Code of Conduct and Business Ethics
A MESSAGE FROM JEFF WATSON, PRESIDENT & CEO

Welcome to the Apotex Code of Conduct and Business Ethics.

At Apotex, we attribute our success to our reputation for quality and innovation, instilled by our founder, Dr. Barry Sherman, over 40 years ago. Today, we continue to take pride in our commitment to manufacturing safe, effective medicines that meet strict regulatory standards. Within the global healthcare community, we hold a position of trust; this means we must always strive to live up to our values and principles.

Our credibility is hard won and easily lost if we are not intentional in our conduct. Wherever we may work and whatever our role may be, at Apotex we hold ourselves to the same high standards, both legally and ethically. Every employee is personally responsible and accountable for helping our company maintain the reputation we have built together.

Apothex’s Code of Conduct and Business Ethics (“Code of Conduct”) clarifies what our standards are. It outlines what is expected of each of us, and the behaviours and ethics our customers and patients can expect from us. Given its importance to all of us and the way we do business, we trust you will read this Code of Conduct with due care and attention, and take full personal ownership. Recognize that breaches of this Code of Conduct will be taken seriously and may lead to disciplinary action, up to and including termination of employment.

If you have any questions or are unsure about a particular policy or compliance issue, we urge you to speak up. Similarly, if you believe this Code of Conduct has been broken by anyone at Apotex, we encourage you to speak out with the full knowledge that you will be protected from retaliation of any kind.

As Apotex employees, embodying the principles of our Code of Conduct is not only critical to the continuing success of our company and reputation - it’s simply the right thing to do.

Jeff Watson, President & Chief Executive Officer
OUR PURPOSE
Improving access to medicines for millions of patients worldwide is our purpose. We do this by providing affordable, innovative and high quality solutions.

COLLABORATION  COURAGE  PERSEVERANCE  PASSION

OUR VALUES

let’s start
1 /// An Introduction (Page 1-6)

01 A Message from Jeff Watson, President & CEO
02 Our Purpose Our Values
04 Our Guiding Principles
05 Introduction to the Apotex Code of Conduct and Business Ethics

2 /// Your Resources (Page 7-8)

07 Speaking Up

3 /// The Workplace (Page 9-15)

09 Working Together
10 Safe and Healthy Workplace and Respecting the Environment
11 Product Safety
12 Quality Standards
13 Research and Development
14 Product Promotion

4 /// Communication (Page 16-19)

16 Interactions with Healthcare Professionals
17 Interactions with Business Partners
18 Interactions with Competitors
19 Interactions with Government

5 /// Diligence (Page 20-26)

20 Conflicts of Interest
21 Accuracy of Business Records, Fraud, and Legal Holds
22 Safeguarding Apotex Information
23 Use of Company Property
25 Social Media and External Communication to the Media and General Public
26 Data Privacy


27 Canada Specific Laws and Industry Codes
28 U.S. Specific Laws and Industry Codes
29 Global Business Ethics and Compliance Program
30 Speak Up
OUR GUIDING PRINCIPLES

as a company

1. **We Are Patient Focused**
   We commit to a patient-centred view of the products we develop and commercialize and the processes and systems which support them. Continuous improvement is a part of everything we do. Quality and integrity are not sacrificed for profitability or expediency. Documentation and data are true and accurate.

2. **We Lead by Example**
   We are committed to ethical and quality behaviours which are aligned with Apotex corporate values. These behaviours are modelled by executives and leaders at all levels and are understood and demonstrated by all employees in everything they do.

3. **We Empower our Employees**
   We commit to creating and sustaining an environment in which all employees are encouraged, empowered, and accountable, without fear of retribution or punishment, to identify and speak up when something must be improved or corrected. Leaders support a variety of reporting channels.

4. **We Recognize and Reward**
   Our ability to excel as an organization relies on the knowledge, skill, diversity, and integrity of our employees. Our leaders and peers recognize and we are rewarded for work performed that exemplifies our ethical and quality behaviours.

5. **We Provide Visibility**
   We commit to creating and sustaining an environment of transparent communications, simple processes, and meaningful metrics throughout the organization.

as an individual

<table>
<thead>
<tr>
<th>Right for the patient</th>
<th>Right the 1st time</th>
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<td>Right from me</td>
<td>Right even when no one is looking</td>
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The Importance of this Code of Conduct

To achieve outstanding business results, fully help patients, serve our industry partners, our various customers and each other, we must conduct all aspects of our business ethically and in compliance with various laws and standards.

This Code of Conduct is our guide and binds all of us to principles of integrity, required by the company and expected among those working in the pharmaceutical industry.

Integrity is a Shared Responsibility

Concerning this Code of Conduct, as a company and as individuals, acting with integrity means:

• Complying with this Code of Conduct and related policies and with the legal and regulatory requirements that apply to our job activities;
• Being honest and using good judgment while conducting business; and
• Seeking advice when unsure about what to do in situations that seem to pose ethical issues.
Framework and Scope

The purpose of this Code of Conduct is to define a framework for our employees worldwide on the conduct of business within our standards of ethical values, and in compliance with regulatory and legal obligations and internal policies. It is not intended to be a comprehensive manual of all company policies or responsibilities under law that apply to your role in Apotex. It should, however, provide and reinforce the core values and principles to help you avoid, resolve, or report ethical and legal issues. This Code of Conduct is supplemented by specific policies and procedures, which set out in more detail Apotex’s expectations and your obligations as an employee. Where expectations are not explicitly stated, employees are expected to adhere to the spirit of this Code of Conduct.

This Code of Conduct applies to all employees around the world; it describes policies that apply to all of us in every country where we operate. As Apotex is a global company, the laws and regulatory requirements of one country may apply to activities in another country. For example, many requirements of Health Canada or the U.S. Food and Drug Administration (FDA) must be followed by Apotex operations outside of Canada or the U.S. In addition, we must also be aware of, and abide by, the legal standards, country laws and regulatory requirements applicable to our business. This means that some employees must adhere to additional, country-specific requirements. You are expected to seek guidance from the Global Business Ethics and Compliance Officer or the Global Legal department if questions arise regarding the impact and relevance of different countries’ laws on our local activities.

What if Someone Violates this Code of Conduct?

Apotex holds each and every employee, regardless of their position in the organization, accountable for any violations of this Code of Conduct. Confirmed violations may result in disciplinary action, including termination of employment and, at times, legal prosecution. Failure to cooperate in a compliance investigation may also lead to disciplinary action including termination. As with all disciplinary matters, principles of fairness and equity are applied.

Periodic Certification

Periodically, all employees will be asked to acknowledge that this Code of Conduct has been provided to them, and that they have read and understood the Code.
SPEAKING UP

What is Expected of Me?

1. You are expected to speak up when you have concerns, even if you have doubts about if the actions are a violation of the Code.
2. Always speak up if you suspect someone may have violated a criminal law, as failure to promptly report the violation can itself be illegal.
3. Each employee has a responsibility to cooperate fully with Apotex’s investigations of compliance concerns.

What Should I Expect?

Apotex takes all reports of non-compliance seriously. As such, Apotex employees should expect that all reports are investigated appropriately and in a timely manner.

Expectations of Managers

All those who manage people—including your direct manager, senior management and executives have a special responsibility to lead the way.

We expect all people leaders to:

- Act as role models
- Champion a culture of ethics and speaking up
- Recognize and reward behaviour that exemplifies our Core Values and our Code of Conduct
- Assist in enforcing the Code of Conduct
- Treat those employees who speak up with respect
- Report any violations or potential violations of the Code in a timely manner

Could Raising a Concern Affect My Job?

Apotex does not tolerate any form of retaliation against employees who report concerns or issues in good faith. Employees who engage in retaliation will be subject to disciplinary action up to and including termination of employment. In addition, Apotex will not condone frivolous, malicious or vexatious complaints and any employee who makes such a complaint will be subject to disciplinary action. Victims of such frivolous allegations or complaints will receive appropriate advice, support and assistance.
What is APOspeaks?

Face-to-face discussions are often best, but there may be times when you may not feel comfortable talking to someone in person or you may prefer to remain anonymous. That is why APOspeaks is available. APOspeaks is a safe, secure, helpline that is managed by a third-party vendor called Convercent. Using this helpline you can ask legal, policy, compliance or ethics questions, disclose conflicts of interest and report suspected wrongdoing. APOspeaks is offered in both phone and web format, which is available 24 hours a day, 365 days a year. It has multiple language options.

Can I Protect My Identity When I Contact APOspeaks?

If you wish to protect your identity, you may contact APOspeaks anonymously in most locations (note: due to regulatory constraints, employees in certain countries may not be able to report concerns anonymously via APOspeaks; this will be made known to you when you initiate your report). In any case, if you disclose your identity, Apotex strives to handle all reports in a sensitive way, and also works to protect you from retaliation as a result of reporting your concerns. In other words, the information you provide will only be shared with individuals that need to know in order to address the issue you reported.
Equal Employment Opportunities
Apotex provides equal employment opportunities to all qualified applicants and employees, and will act fairly and respectfully in all aspects of the hiring, promotion and termination processes, and throughout the employment relationship.

Apotex is committed to providing equal opportunity on the basis of individual qualifications and job performance. Discrimination on the basis of criteria such as race, religion, national origin, age, colour, gender, sexual orientation, marital status, citizenship status, disability, or any other status protected under national and local laws is prohibited.

Freedom from Workplace Harassment and Violence
Apotex has an expectation of professional behaviour by all employees in relation to interaction with other colleagues, customers and other business contacts. Workplace harassment is any unwelcome conduct, whether verbal, non-verbal, or physical, that is based on gender, age, national origin, disability, marital status, political affiliation, sexual orientation, race, color, religion or any other legally protected classification. Harassment, including bullying, is strictly prohibited and may result in disciplinary action up to and including termination of employment.

Workplace violence of any kind, including hostile physical contact, intimidation or threat that causes others to feel unsafe, will not be tolerated.

Refraining from Substance Abuse
Apotex has a responsibility to its employees and the public to deliver services and products in a safe and conscientious manner. Performance of one’s role under the influence of alcohol or drugs is prohibited.

How Noncompliance May Appear
Jenny, a marketing analyst, is excluded from presenting the program she designed, as her management felt a man would be better suited to present to the all-male executive team attending the client presentation.

Kate repeatedly asks Tom to go out for drinks after work, even though Tom has told her it makes him feel uncomfortable. She won’t take ‘no’ for an answer.

Josh, a sales representative, takes business partners out regularly at lunch, where he consumes two or three alcoholic beverages and appears intoxicated upon his return to work.
SAFE AND HEALTHY WORKPLACE AND RESPECTING THE ENVIRONMENT

Meeting Safety and Environmental Standards
All employees have an obligation to fellow staff members and to the general public to ensure work conditions meet our safety and environmental standards. We strive to continuously improve our safety and environmental record by:

• Complying with all applicable safety, health and environmental policies and procedures;
• Attending all relevant safety training and utilizing all necessary personal protective equipment to perform work in a safe manner;
• Promptly reporting all environmental, health and safety issues including unsafe conditions, near misses, workplace injuries and illnesses;
• Cooperating with investigation of health and safety or environmental incidents, and with identification and execution of corrective actions; and
• Practicing environmentally responsible purchasing.

Reporting Concerns
If you become aware of any actual or potential safety or environmental hazard or concern, immediately notify your direct manager.

All direct managers must report all injuries (including near misses) and environmental hazards (e.g., spills).

How Noncompliance May Appear
Marie, a chemist, knocks over a canister of toxic liquid in the lab. She contains most of the spill, but some went down a drain. She does not let her direct manager know.
Adverse Events

We must ensure the safety of Apotex products and protect the patients who use them by collecting, analyzing and reporting any information that could impact the benefit-risk profile of our products. Knowledge of adverse events (AEs) may arise in various ways (e.g., from a customer, friend, or family member), and in different settings (e.g., at a meeting, or via phone, fax, or email).

Every Apotex employee is required to report adverse events potentially relating to Apotex products to Apotex Drug Safety within one day of learning of the AE. Try to obtain the four elements listed below before reporting the AE:

1. Name of the reporter (contact information is highly desirable)
2. Patient information (at least one demographic parameter)
3. Adverse event term
4. Suspected product

All AEs, no matter the severity or seriousness (i.e., life-threatening or not) must be reported.

Apotex Drug Safety
Email: drugsafety@apotex.com
Fax: 1-866-429-9133 or 416-401-3819
Phone: 1-800-667-4708 or 416-401-7780 (follow prompts)

How Noncompliance May Appear

Sidarth is attending a neighbourhood BBQ and asks a neighbour why his wife did not attend. He explains that she has come down with a fever, shortly after taking an Apotex product, which he names. Sidarth does not report this to the Apotex Drug Safety line.

Vinkat, an Apotex employee, learns of a customer who has switched from a brand product to Apotex’s generic alternative. However, the customer reports that it did not seem to take effect. Vinkat decided not to report this to Drug Safety.
Ensuring quality and compliance is everyone’s responsibility; it is embedded in our Total Quality Culture, core values, and vision. We remain steadfast that everything we do is “Fit for Purpose”. Essential to these commitments are three principal drivers:

1. **Critical Quality Attributes (CQA)**
   To comply with this first principal driver, we must have the requisite product and process knowledge.

2. **Quality Management System (QMS)**
   This driver requires that we maintain control over Apotex’s six main quality systems for promoting continuous improvement.

3. **Quality Behaviours (QB)**
   Central to this third principal driver is our maintenance of a culture that supports cross-functional employee engagement, learning, and transparency. This culture must also support a safe, retaliation-free environment, where expressing quality concerns is strongly encouraged.

As part of our quality standards, we are fully committed to ensuring our products are in full compliance with our rigorous internal standards, all applicable regulations, and GxP\(^1\). This commitment applies equally to products produced in our facilities and to those supplied by third party manufacturers.

\(^1\)GxP collectively denotes Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Pharmacovigilance Practice (GVP) regulations.

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**How Noncompliance May Appear**

Lucy works on the production line. She notices that the finished product does not meet the Apotex Quality Standards. She keeps quiet because she does not want her team to miss their deadline.
Non-Clinical Research
We conduct non-clinical research in accordance with applicable laws, regulations and internationally recognized standards, including Good Laboratory Practices.

Clinical Research
Apotex clinical studies are designed and conducted in compliance with applicable laws and regulations, as well as recognized ethical standards such as the Declaration of Helsinki and Good Clinical Practice (GCP). This includes ensuring that clinical research participants are not exposed to unnecessary risks, and that their informed consent is obtained. All clinical investigators and other personnel working on Apotex sponsored clinical studies are trained on the study protocol and GCP. We regularly audit and monitor clinical study sites and processes related to our clinical trials.

Data Integrity
Apotex is committed to ensuring the quality and integrity of clinical data from our sponsored studies, to ensure our regulatory submissions are based on data of the highest quality. Our clinical data systems and processes are built with data integrity considerations as their cornerstone.

How Noncompliance May Appear
Lotte, a Director of Clinical Research, pressures her associates to start a clinical trial site in Europe before the informed consent is approved by the Institutional Review Board (IRB).
Avoiding Prohibited or Misleading Advertising
Apotex is committed to always marketing our products in a truthful, balanced, and accurate manner, and to avoid misleading statements. Apotex’s policy is to comply with all laws and regulations governing the sale and marketing of our products. When we distribute our products through third parties, we must ensure they are aware of their compliance obligations.

Avoiding Off-Label Promotion
All promotional statements and materials must be consistent with the approved Apotex product label. Pharmaceutical companies may not solicit, encourage or promote unapproved (off-label) uses of a product. Off-label promotion of Apotex products is strictly forbidden. Only promotional material, programs and initiatives that have been formally approved by Apotex may be used to solicit and obtain business and promote our products.
Unsolicited Requests for Medical Information

At times, requests may be received for medical information about an Apotex product that is outside the scope of the currently approved product label. Apotex employees must never prompt, suggest or solicit these types of questions, as such actions are viewed as off-label promotion, which could result in severe legal ramifications for our company. Unsolicited requests must be answered only by designated qualified and trained Apotex Drug Information personnel. If you receive any unsolicited requests, indicate that you are unable to respond, and contact Apotex’s Drug Information Service (“Dispedia”) as outlined below.

If you receive a request for medical information, customer service, or a product complaint contact:

DISpedia, Apotex’s Drug Information Service
Email: dispedia@apotex.com
Phone: 1-800-667-4708

If you receive a request for customer service or product complaints contact:

General Information and Customer Service
Email: custserv@apotex.com
Phone: 1-800-667-4708
Fax: 1-800-665-4385

How Noncompliance May Appear

Jeffery is a sales representative for a new Apotex product. The product label indicates it is approved for use in patients with high blood pressure. During a meeting with a physician he advises that the drug can also be used to treat patients with heart failure.

Ming is a marketing associate who is very proud of promotional material she has developed for an Apotex marketing campaign. She distributes this material to her customers, without formal approval from the company.

Additional Information:

See Appendix for more information on country-specific laws.
INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Apotex may partner with healthcare professionals (HCPs) from time to time to advance a benefit to patients. In working with HCPs, Apotex employees must not violate country-specific laws, sometimes referred to as anti-kickback or sponsorship laws, that prohibit payments in any form intended to reward past prescribing behaviour or to induce someone to purchase, prescribe or recommend a product.

Our educational, promotional and commercial relationships with healthcare professionals, including physicians, nurses, pharmacists, and others who administer, prescribe or recommend prescription medicines are strictly regulated. All interactions with HCPs should be guided by all applicable national and regional laws, regulations, and industry associated codes (see additional resources). Employees with roles that interact with HCPs, including sales and marketing, medical and regulatory should be familiar with Apotex policies that apply to their interactions with HCPs.

**General Rules to Follow when Interacting with HCPs**

- Ensure interactions are primarily for the purpose of providing accurate, relevant, valid and up-to-date information about our products.
- Never promise or provide payments or other gifts to an HCP to induce them to purchase, prescribe or recommend our products.
- Ensure that payments to HCPs are appropriate for the services provided, are of fair market value and are for legitimate business purposes (e.g., for bona fide research or consultancy).
- Be aware that country-specific rules may apply to the giving of payments or gifts to HCPs. Marketing activities acceptable in other business sectors may be unacceptable when dealing with HCPs.

Violations of healthcare, fraud and abuse laws may result in severe corporate or individual penalties including large fines, jail sentences, and other country-specific legal ramifications.

**Disclosure of Payments**

Throughout the world, there is a call for increased transparency regarding payments made by the pharmaceutical industry to HCPs. Therefore, payments or other items of value provided to HCPs must be tracked and disclosed as required by country-specific transparency rules. If you make any payments to an HCP, Healthcare Organization or Patient Association (e.g., for consulting, research, meals, travel etc.) contact the Global Business Ethics and Compliance Officer to ensure compliance with country-specific disclosure requirements.

**Additional Information:**

See Appendix for more information on country-specific laws.

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How Noncompliance May Appear

Laars pays his pharmacy client a cash rebate of 10% of the list price of an Apotex product, and disguises this under a ‘consulting’ contract with that client.

Kelsey, a marketing director, plans for an advisory board meeting and pays for three physicians and their spouses to meet at a lavish golf resort where the meeting will take place.
INTERACTIONS WITH BUSINESS PARTNERS

What is Expected of You
Create business partnerships (e.g., with suppliers and wholesalers) after reviewing the relevant background and qualifications of potential partners, and ensure quality and integrity are built into your selection criteria. To the extent possible, your due diligence should include:

• When business partners will represent Apotex, ensuring they know their obligations to follow applicable laws, regulations and Apotex policies;
• Using price, quality, reputation and service as the drivers for making supplier selection, not a conflict of interest (see ‘Conflicts of Interest’ section); and
• Ensuring that prospective business partners commit to proper interactions with government officials and HCPs.

Treat business partners with respect and integrity. Negotiate in good faith and honour agreements made with them.

Business Entertainment and Gifts
The purpose of business entertainment and gifts is to build goodwill and strengthen relationships with customers, suppliers and other business partners, not to gain unfair advantage for Apotex or to obtain a personal benefit. Any business entertainment or gift must be consistent with reasonable customary business practices, and therefore must not be in the form of cash or cash equivalents (e.g., gift certificates), give the impression of influencing business decisions or judgment, or violate any applicable law, regulation or known customer policy.

Business entertainment in the form of sporting or other social events with a business partner may be acceptable if the expense is moderate and in keeping with good business practices, as long as no explicit or implicit obligation is involved in such provision or acceptance.

These expectations apply both when either giving or receiving gifts and entertainment.

How Noncompliance May Appear
Jessica gets offered a ‘fee’ to provide a vendor with the lowest bid she has received on a contract so far.

Jamaal, a National Account Manager, has offered to pay for a weekend at a resort for a customer’s wife to compensate her for the time her husband has spent over the past month evaluating Apotex products.
INTERACTIONS WITH COMPETITORS

ANTITRUST AND COMPETITION LAWS

Avoiding Anti-Competitive Violations

• Compete with others on the basis of innovation, efficacy, quality, service, performance and price.
• Do not communicate with competitors about competitive business matters such as prices, costs, discounts, customer suppliers, marketing plans, production capacities or any terms of conditions of sale that could create the appearance of improper agreements or understandings.
• Do not make agreements or reach understandings with competitors regarding allocation of customers, territories or market share.
• Do not conspire with other bidders when competing for contracts.
• Do not enter into agreements that limit production capacities.

Examples of Unfair Competition

• Using bribes as a method to gain market share.
• Disparaging one of our competitors or its products.
• Interfering with our competitors’ supply chain or customer contracts.
• Obtaining or attempting to obtain competitive business intelligence through unlawful or unethical means such as misrepresentation, deception, theft, espionage or bribery.
• Coercing a customer to buy from us.

It is important that we recognize the potential harm to Apotex’s reputation and the severe monetary and criminal penalties that may result from breaching these laws.

If faced with a situation that may raise anti-competitive (i.e., antitrust) issues, contact the Global Legal department to determine the proper course of action.

Additional Information:
See Appendix for more information on country-specific laws.

How Noncompliance May Appear

At the annual generic industry trade show, Lisa and a sales representative from a competitor talk over drinks and agree to split customers within a territory.

Fabrizio, who works in clinical research, wants to pose as a physician in order to get a copy of a competitor’s clinical trial protocol.

Two competing pharmaceutical companies arrange to set and keep their product prices artificially high.
Anti-Corruption
Apotex conducts its business in many countries around the globe.

Many laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and the Canadian Corruption of Foreign Public Officials Act (CFPOA), specifically prohibit making any offer, promise, or gift of any value to an employee, agent or official of a federal government (foreign or domestic) to secure any concession, contract or favorable treatment. Bribes may include inappropriate gifts, kickbacks or unlawful payments. A government official is an individual, whether elected or appointed, who holds a legislative, administrative or judicial position of any kind. Depending on the jurisdiction, physicians and other HCPs may be considered as government officials. We will not tolerate attempts to improperly influence government officials in order to secure favourable treatment or to advance Apotex’s interests.

Doing Business with Government Officials
The sale of goods and services to governments is heavily regulated. When involved in sales transactions to governmental customers, Apotex employees must take all necessary steps to ensure the transactions comply with applicable laws and regulations, including the provision of gifts and government procurement contract obligations. For example, customs in one country regarding the giving and receiving of gifts may not be lawful in another country.

Trade Issues
There may be legislation authorizing the imposition of trade and economic sanctions where Apotex conducts business. For example, periodically Canada restricts or prohibits doing business with certain countries and parties. In all international business, Apotex employees must comply with those sanctions; any export restrictions need to be checked conscientiously, and legal advice taken as necessary, before business transactions are undertaken.

Contact the Global Legal department to ensure your planned export and import activities fully comply with applicable laws.

Additional Information:
See Appendix for more information on country-specific laws.

How Noncompliance May Appear
Kaori, a sales manager, offers to take a government employee out to lunch to smooth over some price contract talks.

Reza, a company executive, needs to meet a vendor in a country where a visa is required. He agrees to pay a 'facilitation fee' to speed up the process.

Barbara, an Apotex employee, arranges a contract with a North Korean pharmaceutical distributor without contacting the Global Legal department first.
CONFLICTS OF INTEREST

All business decisions that Apotex employees make should be in the best interest of the Company – and not based on personal or other business interests. It is important to avoid even the appearance of conflicts of interest. The appearance of a conflict is what a reasonable person might view as a potential conflict. A conflict may arise because of your own actions or through family connections.

Outside Employment or Business Interests
Having outside business interests or employment with an entity that does business with, or is a competitor, supplier or customer of Apotex, and/or which may interfere with your ability to perform your responsibilities, are considered to be conflicts of interest.

Business Relationships
Conflicts of interest occur when you or an immediate family member has a substantial financial interest in an Apotex supplier, competitor, consultant or customer.

Business Opportunities
Apotex employees must never take for themselves or divert a business opportunity in which Apotex has a financial interest, or that is discovered through the use of company information, position or property, for their own personal gain, either directly or indirectly.

Business, Scientific, Political and Professional Organizations
Apotex supports employee participation in business, scientific, political and professional organizations as long as the affiliation does not conflict with Apotex interests; for example, the affiliation must not negatively impact your ability to perform all of your job responsibilities.

Reporting Actual or Perceived Conflicts of Interest
Apotex requires employees to provide notice of actual or potential conflicts of interest as they arise. Provide notice to your direct manager and receive written approval from the Global Business Ethics and Compliance Officer before engaging in any activity that may invoke any conflict of interest situation.

How Noncompliance May Appear
Tony’s wife is an executive, with ownership interest, at a marketing firm that seeks to be a vendor for advertising a new Apotex product. He is on the panel who will decide on the contract winner.

James, a vice president, sits on the board of directors of an Apotex supplier. He has not disclosed this relationship to Apotex.

Moniqua, a Manager in Regulatory Affairs, hires her niece for a position in her department, bypassing the hiring process and not disclosing her family connection.
ACCURACY OF BUSINESS RECORDS, FRAUD AND LEGAL HOLDS

Apotex must maintain an accurate record of all business transactions. These records are essential to managing our business and fulfilling our legal and ethical obligations to governments and our customers.

What are Business Records?
Business records can be captured on paper, electronically (e.g., computer files, e-mail, audio or video recordings) or using other media. Included in business records are financial “books and records” involved in the preparation of financial statements relevant to audits and financial reviews. Financial records encompass bills and invoices, payroll, benefits, and other company data necessary to provide a complete picture of Apotex’s financial state. Justified and reasonable business expenses must be charged to Apotex through our expense reporting system with appropriate supporting documentation.

Accuracy and Timely Completion
All information must be entered in an honest and timely fashion and retained according to corporate schedules. Knowingly providing false, inaccurate or incomplete information is improper, and, in most situations, is illegal and may constitute fraud.

We have a responsibility to provide accurate, complete, timely and transparent disclosures in reports and documents we file with governmental and regulatory agencies. These requirements also apply to regulated "Good Practice" requirements (e.g., GMPs, GCPs, etc.), collectively referred to as GxP records.

Reporting Fraud
If you become aware of a questionable accounting or record-keeping practice, you must report the concern promptly to your direct manager, to a member of the Executive Team, to the Global Legal department or to the Global Business Ethics and Compliance Officer.

Legal Holds
If we receive a subpoena requesting business records, or if we become aware of actual or potential litigation or investigation, relevant employees will receive notification (i.e., a litigation hold notice) and be required to search their files, or submit to having their files searched, for the requested records. All employees are required to fully cooperate with both internal and external investigations. Upon receiving a litigation hold notice, no records – hard copies or electronic – may be deleted, destroyed, or altered.

How Noncompliance May Appear
Isabelle complains she is low on rent this month. Nigel loans her money from the company.

Karmen, a sales representative, charges personal items to the corporate credit card.

Eunice alters production data to cover up a GMP violation for a batch of product in order to meet production quotas.
SAFEGUARDING APOTEX INFORMATION

Every employee must exercise diligence in maintaining the integrity of Apotex’s proprietary and confidential information by:

- Maintaining the strict confidentiality of Apotex information entrusted to you;
- Obtaining confidentiality agreements before exchanging non-public, confidential, proprietary or sensitive information with any third party;
- Respecting the valid intellectual property rights of others; for example those outlined in Apotex third party contracts;
- Being mindful of sending information externally by convenient forms of communication like email; and
- Notifying GIS immediately if your company assigned assets (e.g., computer, phone or other technical equipment) have been lost or compromised.

These obligations apply even after you leave Apotex. In addition, you may not disclose confidential information to an Apotex employee that you learned during previous employment (e.g., trade secrets).

Some Examples of Proprietary and Confidential Information

- Intellectual property such as patents, trademarks, copyrights and trade secrets;
- Technical specifications, drawings and designs;
- Financial affairs, customer lists, pricing practices, bidding or marketing strategies; and
- Written and oral agreements between Apotex and others.

Additionally, your role may encompass developing proprietary information (i.e., intellectual property) for Apotex. When developing intellectual property for Apotex using Apotex’s resources, it is expected that you do not do anything to compromise Apotex’s ownership of or rights to that intellectual property. This includes refraining from selling it, using it for personal gain, or distributing it to unauthorized third parties.

How Noncompliance May Appear

Stanley and Ravi, sales representatives, are discussing confidential company information onboard an airplane, where they can be overheard.

Trey shares a list of Apotex customers with his brother-in-law who is starting up a small biotech company.

Diane offers to share the results of a completed clinical trial with a former employee, Samantha, as it may help her in her new position.

Jordan stores copies of confidential sales data on his personal cell phone. He subsequently loses his phone on the subway.
USE OF COMPANY PROPERTY

The electronic communication systems, along with Apotex’s physical assets, are in place to enable employees to perform their business related activities.

Use of company systems for personal use should be limited, and under no circumstance should they be used to facilitate illegal or illicit activities. Communications between employees on electronic systems should be conducted professionally. In some situations, these communications may be subject to disclosure to a third party.

All employees must use Apotex’s physical assets responsibly. This includes conserving Apotex funds, to the extent possible, by ensuring that inappropriate expenditures are not incurred.

Precautions and Rules Governing the Proper Use of Company Systems

• Return your company-issued equipment immediately when requested.
• Although you may use Apotex equipment to a limited extent for non-business matters, you are not guaranteed personal privacy on Apotex’s electronic communication systems.
• Apotex assets may not be utilized for the distribution of inappropriate communication (e.g., hoax emails or pornography) or communications that may embarrass, harass or offend others.
• Double check that the recipients are correct before sending out any electronic communication.
• Do not use electronic communication devices in an unsafe or illegal manner (e.g., while driving, on an airplane, in restricted areas of hospitals).

How Noncompliance May Appear

Shannon lends her password to her husband so he can check their banking information on her work computer.

Steve passes along an email with a racially based joke to his coworkers.

Pravinder, a Marketing analyst, downloads “free-ware” marketing software, without authorization, to assist with a new marketing campaign.
SOCIAL MEDIA AND EXTERNAL COMMUNICATION TO THE MEDIA AND GENERAL PUBLIC

Social Media

- Only company-designated personnel may publish content to speak on behalf of Apotex on social media, and such publications must be done solely on official Apotex social media accounts. Employees are encouraged to engage with content published on the company’s official LinkedIn profile including “liking”, “commenting” and “sharing” content.
- Apotex encourages employees to use their best judgment when discussing Apotex in any form of social media, as anything stated on social media may have unintended consequences for both the employee and Apotex.
- Apotex expects that your conduct online is consistent with this Code of Conduct and our Global Corporate Communications and Social Media Policy.
- Protect Apotex’s confidential and proprietary information by refraining from discussions of such matters on social media.
- Do not use company logos or trademarks without explicit permission from an authorized executive.
- Never claim to be speaking on behalf of Apotex or express an official company position without pre-authorization.
- Apotex encourages employees to direct all comments, questions or feedback about Apotex to the appropriate internal channels rather than broadcast them on social media.
- Report any discoveries of inappropriate information that is related to Apotex, on any social medium.

The Media

- Reporters, media representatives and the general public may try to solicit information directly from you.
- All media calls/requests are to be referred to the VP, Corporate Communications or a designated back-up contact immediately upon receipt of a request. Other than the President & CEO, Chief Human Resources Officer and the VP, Corporate Communications, no other employee is permitted to speak with media unless authorized by the above parties.

How Noncompliance May Appear

Jorge, a National Account Manager, uses his Twitter account to let his connections know about an Apotex product without prior approval.

Aleksander, a customer service representative, gets a call from a reporter at a local TV station who inquires about a recent FDA audit. Aleksander gives the reporter the information he knows about the audit findings.
DATA PRIVACY

Apotex may collect personal identifiable information (PII) from many different individuals, including customers, patients, clinical trial subjects, healthcare professionals and employees. Apotex is dedicated to collecting and keeping only personal identifiable information needed for our business purposes and to have safeguards in place to protect such information.

What is expected from you

- Follow local laws regarding data privacy (e.g., in some countries you must give notice and/or obtain consent when collecting, processing, transferring or storing personal information).
- Collect personal information only for legitimate business purposes and maintain it only for as long as necessary to fulfill those purposes and meet our legal obligations.
- Ensure that personal information is protected at every stage, from collecting and processing it, to storing and transferring it.
- Use personal information only for the purpose for which it was collected.
- Obtain written consent before collecting, using or disclosing personal information.
- Share personal information only with individuals who have legitimate need for it and who will protect it properly. Any external individual or organization with whom this information is shared must be bound by a written confidentiality agreement.

The definition of personal identifiable information varies by country, but generally it encompasses any personal identifying information (e.g., name, birth date, gender, address, health card number, etc.) and sensitive identifying information (e.g., religion, race, health status, marital status, telephone number, social security number, credit card number, etc.).

How Noncompliance May Appear

Michael, a Manager in Regulatory Affairs, posts a list of his employees' birth dates (including year) on the company bulletin board as a reminder to wish his employees a happy birthday.

Penny, a Sales and Marketing manager, purchases a mailing list of over 5000 names of individuals who are being treated for psoriasis.
APPENDIX:
SUMMARY OF RELEVANT HEALTHCARE LAWS, REGULATIONS, AND GUIDANCE

Canada Specific Laws and Industry Codes

Canadian Generic Pharmaceutical Association (CGPA) Code of Marketing Conduct
This code was developed to govern the relationships between the suppliers of generic pharmaceutical products and their customers. This code will also enhance transparency in the generic pharmaceutical value chain, thus allowing governments to better manage their drug benefit programs. It is also designed to operate within the various legislative, regulatory and policy environments governing the sale of generic pharmaceuticals in Canada.

Competition Act
The Competition Act prohibits collusion and price fixing, market allocation and other anti-competitive behaviours.

Corruption of Foreign Public Officials Act
This law prohibits bribes and other direct or indirect incentives from being offered or given to foreign public officials. It sets out what constitutes unfair inducements, and what constitutes books and records offences.

Food and Drugs Act
The Food and Drugs Act regulates the manufacture and sale of drugs. It requires manufacturers to comply with rigorous standards and demonstrate that their drugs are safe and effective. It also protects Canadians from advertisements that are false and misleading. All materials used to promote Apotex products in Canada must be consistent with the product monograph approved by Health Canada.

Ontario Health Sector Payment Transparency Act
The purpose of this Act is to require the reporting of information about financial relationships that exist within Ontario's health care system, including within health care research and education, and to enable the collection, analysis and publication of that information.

Ontario Environmental Protection Act (EPA)
The EPA protects and preserves natural environments by regulating the discharge of pollutants and prohibiting the making, using and disposing of ozone-depleting substances. It also outlines the actions to be taken in the event of a spill.

Ontario Human Rights Code
The Ontario Human Rights Code is a law in the Canadian province of Ontario that gives all people equal rights and opportunities without discrimination in specific areas such as housing and services and employment. The goal of this Code of Conduct is to prevent discrimination and harassment because of race, colour, gender identity, sex, sexual orientation, disability, creed, age and other grounds.

Personal Information Protection and Electronic Documents Act (PIPEDA)
PIPEDA sets out the standards by which we must protect personal information.
**Anti-Kickback Laws (Federal and State)**
The federal Anti-Kickback Statute and similar state laws prohibit payments, in any form, intended to reward past prescribing or to induce someone to purchase, prescribe or recommend a product that is reimbursable under a U.S. federal healthcare program. Exceptions, called Safe Harbors, are provided for discounts and certain other arrangements, if specific requirements are met.

**Exclusion of individuals from U.S. healthcare programs**
The U.S. government has the authority to exclude individuals and entities who have engaged in fraud or abuse from participating in Medicare, Medicaid or other healthcare programs or to receive federal contracts or assistance pursuant to sections 1128 and 1156 of the Social Security Act. As a result we need to check the U.S. employees and contractors of Apotex against the List of Excluded Individuals and Entities (LEIE). This list is maintained by the Office of Inspector General (OIG) in the U.S., and includes persons who have been excluded, debarred, or suspended (“ineligible individuals”) from U.S. government health care programs such as Medicare and Medicaid. If we employ such individuals, we ourselves could be liable to civil penalties.

**Food and Drug Administration (FDA) Restrictions on Promotion**
The FDA regulates the labeling and advertising of Apotex products in the United States. A product’s labeling includes all information on the drug package, the prescribing information, and any other written, printed, or graphic materials provided by Apotex about the product. All materials used to promote Apotex products, such as advertisements, brochures, and detail aids, must be consistent with the approved labeling. Promotional materials that are false, lacking fair balance, or otherwise misleading violate FDA rules.

**Food, Drug and Cosmetic Act (FDCA)**
The ultimate purpose of the Federal Food, Drug, and Cosmetic Act (FDCA) is to protect consumer health. Under the FDCA, the Food and Drug Administration (FDA) regulates several areas of prescription drug development and marketing, including clinical studies, manufacturing, market approval, safety and efficacy, and advertising and promotion.

**Physician Payment Sunshine Act**
The Physician Payment Sunshine Provisions of H.R. 3590 § 6002 were signed as federal law as part of the Patient Protection and Affordable Care Act (PPACA). The law requires pharmaceutical manufacturers to annually report and publicly disclose to the Open Payment Program, via the Centers for Medicare and Medicaid Services (CMS), payments and other transfers of value provided to US physicians and teaching hospitals.

**The Federal False Claims Act (FCA) and State False Claims Laws**
The federal FCA and similar state laws make it a crime to deliberately submit a false claim for reimbursement to the US government or do anything to cause, assist or encourage customers to submit false claims to these programs. Pharmaceutical sales and marketing activities that might violate the federal FCA include (but are not limited to) submitting false claims for government payment, fraudulently reporting false pricing information to government agencies and similar activities.

**The Foreign Corrupt Practices Act (FCPA)**
The FCPA prohibits corrupt payments to foreign officials for the purpose of obtaining or keeping business.

**The Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers**
These are guidelines provided by the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) for pharmaceutical manufacturers to consider when developing, implementing, or evaluating a compliance program. The guidance is intended to assist with the development and implementation of internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal healthcare programs.

**State Marketing and Advertising Laws**
Several states (including CA, DC, MN, NV, VT, MA, WV) have enacted laws that require pharmaceutical manufacturers to annually disclose, to state regulatory bodies, either a declaration of the compliance program and/or marketing costs and financial expenditures to physicians, purchasers, and dispensers of prescription drugs. This information often includes the value, nature, and purpose of the payment.

This summary is intended to be a guide to some country-specific laws, regulations and industry codes that relate to this Code of Conduct. This list is not exhaustive, and lists only those laws, regulations and codes that apply where most Apotex business is conducted. Where laws are stricter than this Code of Conduct, those laws must be followed. There are other country-specific laws outside the regions listed above. If you have any questions about those laws, please contact the Global Legal department apogloballegal@apotex.com.
The Global Business Ethics and Compliance Program is dedicated to ensuring that our business is conducted with integrity and is compliant with applicable laws. This program is led by the Global Business Ethics and Compliance Officer, with guidance from the Global Business Ethics and Compliance Committee. They are supported by regional compliance officers and committees. The program consists of the following key elements:

**Training**
Training sessions and educational materials about expectations for compliant and ethical behaviour of employees.

**Anonymous and Retribution-Free Reporting**
Communication channels and tools for employees, customers and vendors to report concerns or misconduct, anonymously and without reprisals for employees (e.g., APOspeaks).

**Monitoring and Auditing**
Systems and procedures to assess adherence to this Code of Conduct and other compliance related matters, and to identify opportunities for enhancing ethical behaviours.

**Investigation and Enforcement**
Taking appropriate action to validate and address issues, when concerns or allegations about misconduct or non-compliance arise.

Contact the VP, Global Business Ethics and Compliance Officer directly to ask questions or raise concerns.

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Confidential
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APOTEX

APOTEX CODE OF CONDUCT AND BUSINESS ETHICS

The information herein supersedes any previously published Apotex Code of Conduct and Business Ethics.

The online version of the Apotex Code of Conduct and Business Ethics, accessible on ApoWeb, supersedes all published versions.

Apotex Code of Conduct and Business Ethics
Version 4.0
June 1, 2020

The code can be found electronically at
External Site: http://www.apotex.com/global/ethics
Internal Site: http://apoteam.apotex.ca/ethics