standards and comply with all ethical and legal requirements that affect the manner in which Aurobindo conducts its business.



Although this Code covers a wide range of business practices, it does not, nor is it intended to, cover every issue that may arise. If an employee is in doubt about the applicability of the Code or other guidance to particular situations or is confronted with situations not covered by the Code or other Company guidance, the employee should seek guidance from their supervisor, Ethics and Compliance, Legal, or Human Resources. However, it is the responsibility of each employee to apply common sense, together with his or her own highest ethical standards, in making business decisions

where there is no stated guidance in this Code.

Officers and supervisors are expected to develop in their employees a sense of commitment to the spirit, as well as the letter, of this Code. The compliance environment, within each supervisor's assigned area of responsibility, will be a significant factor in evaluating the quality of that individual's performance, and employees who make exemplary efforts to uphold our standards will be recognized for that effort during performance reviews. However, nothing in this Code alters the at-will employment policy of Aurobindo.

Actions by members of your family, significant others, or other persons who live in your household (referred to in this Code as "family members") also may result in ethical issues to the extent that they involve Aurobindo business. For example, acceptance of inappropriate gifts by a family member from one of our suppliers could create a conflict of interest and result in a Code violation attributable to you. Consequently, in complying with this Code, you should consider not only your own conduct, but also that of your family and significant others.

Violations of this Code will not be tolerated. Any employee who violates this Code may be subject to disciplinary action, up to and including termination.



Managers are expected to be champions for ethics and compliance within their work teams:

- Set clear expectations with regard to performance and integrity.
- Discuss the importance of applying and advocating for high ethical standards, and living by the Code of Ethics and Business Conduct.
- State the importance of following Aurobindo policies and procedures.
- Remind employees to complete all ethics and compliance training.
- Encourage and answer ethics and compliance questions.
- Refer employees to EthicsPoint when there are ethics violations.



# **Core Principle 2:**

We will be personally responsible for understanding and adhering to the spirit and letter of all laws and company policies that pertain to our daily business.

Aurobindo operates in a heavily regulated industry and is subject to a variety of ethical and legal standards. The Company is committed to operating in compliance with these laws and standards, which include the laws summarized below.

#### Anti-Kickback Statute



In the US, the offering of anything of value as an inducement to purchase a pharmaceutical product may be a violation of law. Such laws prohibit offering or giving anything of value to HCPs or other persons, with the intent to directly or indirectly, implicitly or explicitly, influence or encourage the recipient to purchase, prescribe, refer, sell, or arrange for the purchase or sale of any Aurobindo product. Such conduct may be a

violation of the US Federal Healthcare Programs' Anti-Kickback Law and can lead to severe penalties, including criminal and/or civil fines for the Company and individual employees, imprisonment of individuals, and possible exclusion of Aurobindo products from reimbursement under Medicare and Medicaid. Many states also have Anti-Kickback Laws that apply to items and services reimbursed under Medicaid and other state programs and several states have Anti-Kickback Laws that apply to all items and services, even those not reimbursed under a government program.

#### Aurobindo is committed to complying with these laws

Many elements of your interactions with HCPs or other customers and the programs the Company offers need to be reviewed to ensure compliance with these complex laws. If you are involved in the marketing or sale of Company products in the US, you should become familiar with Company rules and policies in this area. Sale of Aurobindo products and services to customers, and purchases of raw materials and supplies of suppliers, may only be made on the basis of quality, price, and service and never on the basis of giving or receiving payments, gifts, entertainment, or favors. No payment may be approved or made with the agreement or understanding that any part of such payment is to be used for any purpose other than that described by documents supporting the payment.

#### False Claims



Numerous federal and state laws prohibit anyone from knowingly and willfully making or causing to be made any false statement or representation for the purpose of obtaining benefits or payments by government programs, commercial insurers, and other healthcare plans. A document can be false if it omits material information. These laws typically require that the person has actual knowledge that the information is false or is provided in deliberate ignorance or reckless disregard as to the truth or falsity of the information and no proof of specific intent to defraud is required. These laws also prohibit anyone from conspiring with another person to submit false claims. Thus, companies can be liable even if the false claims are actually submitted by another person. Violations of these laws can lead to fines, imprisonment, or exclusion from healthcare programs.

#### Other Applicable Laws

An increasing list of jurisdictions also have enacted laws that prohibit pharmaceutical manufacturers from providing certain economic benefits to healthcare practitioners, require pharmaceutical manufacturers to report certain marketing expenditures or product pricing information to state regulatory bodies, and/or require pharmaceutical manufacturers to adopt ethics and compliance programs consistent with industry guidance. Aurobindo is committed to conducting business ethically and in compliance with these state and municipal requirements.



#### PhRMA Code



In addition to the laws and regulations discussed above, a number of trade groups have issued standards governing pharmaceutical promotional and educational practices. The Pharmaceutical Research and Manufacturers of America ("PhRMA") has issued the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"). Aurobindo's policy is to comply with the PhRMA Code. Aurobindo has also voluntarily committed to compliance with PhRMA standards.

#### Gifts and Hospitality

The receipt and provision, as a normal business courtesy, of meals, gifts, or entertainment,



while a common and acceptable practice in some industries, is subject to additional regulations and restrictions in the healthcare industry, particularly with respect to interactions between pharmaceutical companies and HCPs, both at the federal and

state level. In addition, many governmental agencies have policies which prohibit the receipt of even small gifts, even where the practice is widely considered "a way of doing business." Employees should not accept gifts or entertainment that may reasonably be deemed to affect their judgment or actions in the performance of their duties. Our collaborators, suppliers, and the public at large should know that our employees' judgment is not for sale. Always discuss any proposed gifts or entertainment with the Ethics and Compliance Department.

#### Tips that apply to all gifts and hospitality:

- > Must not be offered to influence official action or obtain proper advantage
- Must be permitted by local law
- Value must be reasonable, appropriate to the position and circumstances of the recipient and occasion, and not create an appearance of bad faith or impropriety
- Frequency of past gifts or hospitality must not raise an appearance of bad faith or impropriety
- All gifts and hospitality must be approved by the Ethics & Compliance Department and be recorded fairly and accurately in your books and records

#### Global Marketing and Disclosure "Transparency" Laws

Interactions between Aurobindo, HCPs, and government officials must be transparent and comply with applicable US laws, local laws, regulations, professional codes of conduct, and adhere to applicable conflict of interest policies.

All transfers of value (e.g., meals, consulting payments, etc.) from Aurobindo to US HCPs must be disclosed via a public website. In addition, several states and municipalities have transparency laws that must be complied with.



# **Core Principle 3:**

We will only collaborate with healthcare professionals, suppliers, and other business partners who share our commitment to understand and uphold the laws and regulations that apply to our operations.

#### Shared Commitment

We rely on our business partners and customers to uphold the law. Their bad acts can have negative consequences for Aurobindo. If not handled properly by Aurobindo, we could be held accountable for:

- Wholesalers, Group Purchasing Organizations, Distributors, etc. who offer improper payments to HCPs or pharmacies.
- HCPs who solicit or accept kickbacks.
- Hospitals who fraudulently submit for government reimbursement.
- Speakers who promote off-label.

When conducting due diligence on a potential business partner, look for these red flags:

$\checkmark$	Requests for excessive or unusually high compensation for services being rendered.
$\checkmark$	Requests for an increase in compensation or advances during the life of a project.
	Requests for payments in third countries or to third parties.
$\checkmark$	Requests for payments in cash or bearer instruments.
$\checkmark$	Lack of adequate facilities or qualified staff.
$\checkmark$	Use of shell companies.
1	Lack of experience or track record with the product, field, or industry.
$\checkmark$	Allegations related to integrity or reputation for impropriety, or unethical or illegal conduct.
$\checkmark$	Requests to perform services without a written agreement.
1	Close social or business relationships with government officials.
1	Recommendation by a government official to use a particular business partner.
	Violations of local law or policy.
$\checkmark$	Misrepresentations or inconsistencies in the application or due diligence process.
$\checkmark$	Involvement of a high-risk country.



It's important to set the right expectations with customers and business partners:

- We don't pay HCPs to use our products
- We don't pay hospitals to get on formularies
- We pay for bona fide goods or services
- o We don't make facilitating payments to gain faster service
- We adhere to contractual provisions
- $_{\odot}\,$  We will walk away from business, if necessary

When dealing with suppliers or vendors:	When dealing with customers:
Do proper due diligence.	Don't offer improper gifts or inducements.
Don't solicit or accept improper gifts or inducements.	Respect office rules and institutional polices.
Don't recommend or select vendors for personal reasons.	Ensure any "extras" are included as part of the contract.
Ensure adequate contracts are in place to protect the Company.	Funding support is never given in exchange for business.
Suppliers and vendors may be required to read and acknowledge Aurobindo policies.	Pay special attention to government employees.



# **Core Principle 4:**

We will respect and protect the dignity and privacy of patients, healthcare professionals and their staffs, business partners, competitors, and our colleagues at work.

#### Health Insurance Portability and Accountability Act (HIPAA)

We respect and protect the dignity and privacy of patients.



- HIPAA was passed by Congress in 1996. HIPAA does the following:
  - → Provides the ability to transfer and continue health insurance coverage for millions of American workers and their families when they change or lose their jobs.
  - $\rightarrow$  Reduces healthcare fraud and abuse.
  - → Mandates industry-wide standards for healthcare information on electronic billing and other processes.
  - $\rightarrow$  Requires the protection and confidential handling of protected health information ("PHI")

HIPAA is designed to protect patients. HIPAA defines "individually identifiable health information" as information that is a subset of health information, including demographic information collected from an individual, and:

- 1. Is created or received by covered entities, like healthcare providers, health plans, employers, or healthcare clearinghouses, and
- 2. Relates to the past, present, or future physical or mental health condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and
  - a. That identifies the individual; or
  - b. With respect to which there is reasonable basis to believe the information can be used to identify the individual.

The HIPAA Privacy Rule imposes obligations on covered entities regarding PHI to mitigate the harm of an unauthorized disclosure. This privacy rule applies indirectly to "Business Associates." If a covered entity engages a **business associate** to help it carry out its healthcare activities and functions (e.g., a vendor that handles billing for a medical practice), the covered entity must have a written business associate contract with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the Rules' requirements to protect the privacy and security of protected health information. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of HIPAA Rules.

If an entity does not meet the definition of a covered entity or business associate, it does not have to comply with HIPAA Rules.

**Regarding Patient PHI:** 

- Aurobindo is not a HIPAA covered entity nor a Business Associate
- Never sign anything declaring that Aurobindo is a Business Associate
- Aurobindo policy is to collect and use only de-identified information
- HIPAA does not prohibit adverse event reporting

Regarding Employee PHI:



- HIPAA protects your health information
- Aurobindo, as the sponsor of your health insurance, is required to protect employee PHI

# Core Principle 5:

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.

#### Non-Retaliation Policy

Aurobindo will not retaliate against any person for filing a complaint in good faith, participating in an investigation, or opposing any unlawful discriminatory practice.

You have a **duty to repor**t any known or suspected violation of the law or unethical behavior. Failure to report is itself a violation of Company policy. You are expected to cooperate in any internal investigation and to keep such investigations confidential.

#### Reporting Known or Suspected Misconduct and Ethical Violations

If you ever suspect unethical, illegal, or general misconduct, don't keep it to yourself. Discuss it with your supervisor, Ethics and Compliance, or Human Resources. If you prefer to remain anonymous, you can contact EthicsPoint at:

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

#### Website: http://aurobindousa.ethicspoint.com

EthicsPoint is a third-party vendor who manages our ethics violations. When you contact them, you don't have to give your name. A customized web form or professional interview specialist will document your suspicion or concern and relay the information to Ethics and Compliance for further investigation and/or follow-up.

#### Complaints and Investigations

Every complaint to Ethics & Compliance or EthicsPoint must be investigated. If Aurobindo becomes aware of the reporting employee's identity, Aurobindo will protect their confidentiality and anonymity to the fullest extent possible. All accounting-related complaints and other serious ethics- or compliance-related complaints are reported to Executive Leadership.

#### What happens if I don't comply with the provisions of the Code of Ethics and Business Conduct?

Not complying leads to different levels of disciplinary action, and could result in termination. In addition, depending on the incident, the government may pursue individual prosecution. Moreover, the government could initiate an investigation of our Company.