



MEDICINES360

BUSINESS CODE OF CONDUCT

A different kind of pharmaceutical company

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*MEDICINES360'S
MISSION
IS TO REMOVE
COST AS A
BARRIER TO
HEALTH BY
DEVELOPING
AND PROVIDING
AFFORDABLE
WOMEN'S
HEALTH
PRODUCTS.*

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OUR CODE & COMPLIANCE

WHAT IS “THE CODE”?

Medicines360’s mission is to remove cost as a barrier to health by developing and providing affordable women’s health products. In pursuing its mission, Medicines360 (“the Company”) strives for a high standard of corporate conduct and is committed to establishing and maintaining an effective and comprehensive corporate compliance program. As a part of this effort, we have created our Business Code of Conduct (“the Code”).

The Code:

- Provides an overview of the legal, regulatory, and ethical requirements of our business
- Defines the way we conduct our affairs according to laws, guidelines, and core principles with each other, our stakeholders, and the communities with which we interact
- Describes our commitment to integrity and sound judgment in everything that we do

While the Code is a foundation for how we do business, it is not intended to be all-inclusive and does not cover every situation you may encounter. Company policies and procedures provide more specific, detailed requirements and processes that we must follow relating to specific business activities we conduct. You are expected to understand and follow both the Code and the Company’s policies and procedures.

From time to time, circumstances may require changes to the Company’s offerings, policies, and procedures. For these reasons, Medicines360 reserves the right to change the Code with or without notice.

WHO DOES THE CODE APPLY TO?

The Code applies to every employee at Medicines360 and its subsidiaries. The Code also applies to “Covered Parties”, defined as any individual working in the service of Medicines360, its affiliates, and subsidiaries worldwide, whether on a paid basis or as a volunteer, including employees, contract employees, consultants, board members, and officers. All Covered Parties will receive a copy of the Code and will be expected to adhere to the content.

Our stakeholders include:

- *Patients*
- *Healthcare Professionals (HCPs)*
- *Business partners*
- *Consultants/Contractors*
- *Professional associations*
- *Government officials and regulators*
- *Advocacy groups*
- *Industry associations*
- *Funders*

WHAT ARE OUR RESPONSIBILITIES?

OUR COMMITMENT

At Medicines360, we are committed to conducting business in a fair and open manner with high regard for our Covered Parties, our stakeholders, our industry, our assets, and our patients. We are dedicated to:

ABIDING BY LAWS AND GUIDELINES

We are committed to compliance with all laws and regulations in the countries where we operate, and to following all Company policies and procedures.

A COMMITMENT TO PATIENTS

Our priority is to protect patient safety and privacy.

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ENSURING A POSITIVE CULTURE OF COMPLIANCE

We are committed to establishing a strong and positive culture of integrity and compliance across all levels of the organization.

3

YOUR RESPONSIBILITIES

Familiarize yourself with and abide by the Code, the laws and regulations, and guidelines that apply to the work that you do and the jurisdictions in which you work.

Failure to follow applicable laws can lead to significant penalties and sanctions against the Company, including (but not limited to) fines, product seizures, import restrictions, criminal prosecutions, product recalls, refusal to approve pending product applications, ineligibility to receive reimbursement from government payer, and the exclusion of individuals from participation in government programs.

Violators may also be personally liable for prosecution, fines, and potentially even imprisonment. Violations of Company policies and procedures may lead to disciplinary action, up to and including termination. All employees at Medicines360 have a responsibility to not only abide by the Code, but to also report violations of this Code by other employees. A failure to do so may result in disciplinary action, up to and including termination.

Always apply these basic principles:

- 1 Act with the highest ethical standard – do the right thing!
- 2 Obey the laws, regulations, and Company policies, both in letter and spirit.
- 3 Maintain honest and fair relationships with all stakeholders.
- 4 Be truthful and accurate in all that you say and do.
- 5 Treat fellow employees with dignity and respect.
- 6 Always protect confidential information.
- 7 Report any concerns and suspected misconduct.

MANAGERS HAVE AN ADDED RESPONSIBILITY

Managers play a critical role in promoting an ethical culture. If you are a manager, be a leader and inspire your team. Always work with integrity and ensure that employees understand their obligation to do the same. Create a culture of non-retaliation, wherein all employees feel comfortable to come forward with any questions or concerns about the workplace.

HOW IS THE CODE ENFORCED?

Medicines360's Head of Compliance has overall responsibility for oversight of Compliance and our compliance program, which has been designed to:

- Assist the Company in maintaining compliance with the laws, regulations, and Company directives and guidance that apply to the commercialization of our products
- Train our employees on these compliance matters
- Prevent, detect, and correct instances of non-compliance

The Head of Compliance is responsible for addressing risk areas through the proactive development and implementation of the Code, policies and procedures, and enforcing compliance through ongoing auditing, monitoring, and investigating suspected or actual violations of law or policy. The Head of Compliance reports directly to the General Counsel and makes recommendations to the Board of Directors concerning operation of the compliance program.

HOW CAN YOU RAISE CONCERNS?

Medicines360 is committed to an environment where open, honest communications are the expectation, not the exception. It is your obligation to raise any concerns and report actual or suspected violations of applicable laws, regulations, or Company policies and procedures in a timely manner.

Here are some signs to watch for:

- You feel uncomfortable about a business decision or something you’ve been asked to do
- You have witnessed a situation that made you or someone else feel uncomfortable
- You feel that the Company would be embarrassed or face legal implications if the situation were revealed to the public
- You witness discrimination in the workplace

We want you to feel comfortable approaching your manager in instances where you believe violations have occurred. All managers are responsible for supporting an open door to all Covered Parties, ensuring non-retaliation, and upholding confidentiality, where necessary. Medicines360 will not tolerate any form of discrimination in the workplace.

In situations where you prefer to place an anonymous report in confidence, you are encouraged to use our hotline, hosted by a third party hotline provider, EthicsPoint.

If you are unsure whether a violation has occurred, it is better to speak up than do nothing.

Reporting Methods

In Person	Email	Internet	Hotline
Your manager Any manager Compliance & Legal	Compliance & Ethics Reporting email: integrity@medicines360.org	Anonymous online report: www.medicines360.ethicspoint.com	Anonymous hotline: 844-239-0562

NON-RETALIATION

“Non-retaliation” means that you will *not* be punished or disciplined nor suffer from any form of retaliation for raising concerns or reporting a suspected violation.

Neither the Company nor the law will tolerate any form of retaliation against an employee or Covered Party who opposes discrimination or harassment, reports a violation, or participates in any manner in an investigation, proceeding, or hearing. Any employee or Covered Party who engages in retaliation will be subject to disciplinary action, up to and including termination, as well as possible legal consequences.

If you believe you have experienced or witnessed retaliation, immediately report it to Human Resources or to a VP or higher.

Click [here](#) to view
 POL-00021
 Internal
 Investigation
 Policy

INVESTIGATIONS

Medicines360 will promptly respond to a report of a violation of the Code, Company policy or procedure, or any other ethical concern. When deemed necessary, the Head of Compliance, or a designee, will conduct an investigation into the potentially non-compliant activity to determine whether a violation has occurred. The Head of Compliance may request the assistance of HR and/or outside experts or legal counsel.

If an investigation is conducted, you are expected to:

✓	Be truthful and honest
✓	Cooperate fully with any investigation. Failure to cooperate in a workplace investigation could result in disciplinary action and possibly termination
✓	Assist in any investigation by giving full access to records and documents
✓	Maintain confidentiality and refrain from discussing the investigation with anyone else
✓	Avoid retaliating against anyone making the report

CORRECTIVE AND DISCIPLINARY ACTIONS

Corrective and disciplinary actions may be taken against employees or Covered Parties who authorize, directly participate in, or are witness to and fail to report a violation of the Code. The Head of Compliance will oversee the implementation of corrective measures in response to non-compliance.

Potential corrective and/or disciplinary actions may include (but are not limited to):

- | | | |
|------------------------|---------------------|-------------------------------------|
| ■ Additional training | ■ Loss of promotion | ■ Referral for criminal prosecution |
| ■ Reprimand | ■ Demotion | ■ Civil action |
| ■ Loss of compensation | ■ Termination | ■ Updates to internal controls |



OUR PEOPLE & WORKPLACE

Sign in to your TriNet HR Passport account to view the TriNet Employee Handbook or contact Human Resources for more information. HR Passport can be accessed through the Company's intranet website ([Employee Portal](#)).

We are committed to providing a workplace environment that is safe, conducive to the free exchange of ideas, fosters teamwork, respects our individual differences and our environment and promotes the highest standard of ethical behavior. For more information related to the content in this section, please refer to the TriNet Employee Handbook.

EQUAL EMPLOYMENT OPPORTUNITY

We are committed to ensuring employment and promotion decisions are made on merit, qualifications, performance, and business needs.

Decisions governing the employment relationship with all employees are made in a non-discriminatory manner – without regard to any of the following legally-protected characteristics:

- | | | |
|----------------------|--|--|
| ■ Gender | ■ Domestic partner status | ■ Medical condition |
| ■ Race | ■ Sexual orientation | ■ Political activities or affiliations |
| ■ Religion | ■ Gender identity or gender expression | ■ Military or veteran status |
| ■ Ancestry | ■ Pregnancy | ■ Status as a victim of domestic violence, assault or stalking |
| ■ National origin | ■ Physical or mental disability | ■ Height, weight or hairstyle |
| ■ Citizenship status | ■ AIDS/HIV status | |
| ■ Creed | ■ Genetic information | |
| ■ Age | | |
| ■ Marital Status | | |

We strive to find ways to attract, develop, and retain the talent needed to meet business objectives, and to recruit and employ highly qualified individuals representing the diverse communities in which we live and the communities we serve. Moreover, in accordance with federal and applicable state law, the Company will make reasonable accommodations for individuals with known disabilities.

No legally-protected characteristic will be utilized to adversely impact decisions regarding any of the following:

- | | | |
|---------------|----------------------|-------------------------|
| ■ Recruiting | ■ Discipline | ■ Compensation/benefits |
| ■ Hiring | ■ Promotion/demotion | ■ Scheduling |
| ■ Termination | ■ Training | ■ Assignments |

See details of the
Harassment and
Discrimination
Policy in the
TriNet Employee
Handbook

HARASSMENT & DISCRIMINATION

At all times be courteous and sensitive to the concerns and values of others. Make a point of paying attention to others' reactions and stated requests and preferences, respecting their wishes, and treating them in a professional manner, regardless of gender, race, religion, nationality, age, sexual orientation, or other protected characteristic.

Harassment or any other form of unwelcome conduct towards another employee, Covered Party or person who has business dealings with our Company will not be tolerated and will result in disciplinary action – up to and including termination.

“Harassment” refers to behavior that is personally offensive, intimidating, hostile, or interferes with work performance, regardless of whether it rises to the level of violating the law. Workplace harassment can come in various forms and can be physical, verbal or sexual in nature.

Harassment may take many forms, including (but not limited to):

Type	Examples of Harassment
Verbal	Derogatory comments; name-calling; inappropriate jokes; repeated requests for dates; threats; unwanted correspondence, phone calls, and gifts
Physical	Assault; physical interference with normal work or movement; unwanted physical contact, such as touching or brushing against another's body
Visual	Inappropriate images; staring at or directing attention to an employee's anatomy; sexually oriented or suggestive gestures
Cyberstalking	Unwanted electronic communication, such as e-mail or instant messaging (IM), or messages posted to a website, blog, or discussion group

Discrimination and harassment in all forms is prohibited, including (but not limited to) inequity that is related to gender, race, religion, ancestry, national origin, citizenship status, creed, age, marital status, domestic partner status, sexual orientation, gender identity or gender expression, pregnancy, physical or mental disability, AIDS/HIV status, genetic information, medical condition, political activities or affiliations, military or veteran status and status as a victim of domestic violence, assault or stalking. In addition, Medicines360 will not discriminate on the basis of height, weight or hairstyle.

WORKPLACE SECURITY

To ensure our Company is a friendly and secure place to work, we ask all employees and Covered Parties to keep the workplace safe, pleasant, and free of aggression of any kind. Medicines360 prohibits actual or threatened violence by employees or Covered Parties against co-workers or other persons, which applies to both on-site and off-site conduct.

Threats and hostile actions in any form have no place in our working environment, including physical altercations, as well as horseplay, intimidation, stalking, and other threats of violence. Do not joke or make off-hand remarks about violence, as all perceived threats and actions will be taken seriously and investigated.

Any employee or Covered Party who commits or threatens any violent act against any person while on Company premises or at work will be subject to immediate discharge.

Employees and Covered Parties are required to report any incident involving a threat or act of violence immediately to their manager, Human Resources, or a VP or higher.

CONFLICTS OF INTEREST

Medicines360 is committed to conducting business free from any conflicts of interest that could compromise our objectivity and reputation.

“Conflicts of interest” arise when your personal activity or interest leads to a biased business decision that may not be in the best interest of the Company. These personal activities or interests may influence your judgment, causing you to make decisions based upon the potential for personal gain, rather than in the best interest of the Company.

When making business decisions, it’s critical that you weigh all relevant criteria, use good judgment, and make decisions based on what’s good for the Company. You must avoid any situation that could impair your ability to be impartial and objective, or any situation that may even have the *appearance* of being a conflict of interest. If an actual, perceived, or potential conflict of interest does arise, you must disclose the matter to Legal and/or Compliance immediately. Often times potential conflicts of interest can be resolved in a mutually acceptable manner before it becomes an issue.

The Board of Directors (BOD) and the Executive Leadership Team (ELT) have additional conflicts of interest obligations, as outlined in the Medicines360 Conflicts of Interest Policy for BOD and ELT.

See the following table for examples of potential conflicts of interest.

Click [here](#)
to view the
AGT-CMP-00001 -
BOD/ELT Conflicts
of Interest Policy.

Situations that could present a potential conflict include (but are not limited to):

Type	Examples of Potential Conflicts of Interest
Employee Relationships	<ul style="list-style-type: none"> ▪ Hiring or transferring a relative or significant other into a position in which they supervise you or you supervise them ▪ Maintaining a romantic relationship with an employee or Covered Party that creates a conflict
Financial Interests	<ul style="list-style-type: none"> ▪ You or a relative holds a personal, business, or interest in – or exercises control or influence over – one of our suppliers, customers, or competitors ▪ Having partial or full ownership of a company that competes or does business with Medicines360 ▪ Borrowing from or lending personal funds to a customer or vendor ▪ Using confidential information for personal investment decisions
Personal Relationships	<ul style="list-style-type: none"> ▪ Using your position or authority to influence Medicines360 to conduct business with relatives or other people with whom you have a close personal relationship
Entertainment & Items of Value	<ul style="list-style-type: none"> ▪ Receiving, giving, seeking, offering or promising anything of value (including favors, money, services, etc.) from or to any person or entity that is doing, or is seeking to do, business with Medicines360 ▪ Providing recreation or entertainment to a customer or vendor to influence decision making about our products
Outside Interests & Employment	<ul style="list-style-type: none"> ▪ Serving as a board member for organizations whose mission or activities are related to Medicines360 business interests ▪ Maintaining outside directorship, employment, or political office that may conflict or compete with your Company time and responsibilities
Confidential Information	<ul style="list-style-type: none"> ▪ Using information developed or learned on the job for personal or familial benefit ▪ Unauthorized sharing of confidential or proprietary information with associates or representatives of other companies
Government Activities	<ul style="list-style-type: none"> ▪ Acting as an elected or appointed official, advisor, or consultant to any branch of government or any governmental agency that has regulatory or supervisory power over Medicines360 (e.g., the FDA).

See details of the
Drug-Free
Workplace Policy
in the TriNet
Employee
Handbook

DRUG- AND ALCOHOL-FREE WORKPLACE

Medicines360 expects all employees and Covered Parties to report to work fit to perform the duties of their jobs. An individual impaired by illegal drugs, prescription drugs, over-the-counter drugs, or alcohol presents a safety hazard to themselves and others, limits our ability to provide high-quality service to our customers, and affects the quality of job performance.

The following conduct is not tolerated and will be subject to discipline, up to and including termination:

Inappropriate Conduct

X	Use, possession, sale, or solicitation of illegal drugs while on duty, on Company premises, or Company time
X	Unauthorized use or possession of alcohol while on duty, on Company premises, or Company time
X	Reporting to work impaired by alcohol or illegal drugs
X	Use of alcohol or any drug that prohibits one from performing his/her duties or endangers one's health or safety or the health or safety of others
X	Withholding consent or failing to cooperate with a lawful investigation (including medical testing) or disciplinary procedure of a drug or alcohol violation
X	Failing to cooperate with disciplinary procedures related to a drug or alcohol violation
X	Convicted of a drug-related charge that occurred in the workplace

HEALTH & SAFETY

We are committed to operating our facilities in a safe and environmentally responsible manner, including following all applicable environmental, health, and safety laws. This includes educating Medicines360 representatives on health and safety, selecting responsible suppliers and business partners, and reporting any unsafe practices or conditions in a complete, accurate, and timely manner.

You are responsible for informing management of health risks or health conditions that may affect your ability to perform required duties.

If you have reason to believe that an individual is under the influence of drugs or alcohol, immediately inform your manager.

Employees with alcohol or drug dependencies are encouraged to take advantage of the free and confidential Employee Assistance Program (EAP), as described in the TriNet Employee Handbook.



OUR ASSETS & INFORMATION

CONFIDENTIAL INFORMATION

See details in
your signed CDA
with
Medicines360

Medicines360 is committed to protecting the confidentiality of proprietary information and the privacy of our employees, Covered Parties and stakeholders. In the course of your work, you may learn of or have access to confidential information. You must not use, reveal, or divulge any such information unless it is necessary for you to do so in the performance of your duties (or except as otherwise allowed by applicable law). All employees will be asked to sign a Confidential Disclosure Agreement (CDA) with Medicines360. Covered Parties may have contractual obligations to maintain confidentiality.

Confidential information *not* available to the public, includes (but is not limited to):

- | | | |
|------------------|-------------------------|----------------------|
| ▪ Business plans | ▪ Projections/forecasts | ▪ Business contracts |
| ▪ Strategies | ▪ Employee information | ▪ Databases |
| ▪ Budgets | ▪ Marketing plans | ▪ Training materials |

Regardless of whether this type of information is identified as confidential, it is your responsibility to keep this information in confidence. Generally, access to confidential information should be granted on a “need-to-know” basis and must be authorized by your manager.

Additionally, you may not use or share confidential Company information for stock trading purposes, including buying, selling or trading the stock of any of our publicly traded partners based on that information.

INTELLECTUAL PROPERTY

Our intellectual property includes our copyrights, trademarks, patents, knowledge and experience developed in our daily business activities. You are expected to protect and maintain our intellectual property, as well as respect the intellectual property of others.

You may not reproduce, adapt, distribute, perform, display, or incorporate into Medicines360's materials any protected work in any form (e.g., print, audio, video or electronic) without the permission of the owner. Employees may reproduce Company Social Media, but must follow Company's Communication Policy ([POL-00011](#)) and Social Media SOP ([SOP-CMP-00015](#)).

All Medicines360 Covered Parties who have access to confidential information must sign a Confidential Disclosure Agreement (CDA) and may be asked to sign a Proprietary Information and Inventions Agreement (PIIA) as a condition of work.

COMPANY’S ELECTRONIC RESOURCES

All business information created, sent, received, or stored on the Company’s electronic resources or on an employee’s or Covered Party’s personal device, such as a cell phone, is considered Company property. Such information is not the private property of any employee or Covered Party, and employees and Covered Parties should have no expectation of privacy in the use or contents thereof.

“Electronic Resources” includes all features of the Company’s electronic communications services such as computer, email, instant messaging, telephone, Company-issued cellular phone, personal devices, voicemail, fax, online services, external/internal networks, Intranets, and the Internet.



General Guidelines for Using Company’s Electronic Resources

✓	Always protect Company assets as you would your own property and take great care to assure that no one besides you has access to Company property, including emails and text messages, while you are away from the office. Use privacy shields on your laptop computer while working in a public space.
✓	The employee or Covered Party whose name is on the account is responsible for its proper use at all times
✓	Never use Company resources to access, receive, or transmit material that is illegal or for non-Company business purposes
✓	Employees may not download or otherwise import programs, files, media or documents onto the Company’s computer equipment, except as authorized by Company
✓	Do not download to a portable device Company information for any purpose other than Company business without management approval. Any confidential or sensitive Company information downloaded to a personal device is to be deleted as soon as it is no longer needed by the employee or Covered Party. If employees use personal devices for business use, Medicines360 may require additional security settings on personal devices to insure business information is secure.

✓	Report any breach of information systems or network security to the Head of Compliance and Company's Chief Financial Officer (CFO)
✓	Do not transmit, retrieve, or store Company information of any kind on personal email systems without management approval
✓	Silence your cell phone and limit personal calls to lunch breaks or other rest periods
✓	Obey laws regarding cell phone use while driving and do not text or email while driving

PERSONAL USE

Employees and Covered Parties may engage in limited personal use of Company's electronic resources, provided that such use does not otherwise violate any Company policy and does not interfere with the employee's or Covered Party's performance of their duties. Medicines360 assumes no liability for loss, damage, disclosure, or misuse of any non-Company data or communications transmitted or stored on the Company's electronic resources.

MONITORING

Medicines360 may monitor the usage of its electronic resources and may access, review, and disclose information stored on its resources, including (but not limited to) messages, personal e-mail communications sent and received on the Company's computers but using private e-mail accounts and other data, at any time, with or without advance notice or consent to the employee/Covered Party.

BUSINESS COMMUNICATIONS

Written or electronic communications can endure forever. Internet, email, and voicemail are not secure forms of communication and may be read or reviewed by unintended recipients. Therefore, special care must be exercised when using these systems to avoid inappropriate disclosures of confidential or private information or information that may be misinterpreted.

- Use email, texts and online communications responsibly and cautiously
- Make sure the language used in email, texts and online communications is clear and concise and not open to misinterpretation
- Use caution when communicating about Medicines360 on any Social Media channel and follow guidelines set forth in Company's Communication Policy ([POL-00011](#)) and Social Media SOP ([SOP-CMP-00015](#))

ACCURATE BOOKS AND RECORDS

We are committed to ensuring that our Company books and records – including time sheets, bills, invoices, expense reports, payroll, personnel records, contracts, government filings, etc. – are accurate, complete with reasonable detail, not misleading, and correctly reflect all business transactions. Any disclosures of Company information must always be conducted by approved procedures and individuals.

- Never destroy or alter any document in anticipation of, or in response to, a request for those documents by an authorized Company individual or any government agency, court, or third-party. If investigated, records may not be hidden, changed, or destroyed.
- No false or misleading entries shall be made for any reason, and no employee shall engage in any activity that results in such prohibited act, even if directed to do so by a manager.
- No undisclosed or unrecorded fund or asset of Medicines360 shall be established for any purpose.

As requested and required, approved Medicines360 employees and Covered Parties must provide accurate, non-misleading reports to government agencies and other regulators in a timely manner. Employees and Covered Parties are required to cooperate with internal and outside auditors and any regulatory agencies examining Medicines360 books and records.

Any employee having information or knowledge of any unrecorded fund or asset or any prohibited act should promptly report such matter to the Head of Finance, Compliance, and Human Resources.

See details in
[POL-00002](#)
Record Retention
Policy

STORAGE OF RECORDS

All records must be stored in a safe and secure location for a reasonable amount of time as determined by Medicines360 policy. Records must be stored in a manner that is consistent with the Medicines360 Internal Records Retention Policy ([POL-00002](#)) and all applicable laws and regulations. Emails, texts, and other forms of electronic communication are not appropriate formats for Company records. Information in such formats comprising Company records should be transferred to a more permanent format (e.g., PDF) and retained outside of these systems.

Access to records will be provided only to those who have an authorized legitimate business need. Anyone with access to such books and records must ensure that the integrity of the information remains intact and that it remains protected from unauthorized disclosure, alteration, and destruction.

PAYMENTS WITHOUT PROPER RECORDS

No payment on behalf of Medicines360 shall be made with the intention or understanding that any part of such payment is to be used for any purpose other than that described by the documents or entries supporting the payment.



OUR INDUSTRY & INTERACTIONS

The pharmaceutical industry is subject to many rules and regulations designed to enhance the quality of health care, protect patients and consumers, and help eliminate fraud and improper influence on medical decisions. Medicines360 is committed to following the applicable laws, regulatory requirements, and industry codes and guidelines that govern our business in the United States and other parts of the world, including research, development, manufacturing, distribution, government contracting and reimbursement, marketing, and the sale, donation and promotion of our products.

As a global company, Medicines360 must adhere to the laws and regulatory requirements of each country for which we do business. In the event local laws and regulatory requirements differ from policy, the stricter requirements generally apply.

KEY HEALTHCARE COMPLIANCE LAWS & GUIDELINES

FOOD, DRUG AND COSMETIC ACT (FDCA)

The Food and Drug Administration (FDA) is responsible for the regulation of drugs, vaccines, biological medical products, blood products, medical devices in the United States (U.S.). It regulates almost every aspect of our business, from research and development to promotion and sales. The FDA administers and regulates the Federal Food, Drug and Cosmetic Act (FDCA), which, in general, oversees every aspect of Medicines360's advertising and promotion in the U.S. The FDCA requires that we promote our products in a manner that is accurate, balanced, and consistent with approved product labeling.

ANTI-KICKBACK STATUTE

The Anti-Kickback Statute prohibits offering anything of value in order to influence an individual's decision to recommend, prescribe, or purchase a healthcare product or service that is reimbursed by a federal healthcare program. This law ensures a healthcare professional's treatment recommendation is based solely on each patient's medical needs and not influenced by motives of personal gain or enrichment.

THE FALSE CLAIMS ACT (FCA)

The False Claims Act (FCA) prohibits an individual from submitting a false or fraudulent claim for payment or reimbursement from the federal government. Under the FCA, the federal government has prosecuted pharmaceutical companies for falsely reporting best price, paying kickbacks to healthcare professionals, and conducting off-label promotion.

SUNSHINE REPORTING (FEDERAL AND STATE LAWS)

All pharmaceutical manufacturers operating in the U.S. and some foreign countries are required to report and disclose payments and other transfers of value to certain defined “Healthcare Providers”, in accordance with “Sunshine” reporting laws promulgated by federal, state and foreign governments. Medicines360 is committed to complying with all relevant laws related to transparency reporting.

OTHER COMPLIANCE LAWS & GUIDELINES

In addition to laws and regulations specifically applicable to the pharmaceutical industry, Medicines360 also obligated to comply with laws and regulations applicable to all industries, including without limitation the following:

ANTI-CORRUPTION

The Foreign Corrupt Practices Act (FCPA) prohibits representatives of U.S. companies, wherever they are physically located, from giving anything of value to a non-U.S. government official, political party or official, or candidate for public office in order to gain an improper business advantage. The FCPA also prohibits an entity or individual from using another entity or individual to engage in such activities.

Similar global anti-corruption and anti-bribery laws exist in many countries prohibiting offering, providing, or authorizing any payment or anything of value (directly or indirectly) to a government official when the payment is intended to improperly influence an official act or decision.

Click [here](#) to view details in SOP-CMP-00003 - Transparency Reporting SOP.

Click [here](#) to view details in POL-00013 Global Anti-Corruption Policy

In many countries outside the U.S., the local government may act as both regulators and customers of our products – therefore, HCPs may be employed by a public institution and considered government officials.

Click [here](#) to view
details in
POL-00009 HIPAA
Compliance
Policy

ANTI-TRUST AND COMPETITION LAWS

Anti-trust and competition laws prohibit agreements between competitors that may affect price or terms and conditions of sale. Medicines360 must be aware of these laws in each country in which we operate, directly or indirectly through third parties (including in the U.S.) and refrain from having discussions with competitors, supplies, and customers that would unfairly restrict a competitive marketplace, access to, or trade in our products.

PRIVACY LAWS

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a privacy law that imposes strict limitations on the use and disclosure of personal information. The collection and use of personal information may also be regulated by state or privacy laws of a foreign country.

As part of your job responsibilities, you may come into contact with personal health information (PHI), such as patient records. You have an obligation to safeguard any PHI you come across. Medicines360 employees or Covered Parties may not discuss or disclose any PHI except as required to receive, evaluate, and/or process Product Complaints and/or Adverse Event information as described in relevant Company policies and procedures.

In addition, certain transfers of information to and from Medicines360 are subject to the General Data Protection Regulation (GDPR) of the European Union. Further, while as a nonprofit entity Medicines360 is not bound to follow the California Consumer Privacy Act (CCPA) many of its provisions have become the de facto standard in the U.S. regarding electronic interactions with consumers and the Company has developed its Privacy Policy ([POL-00008](#)) accordingly.

INTERACTIONS WITH GOVERNMENT EMPLOYEES

Medicines360 is committed to following all applicable laws relating to government interactions, including appropriate interactions with state and federal government officials in the U.S. and with government officials in other countries. As a tax-exempt entity Medicines360 is permitted to engage in a limited amount of legislative lobbying, although these activities cannot account for a “substantial part” of its activities. All employees and Covered Parties should refrain from speaking on Medicines360’s behalf or discussing our Company’s interests with U.S. or foreign government officials without prior permission from Legal.

FUNDRAISING ACTIVITIES

Many states, including California, have enacted comprehensive statutory schemes regulating charitable solicitations of the public. Those statutes vary from state to state, but in general they require registration by the charity and its fundraising agents and certain disclosures in the course of solicitation, with monetary penalties imposed for noncompliance. Medicines360 is obligated to comply with these state statutes in connection with its solicitation of grants or donations.

PHRMA CODE

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) represents research-based pharmaceutical and biotechnology companies, and together the industry group developed the PhRMA Code. The PhRMA Code is intended to protect patients from improper influences on healthcare decision-making by striving to ensure that interactions between Company representatives and healthcare professionals are focused on informing about the benefits and risks of medicines to help enhance patient care. Medicines360 has developed its healthcare compliance policies and procedures with the PhRMA Code as their foundation.

OIG COMPLIANCE GUIDANCE

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services maintains the integrity of federal healthcare programs. In 2003 and 2017, the OIG issued its Compliance Program Guidance and Measurement Guidelines for pharmaceutical manufacturers, which established the fundamental principles of a compliance program and offered specific guidance for implementing and measuring an effective program.

The seven fundamental principles of an effective compliance program are:

- 1** Implementing written policies and procedures
- 2** Designating a compliance officer and compliance committee
- 3** Conducting effective training and education
- 4** Developing effective lines of communication
- 5** Conducting internal monitoring and auditing
- 6** Enforcing standards through well-publicized disciplinary guidelines
- 7** Responding promptly to detected problems and undertaking corrective action

Our compliance program has been structured in accordance with the OIG Guidance.

Click [here](#) to view
details in
POL-00011
Communications
Policy

PROMOTIONAL COMMUNICATIONS

We want to be clear and compliant with laws and regulations in all our promotional communications. Any corporate and product promotional materials and communications must always focus on providing accurate, truthful, non-misleading information that aligns with our corporate mission, industry laws and regulations, and ethical standards.

Product promotional materials are subject to internal Medicines360 review process and approval by the FDA, which regulates the labeling and advertising of all prescription drug products. Any print or electronic materials and messages used to promote Company product(s) must be consistent with relevant policies and procedures.

All product promotional communications must contain statements that:

- 1 Conform to FDA-approved prescribing information (e.g., approved indications)
- 2 Fairly balance information about the product's benefits (e.g., efficacy) with information about the product's risks (e.g., warnings, precautions, side effects)
- 3 Are properly substantiated (i.e., comparative product claims, judgments, or interpretations are considered false and misleading unless there is substantial evidence to support the claim)

INTERACTIONS WITH HEALTHCARE PROFESSIONALS (HCPs)

Click [here](#) to view
POL-00016
Interactions with
Healthcare
Professionals
(HCPs) Policy

Medicines360 believes that our relationships with healthcare professionals (HCPs) are critical to helping patients by developing and marketing new medicines and ensuring HCPs have the latest and most accurate information about those medicines.

Medicines360 interacts with HCPs for many different purposes – from promoting approved product(s), to discussing Medicines360 clinical studies with investigators, to engaging professionals as speakers and consultants. We are committed to interacting with HCPs with the highest level of integrity and fairness, and in compliance with all applicable laws and regulations. We believe that our business relationships should be based on transparency, honesty, and trust, and we strictly prohibit any behavior that is illegal or that seeks to undermine the high ethical standards we have set.

General Guidance on Interactions with HCPs

✓	Interactions must be focused on advancing patient care and the practice of medicine – thereby preserving the independence of the HCP
✓	Promotional product information must always be accurate, substantiated, fairly balanced, and consistent with the approved labeling
✓	All promotional materials must be approved via proper review committee process
✓	Never engage in misleading marketing or sales activities
✓	Never offer, or appear to offer, any remuneration or item of value with the intention to induce an HCP to purchase, prescribe, endorse, or recommend our product
✓	Never provide entertainment or recreational activities of any kind (e.g., sporting events, trips, theater tickets) to HCPs
✓	Enter into legitimate service arrangements with HCPs who perform bona fide consulting services and document these arrangements in written agreements
✓	Do not provide gifts or non-educational items to HCPs or their staff under any circumstances, even if they are practice-related and of minimal value
✓	All Consulting Agreements between Medicines360 and an HCP shall include a standardized rate of pay which is documented and based on Fair Market Value (FMV)

BUSINESS MEALS

Medicines360 may offer meals as a business courtesy to HCPs and their office staff in connection with a legitimate scientific or educational presentation or discussion, such as an in-office presentation, a speaker program, or training session. The focus of such interactions should remain on the substance and quality of the information provided, not on the meal or venue.

The meal must meet the following standards:

- 1** The meal must be occasional and modest as judged by local standards
- 2** Food must be the primary component of the meal. Alcoholic beverages, while discouraged, are permitted when accompanying a meal (no “Happy Hour” meetings).
- 3** The meal must occur at a venue and in a manner conducive and appropriate for a business discussion (e.g., no resorts, bars, or sports venues)
- 4** The meal must not include spouses or guests, unless they independently qualify as an HCP or other appropriate office staff attendee
- 5** The meal must be recorded and disclosed according to Open Payment policies and/or procedures

Covered Parties are required to follow all applicable Company policies and specific state, foreign government or institutional requirements, if they apply.

EDUCATIONAL ITEMS

Where permitted by law, Medicines360 may occasionally offer items of value to HCPs that are either de minimis in value or are designed primarily for the education of patients or HCPs. Such items must be approved in advance by the Head of Compliance and may not have value to the HCP outside of their professional responsibilities, and must not be of substantial value, according to Company policy.

Click [here](#) to view
HCP Meals &
Beverages
Spending Limits
Appendix to
POL-00016

CLINICAL AND REGULATORY ACTIVITIES

Medicines360 is committed to meeting the high expectations of our stakeholders regarding the quality, safety, and efficacy of our products and services. We are committed to conducting our clinical and regulatory activities with the highest level of integrity and in compliance with legal and regulatory requirements and internationally acknowledged good practices (e.g., Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP)).

SCIENTIFIC EXCHANGE

We may only promote our products in a way that is consistent with approved product labeling. The FDA recognizes, however, that valuable scientific and medical information exists about a Company's product that is outside its approved product labeling. Scientific and medical communications may occur between the healthcare community and Medicines360 medical and scientific representatives so long as they follow the principles of scientific exchange.

Scientific exchange must be:

✓	Objective and unbiased
✓	Scientifically rigorous
✓	Non-promotional in nature and intent (i.e., separate and independent of promotional presence or discussion)
✓	Balanced and inclusive of important safety-related data when relevant
✓	Appropriately referenced (i.e., materials must contain relevant sources), when applicable

Medicines360 Clinical and Medical Affairs representatives may respond to unsolicited requests for off-label or pre-approval product information in a non-promotional manner.

PUBLICATIONS

Click [here](#) to view
POL-00012
Publications
Policy

Medicines360 participates in the development and publishing of scientific publications associated with Company-sponsored or co-sponsored research studies (e.g., clinical studies, health economic studies, etc.) as part of Medicines360's commitment to disclose and publish research results to ensure safe and effective use of our products.

Medicines360 may engage healthcare professionals (HCPs) as authors or contributors of a publication with appropriate Company approvals. The engagement of HCPs and other material experts to author publications must never intend to promote, induce, or reward the use of Company products.

Medicines360 complies with applicable reporting and publication process guidelines, regulations, and journal- or congress-specific publication requirements. These include (but are not limited to): Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3, International Committee of Medical Journal Editors (ICMJE) Recommendations, PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, and Food and Drug Administration Amendments Act of 2007.

Medicines360 may also participate in the development and publishing of non-scientific publications associated with either Company-sponsored or co-sponsored studies.

COMMITMENT TO TRANSPARENCY

As a Company focused on innovation, we recognize that access to clinical trial data is valuable for the advancement of public health and science and that greater transparency of clinical trial data promotes better health worldwide. We are committed to sharing clinical trial design and results – regardless of outcome – in a timely, complete, accurate, and transparent fashion through publications, such as peer-reviewed journals and presentations at medical and scientific conferences.

Our goal is to strike the necessary balance between advancing science for public health and fostering innovation with the need to protect the privacy of individual patients, who have made a selfless contribution to the advancement of medicine. We will remain in accordance with evolving industry requirements to advance clinical trial data transparency. At times we may delay or limit publication to secure and protect the Company's intellectual property or to comply with restrictions in third party agreements.

Clinical trial data and results will be posted on the public registry www.clinicaltrials.gov

ADVERSE EVENT AND PRODUCT COMPLAINT REPORTING

Click [here](#) to view
SOP-QAU-00038
Intake & Routing
of Liletta®
Pharmacovigilance
Reporting

Click [here](#) to view
SOP-QAU-00004
Product
Complaint
Handling

Medicines360 is committed to gathering, understanding, and monitoring our product's safety information and meeting our regulatory reporting requirements in a timely fashion. All Medicines360 personnel, including employees and Covered Parties, have the obligation to report Adverse Events (AEs) and Product Complaints (PCs) no later than one (1) Business Day after they become aware of the event or information.

An "Adverse Event" (AE) is any undesirable experience associated with the use of a product in a patient (including a sign, symptom, diagnosis, or laboratory abnormality) regardless of causality, and including medication errors, or any failure of expected pharmacological action.

A "Product Complaint" (PC) is any written, electronic, or verbal communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Medicines360 drug, device, or drug-device combination product after it is released for distribution.

A Medicines360 "Business Day" is when normal business operations are conducted Monday – Friday, excluding Medicines360 holidays identified in the yearly holiday schedule.

Submit AEs and PCs according to SOP-QAU-00038 Intake and Routing of Liletta Pharmacovigilance Communications and SOP-QAU-00004 Product Complaint Handling

Obtain the "Form for Capture of Essential Adverse Event Information" (FRM-QAU-00023) in SOP-QAU-00038 Intake and Routing of Liletta Pharmacovigilance Communications

FINAL WORDS

WHY WE'RE DIFFERENT

We are committed to the highest standards of conduct at every level, and we depend upon the personal and professional integrity and dedication of all covered parties to help uphold these standards. Your honorable character and helpful behavior are assets and a credit to the Company.

With your sustained commitment to this Code, Medicines360 has the opportunity to continue demonstrating why we're truly *a different kind of pharmaceutical company*.

- It starts with our singular focus on making quality medicines and products available to women at a price they can afford; **that's the nonprofit part.**
- We research the health needs of women and identify gaps and barriers in how women access medicines. Based on these insights, we develop women's health products and create strategies to bring these products to market; **that's the pharmaceutical part.**
- We then reinvest our proceeds into advocacy, education, and additional product development so that we can further our mission of making medicines available and affordable to women in the U.S. and globally; **that's the cool part.**

Should you have any questions or concerns about this Code or the Company's offerings, policies, and procedures, do not hesitate to contact Compliance.

Document Approvals

Approved Date: 15 Dec 2020

Approval Task Verdict: Approve	Ethan Knowlden, General Counsel (eknowlden@medicines360.org) Legal 10-Dec-2020 22:38:43 GMT+0000
Approval Task Verdict: Approve	Andrea Olariu, Chief Operating Officer/Interim CEO (aolariu@medicines360.org) Executive 11-Dec-2020 02:39:03 GMT+0000
Approval Task Verdict: Approve	Sally Stephens, Chief Business Officer (sstepphens@medicines360.org) Commercialization 11-Dec-2020 19:44:05 GMT+0000
Approval Task Verdict: Approve	Stephanie Kurteff, Head of Compliance (skurteff@medicines360.org) Healthcare Compliance 11-Dec-2020 20:42:55 GMT+0000
Approval Task Verdict: Approve	Brad Luke, Chief Financial Officer (bluke@medicines360.org) Executive 12-Dec-2020 16:14:52 GMT+0000
Approval Task Verdict: Approve	Mark Busch, SVP, Quality Assurance & Product Safety (mbusch@medicines360.org) Quality Assurance 15-Dec-2020 16:46:36 GMT+0000

Document Approvals

Approved Date: 15 Dec 2020

QA Approval Task Verdict: Approve	Mark Busch, SVP, Quality Assurance & Product Safety (mbusch@medicines360.org) Quality Assurance Approval 15-Dec-2020 16:47:06 GMT+0000
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