

# **GLOBAL DISTRIBUTOR COMPLIANCE** TOOLKIT





### **GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT**

We have created a toolkit which includes many resources. We hope these tools will help you formalize and strengthen your compliance program. A good compliance program can help prevent compliance issues from occurring or detect issues before they become significant. Good compliance is also a competitive advantage as you will be able to demonstrate to suppliers, customers and employees integrity and ethics in your company. Every third party should undertake reasonable steps to implement an appropriate compliance program, based on the size, resource and activities of the business.



This toolkit is a step by step guide to help you implement a compliance program within your business. Your compliance program should start with a Code of Conduct. The toolkit contains a sample Code of Conduct which will help your employees, officers and directors understand and ensure business is conducted in an ethical, lawful and appropriate manner. The next step is conducting training for all employees. The toolkit contains some training material that you can customize for your needs to train your employees and business partners. There is also a template so you can document and record all employees and personnel that attended the training. It is important to retain these attendance records so you are able to evidence that the training was conducted and who attended the training. The toolkit also provides a number of template policies and guidance documents to help you set up a compliance program. Many of these policies focus on the various interactions you may have with healthcare professionals, healthcare organizations and government officials and explain the documentation you must have to record these interactions.

Another section of the toolkit provides you with some communication tools to help your employees and business partners understand your company's compliance requirements. We hope you find the toolkit useful and we welcome any feedback you may have on the toolkit. Please send any feedback or questions to

**Important note:** All the resources contained here **may not** be applicable or permissible in a particular market. You must follow all local laws, regulations and industry codes.

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# KEY AREAS OF GLOBAL COMPLIANCE

**An Introduction** 



GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT



# **Doing Business with Integrity**

Our industry is highly regulated, so it is important to know and observe the law in every country where you do business. Compliance means not only following the letter of the law, regulations, policies and rules, but also their spirit.

Developing an effective compliance program is critical to maintaining the highest ethical standards in the execution of business duties while complying with all applicable laws, rules and regulations.

This training is designed to help you develop an effective compliance program that addresses anti-bribery and anti-corruption issues. Anti-corruption laws do not differentiate between acts done by a Company or acts done by a third party acting on the Company's behalf.



# **Key Areas of Global Compliance**





A Government Official is: Any official or employee of a government agency or other governmental unit or public international organization, along with officers and employees of government owned companies or companies substantially controlled by such governments.



- What is a Conflict of Interest? A conflict between the private interests and the official or business responsibilities of an individual. This conflict means that an individual's business decision may be compromised by the hope of personal gain.
- These are example of conflicts of interest we can **avoid**:
  - Providing a meal or gift to influence decisions for or on behalf of your company or Business Partner.
  - Misuse of your position, company resources or company information for personal gain
  - Contracting with a supplier that is owned by a relative of an employee involved in the decision-making process
- Candidates for any position must disclose any actual or potential conflicts of interest to Management, Compliance, Human Resources, or Legal.



# **Preventing Bribery & Corruption**

Bribery and corruption are global issues and are taken seriously by governments worldwide. Bribery of Government Officials is a crime under local and international laws and regulations, for example the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act, among others.





## **Preventing Bribery & Corruption**

Corruption is not limited to bribery. Global and local anti-corruption laws prohibit activities including, but not limited to, embezzlement, extortion, and the hiring or advancement of certain people for private or political gain.

- You are responsible for following all applicable anti-bribery and anti-corruption laws.
- Failing to follow anti-bribery and anti-corruption laws can result in severe civil and criminal penalties as well as reputational harm for your company and business partners.



## **Preventing Bribery & Corruption**

Global companies have been found responsible for inappropriate actions taken by their business partners around the world to gain an improper business advantage. For example, in 2012, a global medical device company was fined \$22 million USD by U.S. authorities for paying bribes through business partners in Europe to win business.





### **Keeping Good Books & Records**

Companies are required to maintain accurate financial records.

#### You must:

- Accurately and fully describe transactions in your records
- Keep accurate and transparent records of all expenses
- Itemize products and promotional activities in your records

#### You must not:

- × Create false records or documentation
- × Create false accounts
- Hide payments or gifts in the cost of product or discounts offered
- × Provide false documentation or other false information
- Create intentionally vague descriptions to hide improper payments or expenses
- × Mischaracterize payments



# Interacting with Health Care Professionals & Government Officials

Whenever interactions with Healthcare Professionals (HCPs) or Government Officials (GOs) involve payments, meals, travel, or any other benefit to an HCP, you must ensure that the benefits are legal under all applicable laws and regulations, supported by a legitimate and documented business need, and allowed under the written agreement with you.



# Interacting with Health Care Professionals & Government Officials

The benefits should not exceed what is necessary to conduct the interaction and must never be given as a reward for business or as a condition for future sales or referrals.

When interacting with HCPs and GOs, be aware of "red flags" that may be evidence of potential corruption. For example, an HCP and/or GO:

- Proposes linking payments to volume of purchases
- Mentions personal relationships with government entity/official
- Has a questionable reputation
- Guarantees you success in a public tender or bidding contract
- Requests payments outside his/her country
- Declines to provide proper receipts for expenses



# Interacting with Health Care Professionals & Government Officials

# All of your interactions with HCPs and GOs should be grounded in **five general principles**:

You may <u>not</u> provide anything of value to an <u>HCP/GO in</u> exchange for, or as a reward for past, present or future business. Any interactions with an HCP/GO must be supported by a legitimate, clearly defined business need and allowed under the Written Agreement with you. You may only engage HCP/GOs whose expertise and experience are appropriate given the business need. All financial interactions with HCP/GOs must be consistent with relevant agreements, and compensation for these interactions must be reasonable for the local market.

All financial interactions with HCP/GOs must be recorded accurately and in reasonable detail.



# **Reporting a Concern**

Any violation must be reported immediately to

Individuals may make a report by

We will make sure <u>no retaliatory action</u> is taken against anyone who reports, in good faith, actual or suspected misconduct.

We take reported allegations seriously.



### **KEY AREAS OF GLOBAL COMPLIANCE**

Key Areas of Global Compliance that are addressed in the Global Distributor Toolkit



### **OVERVIEW: TEMPLATES & FORMS**

To help you meet your compliance requirements, we are providing a number of reference documents, tools and templates for your use. Some of these documents can be used as they are while others may require modification and adjustments in order to be used properly given that local laws, regulations, or industry codes may include additional or different requirements. Some documents may not be relevant to your regular business operations.



TEMPLATES & FORMS	
Conflict of Interest Declaration	A conflict of interest occurs when a personal activity, relationship or business involvement interferes — or appears to interfere — with our ability to fulfill our job responsibilities. We make business decisions based on what is in the best interest of our Company and not for personal gain or benefit. All employees should proactively and promptly disclose actual or perceived conflicts of interest. An example conflict of interest may be if you have a family member working in a hospital where your company provides products or services. This template can be used to disclose actual, perceived or potential conflicts of interest in a timely and effective manner. It can also be used to document the decision made on how the conflict of interest is resolved.
Due Diligence Quick Check	Due diligence is the investigation or exercise of care that a business or person is expected to take before entering into an agreement or contract with another party. This guidance document explains what is required if you appoint another party to sell, market, deliver and/or promote products or services and guidance on documenting the performance of due diligence on any business partner used or to be used in the fulfillment of a distribution agreement.
Expense Reimbursement Spreadsheet	This spreadsheet can be used to support and document any expenses you incur in the course of business activities including but not limited to hospitality, business travel, meetings and expenses related to interactions with customers and suppliers. Companies should establish spending limits for business related expenditures, such as meals, refreshments, or lodging as per local laws, regulations and industry codes.
Grant or Donation Packet	<ul> <li>Use this packet when agreeing to fulfill a grant or donation request. Templates included:</li> <li>1. Grant/Donation Request - To request approval internally to provide a grant or donation.</li> <li>2. Grant/Donation Agreement - To document your donation or grant agreement with the recipient of the funds.</li> </ul>
HCP Meeting, Event or Training Packet	<ul> <li>Use this packet when inviting an HCP to attend a meeting, event or training. Templates included:</li> <li>1. Internal Approval - To seek approval within your company</li> <li>2. HCP Invitation - To extend an invitation to an HCP</li> <li>3. Employer Notification - To notify the HCP's Employer (this may not be a requirement depending on the local laws, regulation or applicable industry associations codes)</li> </ul>
HCP Sign-in Sheet	Use this template to sign-in HCPs who attend your meeting, event or training.
Notification on Use of Sub-Distributors	A sub-distributor is any third party or affiliate of a distribution company that has entered into a written agreement with a distributor for the distribution of products or services anywhere in the distributor's territory. This template letter can be used to notify partners about any and all sub-distributors used or to be used in the fulfillment of the distribution agreement.
Self-Certification Form	This template can be used to ask employees, sub-distributors and other business partners to self-certify to your company's Code of Conduct and other internal policies.
Sponsorship Packet	<ul> <li>Use this packet when sponsoring a third-party event. Templates included:</li> <li>1. Sponsorship Request - To document the details of the support request and document approval of this support.</li> <li>2. Sponsorship Agreement - To document your support of the event with the organizer of the event.</li> </ul>

# RECOGNIZING GOVERNMENT OFFICIALS





A Government Official is: Any official or employee of a government agency or other governmental unit or public international organization, along with officers and employees of government owned companies or companies substantially controlled by such governments.





### **Examples of Government Officials**

A Government Official can take various shapes or forms including but not limited to:





### Parisian Surgeon: Part 1

- Xavier is working as a surgeon at a hospital in Paris.
- The hospital is managed by the municipality of Paris.
- Xavier has a contract with this hospital and his practice location is owned by this hospital.

### Does Xavier fall under the definition of a Government Official?



### Parisian Surgeon: Part 2

- Xavier is working as a surgeon at a hospital in Paris.
- The hospital is managed by the municipality of Paris.
- Xavier has a contract with this hospital and his practice location is owned by this hospital.

# Does Xavier fall under the definition of a Government Official?

Yes, Xavier is an employee of a government institution/entity and fulfilling a public task with the treatment of patients that are covered under the public social healthcare system.



### Public Tender: Part 1

Your company is participating at a public hospital tender process. Your salesperson has a meeting with your HCP customer to discuss the launch of a new product. The HCP is a member of the buying decision committee of that hospital including that specific tender.

The HCP tells you that he has heard about your company participating at the hospital's tender and says he values the excellent quality of your company's products and wants to help you and your company win the tender. He tells you that he will make sure your company will receive the bid. He also suggests that you reward him by paying a commission based on the value of the business deal or that you find something else in return for his favor such as a speaking engagement.

#### Should you proceed as suggested by the HCP?



### Public Tender: Part 2

Your company is participating at a public hospital tender process. Your salesperson has a meeting with your HCP customer to discuss the launch of a new product. The HCP is a member of the buying decision committee of that hospital including that specific tender.

The HCP tells you that he has heard about your company participating at the hospital's tender and says he values the excellent quality of your company's products and wants to help you and your company win the tender. He tells you that he will make sure your company will receive the bid. He also suggests that you reward him by paying a commission based on the value of the business deal or that you find something else in return for his favor such as a speaking engagement.

#### Should you proceed as suggested by the HCP?

**No, you should not.** Instead, you should explain to the HCP the problematic areas of his suggestion which may include but are not limited to:

- The public tender process and the related evaluation should be based on objective criteria and made independently; free of conflict of interest and/or undue influence.
- The HCP may not have declared his conflict of interest to the buying decision committee and may not have made transparent all the relevant interactions he has with this company (in this case: customer (buying products) and attendee of several product trainings).
- The provision of a benefit (commission, speaking engagement or anything else of a benefit) in return for the business deal (the tender) is illegal.



### **Know Your Customer: Part 1**

A Distributor receives a call from an Engineering, Procurement, and/or Construction (EPC) company. The EPC company won a tender to build a hospital in a project for the Ministry of Health. The EPC company requests a binding quote to furnish all the medical equipment inside this new hospital.

The Controller of the Distributor finds out through due diligence that the Ultimate Beneficial Owner of the EPC company who called the Distributor is also the Primer Minister, Executive Director of the Political Party in power, and the appointer of the current Minister of Health.

What is the potential issue in this arrangement?



### **Know Your Customer: Part 2**

A Distributor receives a call from an Engineering, Procurement, and/or Construction (EPC) company. The EPC company won a tender to build a hospital in a project for the Ministry of Health. The EPC company requests a binding quote to furnish all the medical equipment inside this new hospital.

The Controller of the Distributor finds out through due diligence that the Ultimate Beneficial Owner of the EPC company who called the Distributor is also the Primer Minister, Executive Director of the Political Party in power, and the appointer of the current Minister of Health.

What is the potential issue in this arrangement?

If this arrangement is made, the owner of the EPC company would receive a personal benefit due to the government official's public position. This would be considered a conflict of interest and may violate local anti-bribery and anti-corruption laws and regulations.

# IDENTIFYING CONFLICTS OF INTEREST



- What is a Conflict of Interest? A conflict between the private interests and the official or business responsibilities of an individual. This conflict means that an individual's business decision may be compromised by the hope of personal gain.
- These are example of conflicts of interest we can **avoid**:
  - Providing a meal or gift to influence decisions for or on behalf of your company or Business Partner.
  - Misuse of your position, company resources or company information for personal gain
  - Contracting with a supplier that is owned by a relative of an employee involved in the decision-making process
- Candidates for any position must disclose any actual or potential conflicts of interest to Management, Compliance, Human Resources, or Legal.



### Your Spouse: Part 1

Your spouse works as a Health Care Professional (HCP) at a hospital where they have authority over some purchasing decisions. Your company is attempting to sell products to this hospital. What steps should you take to avoid all potential conflicts of interest?

- A. Disclose the above situation in advance to your primary supplier contact.
- B. If you are not certain if this could be a potential conflict of interest, contact **[insert compliance contact/information source]** for additional information.
- C. Refrain from selling or promoting products at the hospital until you've addressed the situation with the company.
- D. All of the above.



### Your Spouse: Part 2

Your spouse works as a Health Care Professional (HCP) at a hospital where they have authority over some purchasing decisions. Your company is attempting to sell products to this hospital. <u>What steps should you take to avoid all potential conflicts</u> <u>of interest?</u>

- A. Disclose the above situation in advance to your primary supplier contact.
- B. If you are not certain if this could be a potential conflict of interest, contact **[insert compliance contact/information source]** for additional information.
- C. Refrain from selling or promoting products at the hospital until you've addressed the situation with the company.
- D. All of the above.

#### The correct answer is D.

This is a potential conflict of interest between your interests and those of your Company and Business Partners. You must disclose all possible conflicts of interest in advance. If you are not certain if a conflict of interest exists, you can always contact [insert company contact] with questions or to request guidance.



### **New Sales Rep: Part 1**

- You are considering hiring a new sales representative but have not decided whether it is necessary for your business.
- While still undecided, you get a call from a well-known health care professional who is also an important customer.
- He tells you that his son has just graduated from medical school and would be a great asset to your company.
- You agree to interview him and find him to not be an ideal candidate for the role.

#### Should you hire him?



### **New Sales Rep: Part 2**

- You are considering hiring a new sales representative but have not decided whether it is necessary for your business.
- While still undecided, you get a call from a well-known health care professional who is also an important customer.
- He tells you that his son has just graduated from medical school and would be a great asset to your company.
- You agree to interview him and find him to not be an ideal candidate for the role.

#### Should you hire him?

# No. You should not hire the HCP's son:

- It is not clear that there is a legitimate need or business justification for the potential new sales position.
- 2. The HCP's son is not an ideal candidate for the position.
- 3. Hiring the HCP's son, even if he were an ideal candidate, would create a conflict of interest because of his connection to an HCP customer.



### **IDENTIFYING CONFLICTS OF INTEREST**

A Conflict of Interest is a conflict between the private interests and the official or business responsibilities of an individual. This conflict means that an individual's business decision may be compromised by the hope of personal gain.



#### **Examples of Conflicts of Interest we must avoid:**

- Obtaining an improper advantage by providing an impermissible benefit to an HCP
- Misuse of your position, Company resources or Company information for personal gain
- Contracting with a supplier that is owned by a relative of an employee involved in the decision-making process

#### CONSIDER THE FOLLOWING SCENARIOS:

Your spouse works as a Healthcare Provider (HCP) at a hospital where they have authority over some purchasing decisions. Your company is attempting to sell products to his hospital.

#### Can you sell to his hospital?

This is a potential conflict of interest between your interests and those of your Company and Business Partners. You must disclose all possible conflicts of interest in advance.



You are considering hiring a new sales representative. While still undecided, you get a call from a well-known health care professional who is also an important customer. He tells you that his son has just graduated from medical school and would be a great asset to your company. You agree to interview him and find him not to be an ideal candidate for the role.

#### Should you hire him?

No. It is not clear that there is a legitimate need or business justification for the potential new sales position. The HCP's son is not an ideal candidate for the position. Hiring the HCP's son, even if he were an ideal candidate, would create a conflict of interest because of his connection to an HCP customer.

#### **REMEMBER:**

Candidates for any position must disclose any actual or potential conflict of interest to Management, Compliance, Human Resource, and/or Legal. If you are not certain if a conflict of interest exists, you can always contact your employer's Legal, Compliance, and/or HR department for assistance.



### **CONFLICT OF INTEREST DECLARATION**

**WHAT is a Conflict of Interest?** Conflict of interest occurs when a personal activity, relationship or business involvement interferes — or appears to interfere — with our ability to fulfill our job responsibilities.

WHY it matters: The way we conduct ourselves in our business dealings impacts our reputation and the trust we maintain with stakeholders. By discouraging and avoiding conflicts of interest, we send a clear message about our loyalty to our Company's integrity and our determination to do what's right.

**HOW we do it:** We make business decisions based on what is in the best interest of our Company and not for personal gain or benefit. We require all employees to proactively and promptly disclose actual or perceived conflicts of interest.

Any activity which even appears to present such a conflict must be avoided or terminated unless, after disclosure to the appropriate level of management, it is determined that the activity is not harmful to the Company or otherwise improper.

This form is to be completed by any employee who has a real or perceived conflict of interest or a potential conflict of interest in undertaking their obligations to the company.





To:

Date of declaration:

**Employee name:** 

Company name:

(not applicable if employee conflict)

**Contact name:** 

Please provide a brief outline of the nature of the conflict (details may be included privately in a separate confidential envelope if appropriate)

I hereby confirm that the disclosure made above are complete and correct to the best of my information and belief.

Employee Signature

To be completed by company management:

Document how this conflict was addressed by the company:

Reviewed by:

Name Title Signature

Date
PREVENTING BRIBERY & CORRUPTION



Bribery and corruption are global issues and are taken seriously by governments worldwide. Bribery of Government Officials is a crime under local and international laws and regulations, for example, the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act, among others.





### **Corruption is not limited to**

**bribery.** Global and local anti-corruption laws prohibit activities including, but not limited to, embezzlement, extortion, and the hiring or advancement of certain people for private or political gain.

- You are responsible for following <u>all</u> applicable anti-bribery and anti-corruption laws.
- Failing to follow anti-bribery and anti-corruption laws can result in severe civil and criminal penalties as well as reputational harm for your company and business partners.



Global companies have been found responsible for inappropriate actions taken by their business partners around the world to gain an improper business advantage. For example, in 2012, a global medical device company was fined \$22 million USD by U.S. authorities for paying bribes through business partners in Europe to win business.





### **Product Training: Part 1**

- You are hosting a Product Training Meeting on an established product.
- An important key opinion leader will be leading the course. This is the first time he will deliver training on this product.
- The majority of the Health Care Professionals (HCPs) attending the meeting live 2-hours or less away from the event.
- The sales representative for each HCP participant wants to attend the meeting. This would make the ratio of sales representatives to participants about 1:5 (one sales rep to five HCPs).
- The marketing manager for the product wants to attend to evaluate the key opinion leader training ability.

### How many sales and marketing people should attend the meeting?





### **Product Training: Part 2**

- You are hosting a Product Training Meeting on an established product.
- An important key opinion leader will be leading the course. This is the first time he will deliver training on this product.
- The majority of the Health Care Professionals (HCPs) attending the meeting live 2-hours or less away from the event.
- The sales representative for each HCP participant wants to attend the meeting. This would make the ratio of sales representatives to participants about 1:5 (one sales rep to five HCPs).
- The marketing manager for the product wants to attend to evaluate the key opinion leader training ability.

### How many sales and marketing people should attend the meeting?

Commercial personnel may attend product training meetings when participating in the educational and training experience as a co-learner with the HCP to assist in the teaching and training activity.

Sales personnel who are customarily present in the surgical or operating room environment may need to participate to understand the instructions given to HCPs concerning the proper use of the device.

Your company must ensure the attendance of sales personnel does not detract from or interfere with the educational experience of the HCP. It is important to ensure that training meetings do not look like sales/promotional meetings. A large number of commercial employees at a training can lead to this appearance. It is important to assess if the commercial personnel who want to attend have a legitimate need or business reason to do so and if they can achieve their goal at another event/venue/meeting.



### **Conference Booth: Part 1**

- You are interested in purchasing a booth at a medical conference hosted by a reputable third party.
- The meeting will be attended by a key customer group.
- The meeting is at a full-service tropical resort.
- The meeting starts late Friday afternoon and goes through Sunday.
- About 40% of the agenda is focused on educational activities.
- The educational activities end by 3:00PM each day and are followed by recreational options.

#### Should you purchase the booth space?





### **Conference Booth: Part 2**

- You are interested in purchasing a booth at a medical conference hosted by a reputable third party.
- The meeting will be attended by a key customer group.
- The meeting is at a full-service tropical resort.
- The meeting starts late Friday afternoon and goes through Sunday.
- About 40% of the agenda is focused on educational activities.
- The educational activities end by 3:00PM each day and are followed by recreational options.

#### Should you purchase the booth space?

**No.** When deciding if you should purchase a booth, you need to consider the following:

- Perception of your participation at the event
- Benefit your company may receive (ability to speak to a unique set of HCPs, good attendance by target customer group, etc.).
- Requirements of your local industry code of conduct
- Balance of recreational vs educational activities
- Location



### **Customs Official: Part 1**

You are waiting for a shipment of medical device products. A government customs official tells you he'll speed up the import paperwork for an additional fee of \$50 USD. What should you do?

- A. Pay the additional fee to ensure timely shipment of the products as the amount doesn't seem to be high.
- B. Do nothing and hope for the best.
- C. Refuse to pay the fee and report the request immediately.





### **Customs Official: Part 2**

You are waiting for a shipment of medical device products. A government customs official tells you he'll speed up the import paperwork for an additional fee of \$50 USD. What should you do?

- A. Pay the additional fee to ensure timely shipment of the products as the amount doesn't seem to be high.
- B. Do nothing and hope for the best.
- C. Refuse to pay the fee and report the request immediately.

#### The correct answer is C.

You should not make payments to expedite routine government services, or make unofficial, unauthorized payments to Government Officials in connection with their duties. You will never be penalized for making a good faith report of inappropriate or potentially inappropriate conduct, and you should report this kind of behavior to [insert compliance contact] immediately.



### **Procurement Officer: Part 1**

You are participating in a tender on behalf of a medical device manufacturer. The hospital's procurement officer tells you she will select your company to win the tender if you give her spouse a job in your company. What do you do?

- A. This type of request is customary in my country, so I arrange the spouse's employment to gain the business for the medical device manufacturer.
- B. I refuse to employ the procurement officer's spouse and report the request immediately.
- C. I decline the request because I know it isn't appropriate but don't tell anyone what happened.I don't want her to get in trouble.





### **Procurement Officer: Part 2**

You are participating in a tender on behalf of a medical device manufacturer. The hospital's procurement officer tells you she will select your company to win the tender if you give her spouse a job in your company. What do you do?

- A. This type of request is customary in my country, so I arrange the spouse's employment to gain the business for the medical device manufacturer.
- B. I refuse to employ the procurement officer's spouse and report the request immediately.
- C. I decline the request because I know it isn't appropriate but don't tell anyone what happened.I don't want her to get in trouble.

#### The correct answer is **B**.

Bribery takes many forms, including hiring a relative or friend of a decision maker in return for receiving a favor. You must never accept or agree to a favor in exchange for business even if it is considered "normal" or "customary" in your country of business. You will never be penalized for making a good faith report of inappropriate conduct and should report this kind of behavior to [insert compliance contact] immediately.



### **PREVENTING BRIBERY & CORRUPTION**



Bribery & corruption are global issues and are taken seriously by governments worldwide. Bribery of Government Officials is a crime under local and international law; for example, the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act, among others.

Corruption is not limited to bribery. Global and local anti-corruption laws prohibit activities including, but not limited to, embezzlement, extortion, and the hiring or advancement of certain people for private or political gain.

Global companies have been found responsible for inappropriate actions taken by their distributors around the world to gain an improper business advantage. For example, in 2012 a global medical device company was fined \$22M USD by U.S. authorities for paying bribes through distributors in Europe to win business.

You are responsible for following **ALL** applicable local & international anti-bribery and anti-corruption laws.

Failing to follow anti-bribery and anti-corruption laws can result in severe civil and criminal penalties as well as reputational harm for you as an individual, your company & business partners.

#### PUTTING IT INTO PRACTICE...

• You are participating in a tender on behalf of a medical device manufacturer. The hospital's procurement officer tells you she will select your company to win the tender if you give her spouse a job in your company.

• You are waiting for a shipment of medical device products. A government customs official tells you he'll speed up the import paperwork for an additional fee of \$50 USD.

#### WHAT SHOULD YOU DO?

For both scenarios, you should refuse the request and report the request immediately. No payments should be made to expedite routine government services, nor should unauthorized payments be made to Government Officials in connection with their duties.

It's important to note that bribery takes many forms; it is not always financial in nature. Hiring a relative or friend of a decision maker in return for receiving a favor is also a bribe. You must never accept or agree to a favor in exchange for company business even if it is considered "normal" or "customary" in your country of business.

You will never be penalized for making a good faith report of inappropriate conduct, and you should report this behavior to your employer immediately.



### SELF CERTIFICATION FORM

TITLE:	Self-Certification of Compliance with applicable Anti-Bribery and Anti-Corruption Laws, Regulations, Industry Codes, and Company Code of Conduct
PURPOSE:	Use this document to ask your employees, sub-distributors and other business partners to self-certify compliance with applicable Anti-Bribery and Anti-Corruption Laws, Regulations, Industry Codes, and Company Code of Conduct
Please read each of t sign and date the ce	the statements below and then initial each for the certification purposes. When you are finished, rtification.
Initials:	
	• I certify that have received, understand, and will abide by the Code of Conduct and Business Principles provided to me.
	I certify that will comply with all Compliance policies and procedures applicable to me of that have been provided to me.
	• Furthermore, have not and will not, directly or indirectly, pay, offer, promise or authorize the giving of any money or anything of value to any Government Official, any employee or official of a commercial or nonprofit entity in which a government body has any ownership interest or the ability to control ("Instrumentality"), or any official, partner or employee of a public international organization ("Official") either:
	i. for the purpose of influencing any act or decision of such Official in his, her or its official capacity or inducing such Official to do or omit to do any act in violation of the lawful duty of such Official; or
	ii. for the purpose of inducing such Official to use his, her or its influence with a foreign Government or any organization; to affect or influence any act or decision of a Government organization; in order to assist Company in obtaining, retaining business or directing business or securing any improper business advantage.
	• I understand responsibility to promptly report any actual or suspected violations of the law, regulations, or policies and procedures through the appropriate channels, as local laws allow.
	• I certify that have reported any actual or suspected violations of the law, policies and procedures through the appropriate channels, as local laws allow.
First, Last Name and Title (printed):	
Signature:	
Date and location:	



### SPONSORSHIP OF A THIRD-PARTY MEETING

TEMPLATE GUIDANCE			
Type of templates	Sponsorship of a Third-Party Meeting		
Templates	<ul> <li>There are two templates needed when providing financial support to a third-party meeting:</li> <li><b>1. Sponsorship Request</b> – To document the details of the support request and document approval of this support.</li> <li><b>2. Sponsorship Agreement</b> – To document your support of the event with the organiser of the event.</li> </ul>		
Process	<ul> <li>Customise the highlighted sections. Do not make any other changes to the template. Be sure to delete these directions and fill in the brackets [] and highlighting before sending.</li> <li>Adjust to reflect local laws and industry codes, as required.</li> <li>Delete any sections that do not specifically apply.</li> </ul>		



### **SPONSORSHIP REQUEST FORM**

GLOBAL DISTRIBU	TOR
<b>COMPLIANCE</b> TOO	LKIT

REQUEST FORM		
Choose the type of sponsorship	Booth Space Advertising/Promotion Catering costs of an educational meeting Audio-visual costs of an educational meeting Demonstration product for an educational meeting Other	
Provide details of the funding, equipment or services to be provided		
	REQUESTING ORGANIZATION	
Organization Name		
Contact Person		
Address		
ZIP / City		
Country		
Phone / Fax-Numbers		
E-Mail		
Provide a description of the organization's educational or scientific purpose		
State the specific purpose of the requested funds		
APPROVAL PROCESS		
Please send this form compl	leted to	
ADDITIONAL DOCUMENT	ATION	
Include any request letters r	eceived from the requesting organization.	
CERTIFICATION		
I further certify that the func	on provided is true and complete to the best of my knowledge after reasonable investigation. ding is not being offered or provided as a price concession, reward to favoured customers or prescribe or purchase Company products or services, and is not be tied in any way to past, npany products or services.	
Signature:	Date:	
APPROVAL (CEO/CFO/CC	:O/ETC.)	
I approve the support being	provided as detailed above:	
Signature:	Date:	



### **SPONSORSHIP AGREEMENT**

This Agreement is entered into between and the

on

#### BACKGROUND

wishes to provide, and the

the Sponsorship for the Sponsorship Purpose, on and subject to the below:

wishes to accept,

AGREEMENT DETAILS			
Agreement Date			
<b>Company Name</b> Entity providing Sponsorship			
Company Number			
Address			
Contact Person			
<b>Event organiser</b> <i>Receiving the Sponsorship</i>			
Type of Party receiving the Sponsorship	Professional Conference Organizer	Health Care Organization	Professional Association / Society
Name			
Address			
Contact Person			
	Type of Sponsorship	Currency	Total Amount
Sponsorship			



### **SPONSORSHIP AGREEMENT**

	AGREEMENT DETAILS continu	led
Sponsorship Purpose	The Sponsorship is to support medical training and education of healthcare professionals at the Event and for providing the Deliverables (the "Sponsorship Purpose").	
Event Details Note: If more	than one event then please list all events	
Dates	Start Date End Date	
Title of Event		
Location of Event		
Venue of Event		
Area of Specialty		
Deliverables	Describe the obligations to be provided by the Organizer to in exchange for the Sponsorship.	
	The Institution will, in consideration for the Sponsorship, and at no additional cost or expense to , provide	
	• booth space	
	• symposia space	
<ul> <li>advertisement to be published on [insert website/journal];</li> </ul>		website/journal];
	<ul> <li>recognize support by published materials relating to the Event</li> </ul>	in all printed, electronic and as agreed between the parties.
	The Institution will be responsible for the cont faculty, educational method and materials.	rol and selection of the program content,
Payment Terms	Payment will be made within days of the by all parties and upon receipt by	date of the signing of the Agreement of an invoice.
Territory	Country where incorporated	

The above details are agreed to by both parties:

Signature	Signature
Name	Name
Date	Date
Title: Authorized Representative	Title: Authorized Representative



### **GRANT OR DONATION**

TEMPLATE GUIDANCE		
Type of communication	Agreeing to a Grant or Donation Request.	
Templates	<ul> <li>There are two types of templates needed when completing a grant or donation request:</li> <li>1. Grant/Donation Request - To request approval internally to provide a grant or donation.</li> <li>2. Grant/Donation Agreement - To document your donation or grant agrrement with the recipient of the funds.</li> </ul>	
Type of activity	Grant or Donation	
Recipients	Grant or Donation Recipient Organization	
Process	• Customise the highlighted sections. Do not make any other changes to the template. Be sure to delete these directions and fill in the brackets [] and highlighting before sending.	
	<ul> <li>Adjust to reflect local laws and industry codes, as required.</li> <li>Delete any sections that do not specifically apply to the Product Training.</li> </ul>	
	<ul> <li>Document internal approval to fulfil the Grant or Donation request using the Grant/Donation Request form.</li> </ul>	
	• Send the Grant/Donation Agreement to the recipient organization for completion.	
	• Retain a copy of the completed forms for your records.	





GRANT & DONATION TYPES (SUBJECT TO LOCAL LAWS, REGULATIONS & INDUSTRY CODES)		
Туре	Description	Qualified Recipient
Charitable Donation	Financial or in-kind support provided to a non-profit or charitable organisation to further the legitimate and documented objectives of the organisation, and/or to support genuine fund-raising drives for projects undertaken by the organization	Non-profit or charitable organization that is registered under the laws of the applicable country and entitled to receive the donation
Educational Grant - Healthcare Education	<ul> <li>Financial or in-kind support for bona fide educational activities for HCPs</li> <li>May include grants to third party conference organisers to reduce conference costs and/or to fund reasonable honoraria, travel, lodging and meals for HCPs that are bona fide conference faculty.</li> <li>May not be used to fund parties, entertainment or similar events (e.g. sporting or cultural events, city tours, musical performances).</li> </ul>	Healthcare institutions or organisations for accredited or non-accredited healthcare education
Educational Grant - Scholarships/ Fellowships	Financial support for extended medical education programs, such as scholarships and fellowships	Training institutions, healthcare institutions or professional societies
Educational Grant - Research	Financial, in-kind or free product support for clinical or non-clinical research in areas of legitimate interest to the Company	Healthcare institutions or research-based organisations
Educational Grant - Public Education	Financial or in-kind support of education of patients or the public about important healthcare topics	Training institutions, healthcare institutions or professional societies
Grant of Medical Equipment, Materials, Supplies, or Educational Materials	Medical textbooks, subscriptions to medical publications, anatomical models or similar	Training institutions, healthcare institutions or professional societies

### **GRANT/DONATION REQUEST FORM**

#### GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT

REQUEST FORM			
Choose the grant or donation type (see attached list for more details)	Charitable Contribution Healthcare Education / Public Education Fellowship / Scholarship	Research Medical Equipment, Supplies, etc. Other	
Provide details of the funding, equipment or services to be provided			
	REQUESTING ORGANIZATION		
Organization Name			
Contact Person			
Address			
ZIP / City			
Country			
Phone / Fax-Numbers			
E-Mail			
Provide a description of the organization's charitable, educational or scientific purpose			
State the specific purpose of the requested Grant or Donation	<ul> <li>Education: describe the type of educational event, date, location, name and attach any available brochures or printed information; identify the intended target audience:</li> <li>Fellowship: provide the dates, details and location of the program, cost breakdown and provide any available materials, including application forms:</li> <li>Research: provide a description of the study objectives, deliverables, and other available details:</li> <li>Equipment: provide a description of the equipment to be purchased, cost estimate, supplier, intended use and location of use:</li> <li>Charitable Donation:</li> </ul>		
APPROVAL PROCESS			
Please send this form comp	leted to		
ADDITIONAL DOCUMENTATION			
Include any request letters r	eceived from the requesting organization.		
CERTIFICATION			
I confirm that the information provided is true and complete to the best of my knowledge after reasonable investigation. I further certify that the grant or donation is not being offered or provided as a price concession, reward to favored customers or inducement to recommend, prescribe or purchase Company products or services, and is not be tied in any way to past, present or future use of Company products or services.			
Signature:	Date:		
APPROVER (CEO/CFO/CC			
I approve the grant/donatio	n being provided:		
Signature:	Date:		



### **GRANT/DONATION AGREEMENT**

Re:		
Dear		
We have received your request from to be used for the purpose of	for	
understands that	is involved in	
and will use the support for the performance of thes receive the funding, and that the receipt of the supp or organizational policies.		confirms that it is entitled to e any applicable rules, laws, regulations
agrees that the support is reasonate excessive or above fair market value.	able and appropria	te to fulfill the stated purposes and is not
has evaluated the request and will pr	ovide the funding,	as it is intended to
		g given in exchange for the use,
recommendation, prescription, or influence on the us volume of business generated between the parties.	se of	products, or with regard to the value or
To ensure appropriate transparency, at all relevant times and in all relevant materials.	agrees that	support must be clearly disclosed
Please confirm your agreement with and acceptance returning the signed agreement to me.	of the details in tl	nis agreement by signing below, and
Kind regards,		
Name of authorized representative	Name of a	authorized representative
Signature	Signature	

Date



### **DUE DILIGENCE QUICK CHECK**

Due diligence is the investigation or exercise of care that a business or person is expected to take before entering into an agreement or contract with another party.

If appointing additional business partners to facilitate the sale and/or marketing and promotion of products, it is expected that you will perform a level of due diligence on potential distributors or other sales intermediaries. This means collecting important information about the business, the key persons associated with it, and the prospective business relationship. This will help to ensure that the Intermediaries are qualified, competent and reliable, and that they have high ethical standards and are committed to compliance with applicable laws, rules, regulations and the Company Code of Conduct (or equivalent).

The following list represents information that can be useful in evaluating whether a relationship with a potential third party is appropriate. The following is not prescriptive and should be modified to your company's program.

IE BUSINESS	
Company name, address, registration number	Things to consider:
Years in business	<ul> <li>Does this business have a good reputation in the community</li> </ul>
Number of employees, customer-facing	What does a quick internet search reveal about them?
employees	Are they appropriately staffed?
Key financial information (sales, profit, assets and liabilities)	<ul> <li>Will they be able to make the required payments as they become due?</li> </ul>
Banking reference (name & contact information)	• Has the entity been convicted or accused of any civil
Trade references (names & contact information)	or criminal litigation?
Credit rating (if available)	<ul> <li>Are there any anti-corruption regulations enforcements against the company or individuals?</li> </ul>
Y PERSONS	
Major shareholders or partners	Things to consider:
General manager	<ul> <li>Do these individuals have a good reputation in</li> </ul>
Key finance person	the community?
Key legal person	• What does a quick internet search reveal about them?
	• Are any of them government officials?
	• Are any of them related to any government officials?
	<ul> <li>Do any of them have known conflicts of interest with their customers?</li> </ul>
OSPECTIVE RELATIONSHIP	
Products to be sold to this distributor	Things to consider:
Estimated annual sales, the first year and	Would products be exported to another country?
the following 2-3 years	(If so, please seek authorization for these transactions
Territory and targeted end-customers	from the primary supplier of the products.)
	<ul> <li>Would this party be willing to operate under the ethics and compliance requirements in the Distributor Code of Conduct</li> </ul>

# KEEPING GOOD BOOKS & RECORDS



Companies are required to maintain accurate financial records.

#### You must:

- Accurately and fully describe transactions in your records
- Keep accurate and transparent records of all expenses
- Itemize products and promotional activities in your records

#### You must not:

- × Create false records or documentation
- × Create false accounts
- × Hide payments or gifts in the cost of product or discounts offered
- × Provide false documentation or other false information
- Create intentionally vague descriptions to hide improper payments or expenses
- × Mischaracterize payments



### **Documenting Dinner: Part 1**

You arrange a modest dinner with a current customer to discuss legitimate business matters related to medical device products. After the dinner, you ensure that all of the information related to the interaction is properly documented. <u>What are some best practices?</u>

- A. Consult your company's guidelines for keeping complete and accurate records or contact [insert company contact] for guidance to make sure you have everything you need.
- B. Gather the dinner receipt and information related to the customer, the date, and the business purpose of the meal and if applicable, provide the documentation to the individual responsible for recording transactions in your company.
- C. Follow up with the individual(s) responsible for recording the transaction in your company's records and double check your entry to ensure it is documented completely and accurately.
- D. All of the above.



### **Documenting Dinner: Part 2**

You arrange a modest dinner with a current customer to discuss legitimate business matters related to medical device products. After the dinner, you ensure that all of the information related to the interaction is properly documented. What are some best practices?

- A. Consult your company's guidelines for keeping complete and accurate records or contact [insert company contact] for guidance to make sure you have everything you need.
- B. Gather the dinner receipt and information related to the customer, the date, and the business purpose of the meal and if applicable, provide the documentation to the individual responsible for recording transactions in your company.
- C. Follow up with the individual(s) responsible for recording the transaction in your company's records and double check your entry to ensure it is documented completely and accurately.
- D. All of the above.

#### The correct answer is D.

A great way to ensure you have complete and accurate records is to consult your guidelines for recording expenses relating to interactions with HCPs, Government Officials and other customers. Make sure to keep a copy of the itemized receipt from the dinner or interaction and document the date, attendees and purpose of the meeting. Timely provide this information to the individual responsible for keeping records and follow up with them or check your records to ensure they were documented completely and accurately.

You can always contact [insert company contact] with questions or to request guidance.

### **Hiding Illegal Payments**

A Distributor partnered with a Marketing Services Company. Several months after the partnership was formed, the Distributor audited the Company's transactions and discovered a section for "marketing payments" in the Company's books and records that had been used to facilitate improper payments to health care professionals. Company employees were using these accounts to bribe employees of the Ministry of Health. Payments were also made to employees from state owned companies with influence over purchasing decisions related to the Company's products.

After finding these payments inside the Company's books and records, the Distributor terminated all other marketing accounts to stop this practice.

Seasonal books and records audits are a good risk mitigation measure to detect the use of accounts hidden in books and records to commit crimes like fraud or to hide illegal payments to government officials.





### **Financial Controls & Bookkeeping**

A distributor was found to have participated in various corrupt schemes hidden under financial transactions to obtain business illegally. These include:

- Signing storage contracts with a company owned by the sons of the military's top medical device procurement officer to provide warehousing space where no products were ever stored.
- Signing consultancy agreements with publicly employed doctors for which no services were ever performed.
- Entering into fake collection commission agreements while making payments to a government charity and giving gifts and paid travel to publicly employed doctors without documented business or educational purposes.



### **Financial Controls & Bookkeeping**

In court, the distributor admitted that it failed to implement internal accounting controls and maintain comprehensive books and records. Bribes were paid through a combination of direct payments and sub-distributors.

Keeping strong internal controls on financial transactions and maintaining accurate books and records that reflect daily transactions in organizations are essential for remaining compliant with local laws, regulations and industry codes of conduct.



### **KEEPING GOOD BOOKS & RECORDS**

Companies are required to maintain accurate record keeping practices. Accurate books and records are crucial to the success of your business in addition to complying with local laws, regulations and industry codes.



#### YOU MUST:

- Accurately and timely describe transactions in your records
- Keep accurate and transparent records of all expenses
- Itemize products and promotional activities
- Maintain reliable and transparent records of cash transactions

#### YOU MUST NOT:

- Create intentionally vague or misleading descriptions to hide improper payment or expenses
- X Create false accounts
- X Mischaracterize payments
- X Hide payments or gifts in the cost of products or discounts offered
- X Create and/or provide false documentation or other false information

#### **CONSIDER THIS...**

You arrange a modest dinner at an appropriate venue with a current customer to discuss legitimate business matters related to your company's products. After the dinner, you ensure that all the information related to the interaction is properly documented.



#### What are some best practices?

- Consult your company's guidelines for keeping complete and accurate records to make sure you have everything you need.
- Gather the itemized dinner receipt and information related to the customer, the date, and the business purpose of the meal and if applicable, timely provide the documentation to the individual responsible for recording transactions in your company.
- Follow up with the individual(s) responsible for recording the transaction in your company's records and double check your entry to ensure it is documented completely and accurately.



### **EXPENSE REIMBURSEMENT FORM**

#### NOTE:

All of the following information is required for expensing reasonable and legitimate meals/entertainment (please note that entertainment is prohibited for meetings/events/activities in relation with HCPs/GO/HCOs/Government Institutions):

1. Date

- 2. Name of guest/s (please note that for meetings/events/activities with HCPs/GO it is prohibited to faciliate, arrange, or pay for guests)
- 3. Title of guest
- 4. Name of guest's company
- 5. Type of expense, i.e. dinner, lunch, etc.
- 6. Location name
- 7. Location city
- 8. Business justification/purpose, i.e., topics discussed
- 9. Amounts all itemized receipts must be attached.

Note that applicable local, regional laws, regulations and industry best practices codes must be considered when interacting with HCPs/GO/HCO's/Government Institutions.

#### Employee First & Last Name:

Date:

Employee Signature	Date	Print First & Last Name
1anager Signature	Date	Print First & Last Name
inance Signature	Date	Print First & Last Name

Total Reimbursement Requested:



item #	Date	Type of Expense	Amount	HCP/ GO-related expense? Yes/No	Number of Company Attendees	Company Attendee Name	Company Attendee Job Title	Number of HCPs/GOs Attendees	HCPs/GOs First & Last Names, Titles, Hospital Name	Any other Attendees? Yes/No	If yes, indicate First & Last Name, Title, Institution/Company
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											



item #	Date	Type of Expense	Amount	HCP/ GO-related expense? Yes/No	Number of Company Attendees	Company Attendee Name	Company Attendee Job Title	Number of HCPs/GOs Attendees	HCPs/GOs First & Last Names, Titles, Hospital Name	Any other Attendees? Yes/No	If yes, indicate First & Last Name, Title, Institution/Company
19											
20											
21											
22											
23											
24											
25											
26											
27											
28											
29											
30											
31											
32											
33											
34											
35											
36											



### **NOTIFICATION ON USE OF SUB-DISTRIBUTORS**

The undersigned, representative of "Your Company Name", confirms on behalf of the Company that in accordance with the Distribution Agreement executed between the Company and effective (the "Agreement") the below sub-distributors are proposed by the Company to provide activities under the Agreement.

#### **Information of the Sub-Distributor(s):**

Full Name:

**Business Address:** 

**Business Registration Number:** 

**Contact Person:** 

Activities to be Provided:

**Rationale of Appointment:** 

Name

Signed For and on behalf of

Date



### **KEEPING GOOD BOOKS & RECORDS** SUMMARY GUIDANCE

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#### Description

Companies must maintain books and records that accurately and completely reflect their business transactions. The Books and Records Guidance outlines best practices to ensure appropriate supporting documentation is retained for business transactions, including those high-risk transactions (e.g., involving government officials, healthcare professionals, etc.).

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#### Purpose

Maintaining accurate books and records will help you record business transactions in reasonable detail and help maintain an adequate system of internal accounting controls. Accurate books and records will assist your business with planning, budgeting, reporting and allocating resources.

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<b>[</b> ]	
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	•

#### **Related Resources**


## **KEEPING GOOD BOOKS & RECORDS**

Transactions must be recorded timely and accurately in order to assess our company's financial position. Detailed records and supporting documentation are required to evidence the business purpose of our transactions and ensure our books and records are complete and accurate. Supporting documentation includes, but is not limited to, items such as: invoices, receipts, agreements, amendments, and approval forms. Alteration, falsification and destruction of required books and records are serious violations.

#### **1. BENEFITS OF ACCURATE BOOKS AND RECORDS**

Maintaining accurate books and records that reflect the nature of transactions are beneficial as it allows us to make better business decisions, quickly respond with proper documentation in the case of an audit, and separate transactional information for each of the manufacturers for which we sell product.

#### 2. CASH PAYMENTS

Limiting the amount of cash or cheques used as a form of payment in any transaction is best practice. To the extent that cash is the only option for payment specific documentation must be retained for company records such as detailed receipts.

#### **3. SUPPORTING DOCUMENTATION REQUIREMENTS**

Complete supporting documentation should be retained for all transactions. Here are some examples:

#### a. Employee Expense Reports

- i. Expense approvals.
- ii. Original itemized receipts.
- iii. Explanation of the business purpose for each expense.

#### b. Disbursements (e.g., payments to vendors, suppliers, etc.)

- i. Contracts, written agreements and addendums.
- ii. Purchase orders.
- iii. Invoices detailing amounts, dates of service and the types of services
- and/or products received
- iv. Internal approvals.
- v. Proofs of performance (e.g., delivery notices, materials, presentations).
- vi. Proof of payment (e.g., cancelled check, bank statement, wire transfer advice).
- vii. Correspondence.

#### c. Grants, Donations and Sponsorships

- i. Documentation to evidence the request and business justification (e.g., HCP invitation letter prior to transaction / proposal, program agenda, etc.).
- ii. Transportation, lodging and meal documentation.

#### d. Sales Orders

- i. Customer purchase orders.
- ii. Sales invoices (identifying any free goods, rebates, discounts and their related approvals).
- iii. Shipping documentation.
- iv. Price listings inclusive of any provided discounts.
- v. Evidence of payment received from the customer.

INTERACTING WITH HEALTHCARE PROFESSIONALS & GOVERNMENT **OFFICIALS** 



Whenever interactions with Healthcare Professionals (HCPs) or Government Officials (GOs) involve payments, meals, travel, or any other benefit to an HCP, you must ensure that the benefits are legal under all applicable laws and regulations, supported by a legitimate and documented business need, and allowed under the written agreement with you.



The benefits should not exceed what is necessary to conduct the interaction and must never be given as a reward for business or as a condition for future sales or referrals.

When interacting with HCPs and GOs, be aware of "red flags" that may be evidence of potential corruption. For example, an HCP and/or GO:

- Proposes linking payments to volume of purchases
- Mentions personal relationships with government entity/official
- Has a questionable reputation
- Guarantees you success in a public tender or bidding contract
- Requests payments outside his/her country
- Declines to provide proper receipts for expenses



## All of your interactions with HCPs and GOs should be grounded in **five general principles**:

You may <u>not</u> provide anything of value to an <u>HCP/GO in</u> exchange for, or as a reward for past, present or future business. Any interactions with an HCP/GO must be supported by a legitimate, clearly defined business need and allowed under the Written Agreement with you. You may only engage HCP/GOs whose expertise and experience are appropriate given the business need. All financial interactions with HCP/GOs must be consistent with relevant agreements, and compensation for these interactions must be reasonable for the local market.

All financial interactions with HCP/GOs must be recorded accurately and in reasonable detail.



### Meals

### What you may do:

 You may offer modest and infrequent business-related meals to HCPs and GOs.

### Tips for a compliant interaction:

- Keep the focus on the business or educational purpose.
- Choose a modest restaurant where you can have an effective discussion.
- Ensure the meal's cost will be within your company's internal meal limit.
- Do not provide meals to the personal guest of an HCP or GO.
- Discourage HCPs or GOs from bringing personal guests to a meal.
- Keep itemized receipts



## **Gifts & Entertainment**

You may **not**:

- × Provide gifts to the personal guest of an HCP or GO.
- × Provide entertainment or recreation to an HCP or GO.
- × Provide cash or cash equivalents such as gift certificates to an HCP or GO.



### **Charitable Donations**

Companies and their representatives may make monetary and in-kind donations to support bona fide charitable organizations and missions, provided that the donation is not intended as an inappropriate inducement and does not privately benefit an HCP.



## **Sponsorship of an Individual HCP**

You may sponsor an individual HCP to a third-party educational conference or product training and medical education meeting, ONLY if allowed by local laws, regulations and industry codes.



## **Sponsorship of an Individual HCP**

You should ensure any event or meeting meets these criteria:

- The meeting agenda is focused on scientific or educational topics relevant to the HCP's specialty
- The location of the meeting is modest and appropriate
- Your sponsorship for this meeting does not contribute to entertainment or recreational activities



### **Educational Grants**

Companies and their representatives may provide grants for legitimate educational purposes including grants to support medical education, the education of patients about important healthcare topics and to support thirdparty educational conferences



## **Public Tenders**

What you may do:

 Bid on tenders for Company products where permitted under your company's internal procedures and contract with the manufacturer of your medical device products. Tips for a compliant interaction:

- Act fairly.
  - Do not collaborate with tender authorities in a way that would compromise fairness of the process.
  - Follow fair competition laws and do not collude with competitors.

- Do not provide gifts, donations, or anything of value to try to influence the tender specifications, documentation or decision.
- Do not submit "false bids" to try to influence the tender's decision.



## **Demonstration Products & Samples**

You may provide demonstration, sample and evaluation products at no cost to HCPs as follows:

### **Demonstrations:**

Capital equipment or singleuse product used to demonstrate the appropriate use and functionality of the product to HCPs excluding use on patients.

### Samples:

Single-use products provided to HCPs to enable them to evaluate a product's effects on a patient or in conjunction with a patient procedure.

### **Evaluations:**

Capital equipment or singleuse products provided to HCPs as part of a formal evaluation to assess product features, performance and functionality on patients or inpatient procedures.



## **Demonstration Products & Samples**

You may **not** provide free of charge products:

- X To reward or compensate individual HCPs or healthcare institutions for past purchases, future purchase commitments, or in exchange for marketing information or alleged product deficiencies.
- X That have not been approved or cleared by the local regulatory authority in that market, unless specifically authorised by applicable law in the market.
- × For an unapproved use of the product.



### **Example Scenarios**

ACTION	RESPONSE
Provide an educational grant to a hospital to gain favour with the tender committee to select the products that you sell.	This is <u>improper</u> . You may not provide gifts, grants, donations, or anything of value to tendering authorities to try to influence the tender decision, materials or documentation.
Regularly offer meals to a healthcare professional after a surgery because he appreciates the gesture.	This is improper. You may not regularly provide meals to an individual HCP. You may provide infrequent meals to healthcare professional or government officials if they are offered as part of a legitimate business or educational interaction.



### **Example Scenarios**

ACTION	RESPONSE
Sponsor a healthcare professional to product training in a city outside of his region because he wants to vacation there after the training.	This is <u>improper</u> . You may not use an educational event to facilitate a healthcare professional's family trip or vacation. You cannot send him because he wants to visit a city or country, even if he pays for his own hotel room for the personal days. You may only sponsor a healthcare professional if he has a legitimate educational need for attending.
Give an educational grant to an individual healthcare professional who is the head of a medical association.	<b>This is <u>improper</u>.</b> You may not give a grant or donation to an individual healthcare professional or government official.



## **Business Dinner: Part 1**

- You are planning a business meeting over dinner with some key customers during an important conference.
- Several restaurants are already booked because of the conference.
- You found one restaurant that has availability.
- A respected and independent reviewer has ranked the restaurant as one of the top five in the city.
- The restaurant only offers a fixed four-course meal with a wine pairing for per person.

## Should you choose this restaurant for the business dinner with the HCPs?



## **Business Dinner: Part 2**

- You are planning a business meeting over dinner with some key customers during an important conference.
- Several restaurants are already booked because of the conference.
- You found one restaurant that has availability.
- A respected and independent reviewer has ranked the restaurant as one of the top five in the city.
- The restaurant only offers a fixed four-course meal with a wine pairing for per person.

## Should you choose this restaurant for the business dinner with the HCPs?

There are several things to consider in deciding whether to choose this restaurant including the following:

- Local industry code requirements for venues and hospitality limits
- If your manufacturer permits you to undertake this activity and if they impose hospitality limits
- It is recommended you choose a more modest restaurant to avoid public scrutiny or defer the meeting to another time
- If the HCPs are also government officials, they may not be permitted to accept these courtesies



## Small Talk: Part 1

During a business dinner with a respected HCP, he says to you:

As you know, I have used your company products for a long time. I plan to use my knowledge to educate other doctors and I would be happy to use your products in those surgeries if you can compensate me for my efforts. I'll send you further details next week. I am counting on receiving good news from you.

### How should you respond?



### Small Talk: Part 2

During a business dinner with a respected HCP, he says to you:

As you know, I have used your company products for a long time. I plan to use my knowledge to educate other doctors and I would be happy to use your products in those surgeries if you can compensate me for my efforts. I'll send you further details next week. I am counting on receiving good news from you.

How should you respond?

I am not permitted to offer you any benefit as a reward for business or as a condition of future sales. This could be a violation under the Foreign Corrupt Practices Act or local antibribery laws and could be considered corruption. There are very serious penalties that both you and I could face in this instance.



## Small Talk: Part 3

During a business dinner with a respected HCP, he says to you:

As you know, I am very involved in a local charity that services the community. A donation of 50,000 USD would go a long way in helping us fulfill our charitable mission.

What should you do?



### Small Talk: Part 4

During a business dinner with a respected HCP, he says to you:

As you know, I am very involved in a local charity that services the community. A donation of 50,000 USD would go a long way in helping us fulfill our charitable mission.

What should you do?

Reply to the HCP that you are not permitted to provide a donation to a charity of any HCP's choice as this could be seen as a bribe under the Foreign Corrupt Practices Act and local anti-bribery legislation.



## **Travel Request: Part 1**

An HCP customer of your medical device products asks you to pay for travel to a medical device manufacturer's office to attend a hands-on technical device training. The customer also requests that the itinerary include a side trip to a popular vacation destination. **How should you respond?** 

- A. Pay for the entire trip, because it is for a legitimate purpose.
- B. Ask a travel agency to pay for the customer's entire trip and then reimburse the travel agency.
- C. Pay for the customer's trip to the medical device manufacturer's office if there is a legitimate business need for this HCP to attend the training but refuse to pay for the side trip because it is not related to the business purpose of the travel.



### **Travel Request: Part 2**

An HCP customer of your medical device products asks you to pay for travel to a medical device manufacturer's office to attend a hands-on technical device training. The customer also requests that the itinerary include a side trip to a popular vacation destination. **How should you respond?** 

- A. Pay for the entire trip, because it is for a legitimate purpose.
- B. Ask a travel agency to pay for the customer's entire trip and then reimburse the travel agency.
- C. Pay for the customer's trip to the medical device manufacturer's office if there is a legitimate business need for this HCP to attend the training but refuse to pay for the side trip because it is not related to the business purpose of the travel.

### The correct answer is C.

Paying for the travel expenses of HCPs is permitted when there is a legitimate purpose or need and is allowable according to your company's internal procedures and contract with the manufacturer of your medical device products. Side trips that do not have a legitimate business purpose are never permissible. You can always contact [insert company contact] if you need more guidance on what is allowable when interacting with HCPs.



## **Concert Tickets: Part 1**

Mary wants to offer a gift to the team of nurses at the hospital where she has business.

She decides to give everyone a "modest" ticket for a concert that costs only USD 60 per person.

Question: Is Mary allowed to do that?



### **Concert Tickets: Part 2**

Mary wants to offer a gift to the team of nurses at the hospital where she has business.

She decides to give everyone a "modest" ticket for a concert that costs only USD 60 per person.

Question: Is Mary allowed to do that?

No. Only items that have a genuine educational function or benefit patients, such as textbooks, if *modest* in value and in accordance with local laws are allowed. It is important to ensure it is not and will not be perceived by others to be a potential means of corrupt influence.



### **State Monument: Part 1**

The sister of an employee of the Ministry of Health sits on the Board of Directors of a charitable organization that donates various funds to philanthropic purposes throughout the country.

The organization requested a USD 10,000 donation from your company for the refurbishment of a state monument, in exchange for a private dinner meeting with the Ministry of Health.

Question: Should you make a contribution to the organization?



### State Monument: Part 2

The sister of an employee of the Ministry of Health sits on the Board of Directors of a charitable organization that donates various funds to philanthropic purposes throughout the country.

The organization requested a USD 10,000 donation from your company for the refurbishment of a state monument, in exchange for a private dinner meeting with the Ministry of Health.

**Question:** Should you make a contribution to the organization?

No. Charitable donations should never be given in exchange for undue influences. Remember, that the anti-corruption laws prohibitions also extend in some instances to the spouses and family members of Government Officials.



## Free Samples: Part 1

You've just met the Director of Purchasing of Mother & Life Prenatal Center. The meeting went well and the Director told you that there was a special government project to open ten prenatal centers across the country.

The director along with his team is looking to appoint several experienced companies to supply medical and surgical equipment and consumables. He asked you to provide him with product samples (the value is approximately USD 3,000).You agreed and rushed back.

The finance team in your company tells you that the free samples have individual prices ranging from USD 200 to USD 500.

Question: Is it correct to proceed with this request?



### Free Samples: Part 2

You've just met the Director of Purchasing of Mother & Life Prenatal Center. The meeting went well and the Director told you that there was a special government project to open ten prenatal centers across the country.

The director along with his team is looking to appoint several experienced companies to supply medical and surgical equipment and consumables. He asked you to provide him with product samples (the value is approximately USD 3,000). You agreed and rushed back.

The finance team in your company tells you that the free samples have individual prices ranging from USD 200 to USD 500.

Question: Is it correct to proceed with this request?

You may provide customers a limited number of sample products for evaluation purposes in accordance with local laws, regulations and industry codes. The provision of samples should not result in personal benefit to any HCP or GO.



### INTERACTING WITH HEALTHCARE PROFESSIONALS & GOVERNMENT OFFICIALS

Whenever interactions with Healthcare Professionals (HCPs) or Government Officials (GOs) involve payments, meals, travel, or any other benefit to an HCP or GO, you must:



Ensure that the benefits should not exceed what is necessary for the interaction and must never be given as a reward for business or as a condition for future sales or referrals.

Be aware of "red flags". For example, an HCP and/or GO:

- Proposes linking payments to volume of purchases
- Mentions personal relationships with government entity/official
- Has a questionable reputation
- Guarantees you success in a public tender or bidding contract
- Requests payments outside his/her country
- Declines to provide proper receipts for expenses

#### Let's put it into practice...

- **Q:** An HCP customer of XYZ Corporation products asks you to pay for travel to a XYZ Corporation office to attend a hands-on technical device training. The customer also requests that the itinerary include a side trip to a popular vacation destination. How should you respond?
- A: Pay for the customer's trip to the XYZ Corporation office if there is a legitimate business need for this HCP to attend the training, but refuse to pay for the side trip because it is not related to the business purpose of the travel. Paying for the travel expenses of HCPs is permitted when there is a legitimate purpose and need, and is allowed under their contract with the company. Side trips that do not have a legitimate business purpose are never permissible.
- **Q:** During a business dinner with an HCP, he says to you, "As you know, I have used your products for a long time. I plan to use my knowledge to educate other doctors and I would be happy to use your products in those surgeries if you can compensate me for my efforts. I'll send you further details next week. I am counting on receiving good news from you." How should you respond?
- A: Tell the HCP that you are happy he has had a great experience using your company's products for years; however, the company does not compensate HCPs as a reward for an explicit or implicit agreement to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe company products. You should then report this interaction to your company's head of ethics and compliance.



## **MEETING, EVENT OR TRAINING**

	TEMPLATE GUIDANCE
Type of communication	Inviting a Health Care Professional (HCP) to attend a Meeting, Event or Training
Templates	There are three types of templates needed when inviting an HCP to a Meeting, Event or Training:
	1. Approval – to seek approval within your company
	2. HCP Invitation - to extend an invitation to an HCP to attend
	3. Employer Notification - to notify the HCP's employer (requirement depending on local laws, regulations or industry codes)
Recipients	HCP & HCP Employer
Process	• Customise the highlighted sections. Do not make any other changes to the template. Be sure to delete these directions and fill in the brackets [] and highlighting before sending.
	Adjust to reflect local laws and industry codes, as required.
	• Delete any sections that do not specifically apply to the Meeting, Event or Training.
	• Document internal approval to invite an HCP to a Meeting, Event or Training using the Approval form.
	• Send the HCP Invitation to the HCP you would like to invite to attend a Meeting, Event or Training.
	• Send the Employer Notification to the HCP's employer and copy the HCP invited to the Meeting, Event or Training (requirement depending on local laws, regulations or industry codes).
	Retain a copy of the completed forms for your records.



### **APPROVAL**

INFORMATION			
Title		Dates	
Location & Venue		Venue costs (if applicable)	
Description			
ATTENDEE INFORMA	TION		
HCP attendees	List name and employer of HCP atte	ndees:	
TRAVEL EXPENSES			
Total HCP <b>estimated</b> travel costs	• Airfare: • Train fare: • Ground:	Total HCP <b>actual</b> travel costs	• Airfare: • Train fare: • Ground:
HCP travel class (if not economy/ coach class)	For HCPs who are <b>not</b> traveling economy/coach, indicate HCP name and reason for travel class selected:		
ACCOMMODATIONS	(IF APPLICABLE)		
Hotel name		Hotel location	
Total <b>estimated</b> hotel costs		Total <b>actual</b> hotel costs	
Reason for hotel selection			
MEALS			
Total <b>estimated</b> meal costs	<ul><li>Number of meals per event</li><li>Price per meal</li></ul>	Total <b>actual</b> meal costs	<ul><li>Number of meals per event</li><li>Price per meal</li></ul>
OTHER COSTS			
Total <b>estimated</b> costs		Total <b>actual</b> costs	
APPROVAL PROCESS	; ;		
Please send this form c	completed to		
ADDITIONAL DOCUM	IENTATION		
Include program detail	s or agenda, etc.		
COMPLETER CERTIFI	CATION		
I confirm that the inform	nation provided is true and complete t	to the best of my knowle	edge after reasonable investigation.
Signature:		Date:	
REVIEWER CERTIFIC	ATION (CEO/CFO/CCO/ETC.)		
I approve the support k	peing provided to the HCPs listed:		
Signature:		Date:	



### **HEALTHCARE PROFESSIONAL INVITATION**

Dear
------

is pleased to invite you to attend

This

is relevant to your area of medical expertise and will provide

Please see the attached agenda for further details.

This invitation is not being extended in exchange for the use, recommendation, prescription, or influence on the use of products, or with regard to the value or volume of business generated between the parties. Per Code of Conduct, we do not offer anything of value.

We hope that you find this to be informative and useful. If you require any further details concerning our invitation, please contact

Best regards,

cc:



## **EMPLOYER NOTIFICATION**

Dear

has invited

to attend

This will provide Please see the attached agenda for further details.

This invitation is not being extended in exchange for the use, recommendation, prescription, or influenceon the use ofproducts, or with regard to the value or volume of business generatedbetween the parties. PerCode of Conduct, we do not offer anything of value.

We will provide the following:

- Reasonable meals and refreshments during the
- Transportation to and from the
- Reasonable accommodation from

If you approve of this activity, no action is required. If we do not receive a reply from you, we will assume that you approve of our offer to invite to

#### If you do not approve of this activity, please contact

stating your disapproval.

Please provide your response by

Best regards,



## **HEALTHCARE PROFESSIONAL SIGN-IN SHEET**

Date

Location

**Trainer Name** 

NAME	POSITION	E-MAIL	SIGNATURE



## INTERACTING WITH HEALTH CARE PROFESSIONALS AND GOVERNMENT OFFICIALS

### CODE OF CONDUCT

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#### Description

The Code of Conduct establishes fundamental guidance on how to conduct business in compliance with your company's commitment to ethical and lawful behavior. This Code of Conduct can be used as a sample to formally structure a code of conduct for your company.

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#### **Purpose**

The Code of Conduct helps your employees, officers and directors to ensure business is conducted in an ethical, lawful and appropriate manner. Adopting a Code of Conduct provides greater confidence to your business partners and global stake holders.

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#### Instructions

- 1. Customize the Code of Conduct according to your company's needs.
- 2. Provide the Code of Conduct to all officers, directors, employees (including new employees at time of hiring) and all relevant business partners, such as sub distributors and agents.
- 3. Ensure employees understand their duties and responsibilities as it relates to your company's commitment to ethical and lawful conduct.
- 4. Ensure the Code of Conduct is posted and/or accessible to all employees.
- 5. Train your employees on the Code of Conduct and keep training records.



#### **Related Resources**



### CODE OF CONDUCT

#### Introduction

is committed to maintaining the highest ethical standards in the execution of our business duties while complying with all applicable laws and regulations. This document is not intended to be a substitute for more detailed policies that relate to standards of conduct, if applicable.

reputation is important. employees shall not engage in any misconduct that could jeopardize the Company's reputation, its client, or third-party relationships, as well as avoid situations that have any appearance of impropriety. No bribes should be offered, requested, paid or accepted. [*This paragraph should be customized to your Company's vision, mission and values*]

Company resources should only be used for legitimate business purposes in the best interest of Incidents, risks and issues contrary to this document should be reported to

The Code of Conduct will apply to all officers, directors, employees (including new employees at time of hiring) and all relevant business partners, such as sub distributors and agents.

#### **Basic Principles**

#### **1. COMPLIANCE WITH LAWS**

will conduct its business and affairs in compliance with all applicable laws, rules and regulations and in accordance with Code of Conduct and its underlying policies and procedures.

#### 2. CONFLICT OF INTEREST

A conflict of interest occurs when a person's private interest interferes or appears to interfere in any way with interests and may also arise when the Company, employee, director, or a member of his or her family receives improper benefits because of his or her position within . These situations include, but are not limited to, relationships with government officials, health care professionals, health care organizations, physician owned companies, or any other situation where it may appear that company decisions can be influenced by personal interests or relationships. You should avoid a conflict, or an appearance of a conflict, between your personal interests, your official responsibilities and your Company's interests. Any potential conflict of interest should be declared.

#### **3. FAIR DEALING**

All employees will deal with 's customers, suppliers, competitors and independent auditors in a fair and transparent way and will not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information or misrepresentation of facts. Even the perception of unlawful conduct should be avoided, including inappropriately disclosing pricing, costs, production, products and services, bidding practices, other nonpublic business matters, and sales territories.

Tenders require a transparent, fair and equal bidding process. must not collaborate with a tendering authority in the creation or interpretation of tender materials or documentation in a way which could compromise fairness of the process.

#### 4. PROMOTIONAL ACTIVITIES, MARKETING AND SALES

will represent its products and services accurately and will comply with applicable regulatory and legal requirements including applicable industry codes including governing the marketing and sale of products and services.



#### 5. RECORDING AND REPORTING INFORMATION

will record and report all information completely and accurately in the books, records and accounts in a timely manner and in reasonable detail.

#### **6. IMPROPER PAYMENTS**

Improper payments mean unlawful or with a corrupt intent.

Payments in cash or kind or in the form of anything of value to government officials with the purpose of obtaining an improper business advantage are considered improper payments and are prohibited.

Improper payments can also be payments of low value intended to expedite or facilitate routine bureaucratic processes.

#### 7. INTERACTING WITH HEALTH CARE PROFESSIONALS AND GOVERNMENT OFFICIALS

Whenever interactions with Government Officials or Healthcare Professionals (HCPs) involve payments, meals, travel, or any other benefit to an HCP, will ensure that the benefits are legal under all applicable laws and regulations, supported by a legitimate and documented business need, and allowed under the written agreement.

Any interactions with an HCP/GO must be supported by a legitimate, clearly defined business need and allowed under the written agreement.

may only engage HCP/GOs whose expertise and experience are appropriate given

the business need.

All financial interactions with HCP/GOs must be consistent with relevant agreements, and compensation for these interactions must be reasonable for the local market.

#### COMPLIANCE

#### **1. ROLES AND RESPONSIBILITIES**

It is every employee's responsibility to understand and comply with the Code of Conduct and to report any potential violation of policy or law, including violations raised by third parties.

#### 2. COMMUNICATIONS AND TRAININGS

Owners, officers, directors and managers must communicate the Code of Conduct to ensure that all employees and relevant business partners understand and comply with the policies herein.

Each employee will receive relevant training and new employees will be trained upon hiring. Employees will be required to confirm in writing that they understand and comply with these policies and will report any violations that comes to their attention.

#### **3. REPORTING**

Any violation of the Code of Conduct must be reported immediately to Reporting may be anonymous if allowable by local law and will not be subject to retaliation of any sort.

Failure to comply with the Code of Conduct may result in disciplinary action according policies, up to and including termination of employment, where appropriate.

### KEY AREAS OF GLOBAL COMPLIANCE







Recognizing Government Officials

Identifying Conflicts of Interest



Preventing Bribery & Corruption



Keeping Good Books & Records



Interacting with Health Care Professionals & Government Officials



Reporting a Concern



Interacting with Health Care Professionals & Government Officials



### Do and Dont's

It's important that all interactions with HCPs and Government Officials are in accordance with all local laws, codes, and regulations. Let's look at some Dos and Don'ts when interacting with HCPs and Government Officials.

## DO

- Respect medical decision making
- Hold business meetings and meals at appropriate venues; perception matters
- Ensure there is a genuine business need for interacting with an HCP or Government Official
- Maintain records that accurately detail and support anything of value (e.g travel, lodging) provided to or by HCPs or Government Officials
- Ensure an appropriate contract is in place before engaging third parties for services
- Contact Compliance if you are unsure about any interaction with an HCP or Government Official



## **DON'T**

- Provide anything of value in exchange or as a reward for past, present, or future business
- ★ Provide gifts or entertainment
- ➤ Hold meetings or business meals in extravagant restaurants or entertainment venues
- ➤ Provide sample or demonstration product in unreasonable quantities
- Provide anything of value not directly related to a documented business need
- ★ Make pre-determined commitments about services or payment for services without a contract in place



## Know where to find resources

Familiarize yourself with available resources, such as the **Global Distributor Compliance Toolkit**. Understand the Compliance requirements of the companies for which you distribute products. Make compliance resources available to all employees of your company and promote an ethical culture.

Compliance matters. We protect patients by acting with integrity in our interactions with HCPs and Government Officials.

#### **CONTACT US**

## REPORTING A CONCERN



## **Reporting a Concern**

Any violation must be reported immediately to

Individuals may make a report by

We will make sure <u>no retaliatory action</u> is taken against anyone who reports, in good faith, actual or suspected misconduct.

We take reported allegations seriously.



## **REPORT A CONCERN**

Everyone is responsible for ethical business practices. If you suspect a potential violation of the law or have a concern about unethical business practices, we want to hear about it. We take reported allegations seriously. All reported concerns will be treated as confidential to the extent possible.

$\bigcirc$	Name
$\sum$	Email
E	Call
	Website

We do not tolerate retaliation of any kind against individuals who report matters in good faith.

