

Distributor Training Tool



This training tool was prepared by Amy Conway-Hatcher of Kaye Scholer LLP,
in consultation with the Joint AdvaMed and Eucomed Distributor Working Group.

Disclaimer and Purpose of Distributor Training Guide

- This training tool is prepared in consultation with, and for the benefit of, AdvaMed and Eucomed and their member companies to facilitate training of distributors and other third parties involved in the marketing or sale of medical device products.
- The tool is provided to AdvaMed and Eucomed member companies solely for informational purposes and should not be construed as providing recommendations, endorsements or legal advice to any company, distributor or other party.
- The tool is intended as a general guide and is not tailored to specific risks. Companies should, as appropriate, adjust, shorten or complement the content of the tool to address specific risks presented by the region, business, third party or activity.
- To facilitate the use of this tool, Kaye Scholer, in consultation with AdvaMed and Eucomed and their member companies, has prepared additional guidance that is available along with the tool.

Disclaimer and Purpose of Distributor Training Guide

- The tool and guidance should be read with:
 - Guidance for Training Tool
 - AdvaMed and Eucomed Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships
 - The Third Party SMI Common Questionnaire (coming soon)
 - AdvaMed Code of Ethics on Interactions with Healthcare Professionals
 - Eucomed Guidelines on Interactions with Healthcare Professionals
- The content of the tool is made as of the date of the tool’s issue and is subject to change without notice.

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 (con't)

- 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 and company internal Codes of Conduct
 - You **must consult** with your company business partners to determine the rules **before making or considering facilitating payments**

CANADIAN ANTI-CORRUPTION LAW:

Corruption of Foreign Public Officials Act (COFPA)

- Passed in 1998. 2013 Amendments strengthen effectiveness of the Act.
- Greater focus on investigating and prosecuting as a result of activities.
- Contrasted with the FCPA Jurisdiction is more limited in that the activities must have a real and substantial link to Canada.
- 2013 Amendments make it clearer that Canadian companies' activities in foreign jurisdictions are subject to the COFPA. Applies to both Canadian companies and Canadian based subsidiaries.
- Also public international organizations and non-profits. Illicit accounting records to hide a payment or advantage are covered under the COFPA.
- Sanctions are criminal (no civil remedy in the COFPA) and investigation and charges laid only by the Royal Canadian Mounted Police.

CANADIAN ANTI-CORRUPTION LAW:

Corruption of Foreign Public Officials Act (COFPA)

- Breach of COFPA is an indictable offence (greater penalty) and maximum prison term increased from 5 to 14 years.
- Offence occurs when a loan, reward, advantage or benefit of any kind is given to a foreign public official in consideration of either an act or omission by the official in connection with the official's duties or functions or to induce the official to do so.
- Not an offence if payment is made as required by the laws of the foreign state or public international organization for which the official performs duties or where good faith expenses are paid to the public official to promote or explain the products or services of the Canadian Company or the execution or performance of a contract between the company and foreign state the public official performs duties for.
- The exemption for facilitation payments is to be repealed and eventually eliminated. The amendments providing for this are not yet in force.

Australia & New Zealand

Australia:

- Attorney General's Department information: foreign bribery
- Medical Technology Industry Code of Practice

New Zealand:

- Crimes Act 1961
 - Part 6: Crimes affecting the administration of Law & Justice
- Fair Trading Act 1986
 - Part 1: Misleading & Deceptive Conduct, False Representation, Unfair Practices

Promotional activities

- 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 company business partner for specific rules.

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

Accurate record keeping

- 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
- Damage to corporate brand
- Loss of employees
- Credit line and insurance risk

Minimizing Anti-Bribery Risk

Steps to limit Anti-Bribery Risks

- Training and education
- 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



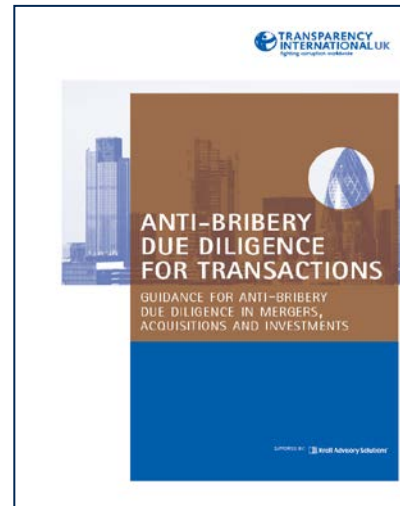
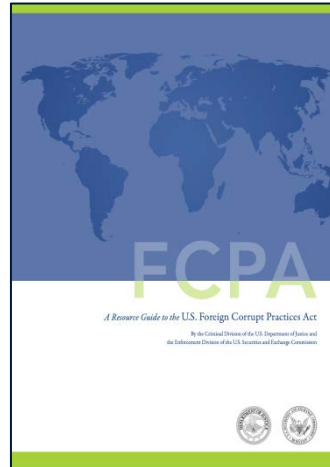
Examples of Resources – Guidance by International Organizations



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

Anti-bribery convention

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



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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

Examples and Q&A

[Placeholder for Company Specific Content]

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- Companies should consider whether to include examples tailored to their specific risks
- Examples may be based on audit findings, risk assessments, employee questions, enforcement actions or other factors
- Distributors should always check back with their supplier company if they have any questions

Chicago · Frankfurt · London · Los Angeles · New York · Palo Alto · Shanghai · Washington DC · West Palm Beach

A light blue world map is centered in the background of the slide. The continents are shown in a slightly darker shade of blue, and the oceans are a lighter blue. The map is oriented with North at the top.

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