

BAIRD

Distributor Training

Training Topics

- Why Compliance with Global Anti-Bribery Laws Matters
- What is Bribery
- Risks to Medical Device Companies and Distributors
- Minimizing Anti-Bribery Risk
- Examples and Q&A

Why Compliance with Global Anti-Bribery Laws Matters

Why Compliance with Global Anti-Bribery Laws Matters

- Bribery is prohibited by law:
 - Local criminal, civil and administrative laws of countries where you do business
 - Some national laws prohibit bribery by companies, their employees, distributors and agents wherever they conduct business
- Violation of anti-bribery laws can:
 - Lead to termination of contracts with manufacturers, local governments and other companies
 - Lead to criminal prosecution of distributors under: (i) local laws; and (ii) the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act or other national laws
 - Lead to additional civil and administrative penalties, lawsuits and debarment from government contracting
- Companies may have additional compliance and business procedures that must be followed

What is Bribery?

What is a Bribe?

- Offer, payment, promise or agreement to pay, authorization of payment, or receipt of payment
- Directly or indirectly
- Of “anything of value”
- To or by a government official or a private party
- For the purpose of obtaining or retaining business or securing any improper business advantage

Prohibited Payments

- Promise, offer, agreement or authorization of a bribe
 - Actual payment or receipt of a bribe is not necessary
 - An offer to pay a bribe is enough to face criminal liability
- A bribe paid through a third party is still a bribe
 - Distributors may be prosecuted for bribes made directly or indirectly through a sub-distributor, agent or other third party

Prohibited Payments

- Bribes Can Come in the Form of “Cash” or “Anything of Value”
 - Examples: Cash or cash equivalents, favorable pricing, discounts, rebates, loan forgiveness or assistance, entertainment, travel, gifts, gratuities, charitable contributions, free product, political contributions, meals, *if provided for an unlawful purpose*, may be considered unlawful payments under applicable laws.
- Even small value items can be bribes
 - If the item is intended to improperly influence the recipient’s decision-making or provide a competitive advantage

Knowledge and Intent

- A bribe includes:
 - A payment made or offered
 - While knowing or having reason to know
 - That all or a portion of the money or thing of value
 - Is intended to improperly influence the recipient's judgment or actions
- Knowledge includes:
 - Actual knowledge
 - Awareness or suspicion that a bribe is likely to be paid
 - Deliberate ignorance, willful disregard of payments, or trying to “avoid” knowledge that a bribe will be paid
- You may commit a crime if you have reason to know that a bribe will be paid by another person, and you do nothing to stop it

Improper Influence

- Bribes include payments intended to influence the recipient to:
 - Act or fail/omit to do any act in violation of his or her official duties
 - Influence discretionary decision-making of the recipient
 - Assist in obtaining or retaining business
 - Direct business to any person or entity
 - Secure any improper competitive advantage
- Examples include:
 - Purchasing or using product
 - Issuing a government license or permit
 - Special tax or customs treatment

Recipients of Bribes

You must not engage in any activity that would be considered a bribe or an illegal kickback – regardless of the intended recipient

Government Officials

- Employees of or anyone in an official capacity in any government owned or controlled entity
 - Includes doctors, nurses, pharmacists, or contracting officers in government owned or controlled hospitals, universities, laboratories, and research centers
- All employees of any government agency or department, regardless of position/rank
- Any candidate, elected, appointed, or career official
- Employee of a public international organization
- Note: Prohibited payments may not be made to the children, spouse, close relatives or other close affiliates of any Government Official

Commercial Parties

- Anti-bribery laws also prohibit;
 - Bribes to commercial parties
 - Receiving illegal kickbacks

Local Law Variations

- Anti-bribery laws vary by country
- You must consult your company business partner if you have questions about applicable law requirements
 - **Customs and practices are not sufficient to avoid liability**
- Facilitating or “Grease” Payments
 - Payments to facilitate, expedite or secure the performance of routine, non-discretionary government action
 - **Not allowed** by many national laws or Bard’s policies

Promotional Activity

- Legitimate promotional activity is allowed provided it is:
 - Permitted under local law
 - Reasonable and bona fide
 - Directly related to the product sales or service of a contract
 - In an amount that covers only the costs actually incurred
 - Properly recorded in books and records

Expenses

Can:

- Pay for reasonable and bona fide business expenses related to:
 - Training and education to enhance the safe and effective use of medical technologies
 - Promotion of products and services
- Pay for modest meals during business meetings
- Support bona fide medical research and education

Cannot:

- Be for an improper purpose
- Be unrelated to legitimate promotional purposes
- Be lavish
- Pay for visits to tourist attractions
- Pay for entertainment and recreation
- Pay for family members
- Pay a per diem if also paying for meals and other expenses

Consult with Bard for specific rules.

Additional limitations regarding both categories may be applicable based on local laws.

Accurate Recordkeeping

- 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 **may 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

Risks to Medical Device Companies and Distributors

Risks of Anti-Bribery Law Violations



Risks of Criminal Actions

- Possibility of criminal prosecution against:
 - Distributors and their agents
 - Companies
 - For direct or indirect payments through distributors or other third parties
 - UK government may prosecute companies for failing to prevent bribery
 - Individuals
- Possible criminal penalties vary by country and may include:
 - Jail sentences for individuals
 - Significant financial fines and penalties
 - Actions by multiple countries
 - Requirement of future reporting to the government or monitoring by the government of company business

Other Serious Consequences

- Litigation, such as:
 - Civil enforcement proceedings
 - Shareholder lawsuits
 - Business partner or third party litigation
 - Business competitor claims that the bribery caused them to lose business
- Loss of business and future business uncertainty
 - **Termination of distribution contract**
 - Debarment or exclusion from government contracting
- Costly investigation and litigation fees
- Public embarrassment and damage to corporate brand
- Loss of employees
- Credit line and insurance risk

Other Serious Consequences

Bard can and will exercise its right to TERMINATE any distribution agreement in the event that Bard determines that the Distributor's actions on behalf of Bard were in violation of the FCPA or local laws governing bribery and corruption!

Minimizing Anti-Bribery Risk

Steps to Limit Anti-Bribery Risk

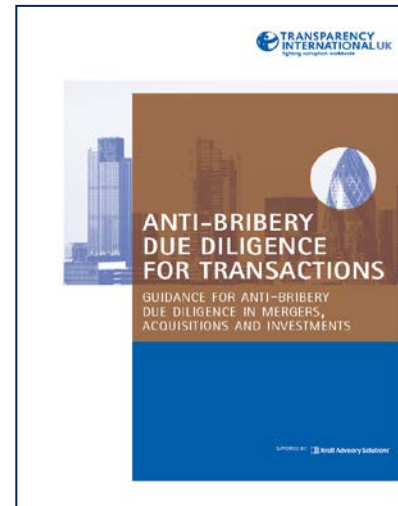
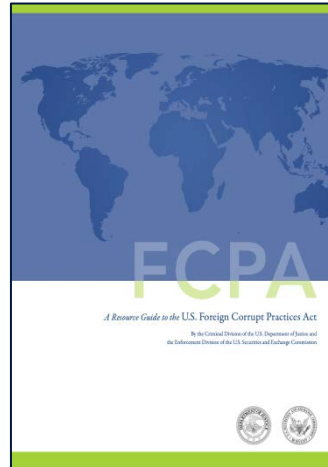
- Understand applicable anti-bribery laws and prohibited activity
- Ask questions
- Discuss specific anti-bribery risks
- **Do Not Bribe!**

Examples of resources – industry codes

- AdvaMed Code of Ethics
- Eucomed Code of Ethical Business Practices
- National Codes of Ethics



Examples of Resources – Guidance by International Organizations



[OECD Home](#) > [Directorate for Financial and Enterprise](#)

Anti-bribery convention

> Competition
> Corporate affairs
Bribery in international business
> Financial markets, insurance and pensions
> International investment
> Private sector development

[Home](#) > [Advocacy codes and rules](#) > [Areas of work](#) > [Corporate Responsibility and Anti-corruption](#) >

ICC Rules on Combating Corruption



The Rules assist enterprises to comply with their legal obligations and with the numerous anti-corruption initiatives at the international level.

First published in 1977 and just significantly revised in 2011, these flagship ICC Rules outline the basic measures companies should take to prevent corruption. These ICC Rules are intended as a method of self-regulation by international business and constitute what is considered good commercial practice in fighting corruption.

The ICC Rules on Combating Corruption respond directly to the G20's call and to UNCAC's requirement that business step up its efforts to fight against corruption.

The 2011 edition of the ICC Rules for Combating Corruption consists of three parts:

- Part I states the Rules proper;
- Part II deals with policies which Enterprises should enact to support



Examples of Resources

- National Anti-Bribery Statutes/laws
- Guidance by National Governments. Examples include:
 - U.S. Department of Justice
 - U.K. Serious Fraud Office

C. R. Bard Policies and Procedures

Bard's Distributors must:

1. Fully complete diligence questionnaire before appointment
2. Pass company due diligence investigation
3. Sign contract containing anti-corruption provisions
4. Certify annual compliance with contractual provisions

C. R. Bard Policies and Procedures

1. Complete questionnaire before contract and renewal of contract
 - Proposed distributors must complete detailed questionnaire
 - Questionnaire requests names of employees, ownership structure, commercial references, and relationships with government officials
 - Certify ability to comply with Bard's *Business Ethics Policy*

C. R. Bard Policies and Procedures

PROPOSED REPRESENTATIVE QUESTIONNAIRE

The following information will assist Bard in assessing the qualifications of _____ ("Proposed Representative") to act as a Bard Representative in the country of _____. Your cooperation in completing this form is important to Bard and is greatly appreciated. Please attach additional sheets of paper as needed.

A. General Background

1. Name of Proposed Representative:
Name of Principal Contact:
Address:
Telephone:
Fax:
Email:
Website:
2. Year established:
3. Registration number:
Please attach a copy of your government registration certificate or similar document.
4. Type of entity:
 Publicly-traded company Partnership Individual
 Privately-owned company Government-owned company
 Other (describe)

Distributors & Other Third Parties: Bard Policies

2. Pass company due diligence investigation

- Bard conducts a thorough due-diligence investigation of each of our Distributors, including reviewing publicly available information and contacting references

Distributors & Other Third Parties: Bard Policies

3. Sign contract containing anti-corruption provisions

- All Bard contracts with third parties include anti-corruption provisions:
 - no third-party employees or agents are or will become government officials
 - government officials directly or indirectly has ownership in third party
 - third-party employees or agents will not give anything of value to government officials on behalf of Bard to influence decisions or promote Bard's interests

Distributors & Other Third Parties: Bard Policies

3. Sign contract containing anti-corruption provisions (continued)

- third party will notify Bard if it receives notice from any government about possible violation
- third party will maintain accurate books and records
- Bard has right to audit books
- Bard has right to terminate if breached

Distributors & Other Third Parties: Bard Policies

this Agreement to use the corporate names, trademarks, brand names and other names, set out in that Trademark Use Policy (the "Trademarks") for the sole purpose of promoting, marketing and selling the Products in the Territory. Distributor acknowledges that, except for the limited license rights granted in this Section, it shall not acquire any rights in respect of any such Trademarks and that all such rights and goodwill are, and shall remain, vested exclusively in Bard and/or its affiliates. Distributor acknowledges receipt of a copy of the current Trademark Use Policy if the box on the Cover Sheet has been checked. Distributor shall, when referring to the Trademarks, diligently comply with all relevant law, rules and regulations in force in the Territory and with all instructions provided by Bard. Distributor shall not, by any act or omission, cause or contribute to the deterioration of a Trademark or adversely affect Bard's or its affiliates rights in a Trademark.

14. OTHER INTELLECTUAL PROPERTY. Distributor shall promptly notify Bard of any actual, threatened or suspected infringement in the Territory of any copyright, trademark or other intellectual property rights of Bard and/or any of its affiliates, and of any claim by any third party that the importation of the Products into the Territory, or their sale or use in the Territory, infringes any rights of any other person or entity. Bard shall have the exclusive right to determine what action, if any, shall be taken with respect to any such matters and to take such actions as it deems appropriate. At Bard's request and expense, Distributor shall assist Bard in taking or resisting any proceedings in relation to any such infringement or claim.

15. CONFIDENTIALITY. Distributor acknowledges and agrees that all Bard Information is confidential and proprietary to Bard. Distributor shall keep completely confidential, shall not publish or otherwise disclose and shall not use directly or indirectly for any purpose (other than as permitted or required for performance by Distributor hereunder) any Bard Information. As used herein, "Bard Information" means all information, other than information in published form or expressly designated by Bard as non-confidential, which is directly or indirectly disclosed to Distributor or embodied in Products provided hereunder, regardless of the form in which it is disclosed, relating in any way to Bard's markets, customers, products, inventions, procedures, methods, designs, strategies, costs, revenues, profits, trade secrets, organization, employees, agents, distributors or business in general. This Section shall survive the expiration or termination of this Agreement for a period of five (5) years.

16. COMPLIANCE AND GOOD ETHICAL PRACTICES. Distributor represents, warrants and covenants to Bard, as of the date hereof and as of each date that an order for products or an invoice for services is submitted to Bard, that (a) in carrying out its responsibilities under this Agreement, neither Distributor, nor any of its equity holders, partners, officers, directors, employees,

representatives, or agents, shall: (i) directly or indirectly, offer, pay, promise to pay, or authorize the payment of any money, or offer, give, promise to give, or authorize the giving of anything of value to (A) any official or employee of any government, or any department, agency, or instrumentality thereof, (B) any political party or official thereof, or to any candidate for political office, or (C) any official or employee of any public international organization, in each case for the purpose of influencing any act or decision of such official, employee, party or candidate, or inducing such official, employee, party or candidate to do or omit to do any act in violation of the lawful duty of such official, employee, party or candidate, or securing any improper advantage for Bard, or inducing such party, official, or candidate to use its or his influence with a foreign government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, or otherwise promoting the business interests of Bard in any respect; or (ii) directly or indirectly, offer, give, pay, promise to pay, or authorize the payment of anything of value, on behalf of Bard, to an officer, employee, agent, or representative of another company or organization, without that company's or organization's knowledge and consent, with the intent to influence the recipient's action with respect to his or her company's business, or to gain a commercial benefit to the detriment of the recipient's company or organization; (b) no payment, promise to pay, authorization, offer or gift of the sort described in this Section has been made in connection with the promotion of the business interests of Bard; (c) no official or employee of any government, or of any agency or instrumentality of any government, or of any political party, or of any public international organization, and no candidate for public office, owns, or during the term of this Agreement shall own, directly or indirectly, any shares or other beneficial interest in Distributor; (d) Distributor has not received any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority at any time in the last five (5) years regarding Distributor's actual, alleged, possible or potential violation of, or failure to comply with, any laws, regulations or industry codes governing bribery, money laundering, or other corrupt payments and, to its best knowledge, Distributor is not now, and has not been at any time in the last five (5) years, the subject of any governmental investigation, audit, suit or proceeding (whether civil, criminal or administrative) regarding its violation of, or failure to comply with, any such laws, regulations or industry codes; and (e) except as disclosed in an attachment to this Agreement, none of Distributor's partners, officers, directors, employees, representatives, or agents is, or without the prior written notice to Bard will become, an official or employee of any government, or of any department, agency or instrumentality of any government, or of any political party, or of any public international organization, or a candidate for public office.

Distributors & Other Third Parties: Bard Policies

4. Certify annual compliance with contractual provisions

- information provided in questionnaire is still current and correct (or update information)
- no employee or agent has offered or given anything of value to government officials on behalf of Bard to influence decisions or promote Bard's interest
- has not received any notice or subpoena from any government related to corruption

Distributors & Other Third Parties: Bard Policies

C. R. BARD REPRESENTATIVE'S ANNUAL CERTIFICATION

INSTRUCTIONS: Please complete the form below, attach a copy of your completed Questionnaire, and return to Bard.

I _____ certify, represent and warrant on behalf of my company _____ ("Representative") that:

1. I am authorized to make the representations and warranties contained herein and to execute this certification on behalf of Representative.
2. Representative previously completed and submitted a "Proposed Representative Questionnaire" dated _____ ("Questionnaire"). A copy of the completed Questionnaire is attached to this Certification.
3. I have carefully reviewed the attached Questionnaire. Except as noted in the attached sheet, all of the information in the Questionnaire is **correct and unchanged** as of this date. (If any information needs to be updated, please attach a separate sheet noting any changes.)
4. Bard has provided me with a copy of "What Every Bard Representative Must Know ~~about~~ Bard's Anti-Corruption Compliance Policy".
5. With respect to services provided to Bard, neither Representative nor any director, officer, employee, partner, agent, representative, or shareholder thereof has, directly or indirectly, paid, promised to pay, or authorized the payment of any money, or given, promised to give, or authorized the giving of anything of value to (i) any health care professional, including any doctor, nurse, hospital administrator, or university medical professor; (ii) any official or employee of any government, or of any agency or instrumentality of any government; (iii) any political party or official thereof; (iv) any candidate for political office; or (v) any official or employee of any public international organization, in each case for the purpose of influencing a purchasing or prescribing decision, influencing any other official act or decision, securing any improper advantage, or otherwise promoting the business interests of Bard in any respect.
6. Representative has not received any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority regarding Representative's actual, alleged, possible or potential violation of, or failure to comply with, any laws, regulations or industry codes governing bribery, money laundering, or other corrupt payments and, to its best knowledge, Representative is not the subject of any governmental investigation, audit, suit or proceeding (whether civil, criminal or administrative) regarding its violation of, or failure to comply with, any such laws, regulations or industry codes.
7. Representative has complied with and will continue to comply with all applicable laws, regulations and industry codes governing bribery, money laundering, and other corrupt payments.