

Where Can I Find More Information?

Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary ["SMI"] Relationships
<http://advamed.org/res.download/481>

National Industry Code of Conduct – contact your national medical technology industry association.

AdvaMed Code of Ethics
www.advamed.org/CodeOfEthics

AdvaMed Distributor Guidance Webpage
www.advamed.org/Distributor-Guidance

EDMA Code of Ethics
<http://www.edma-ivd.be/index.php?page=code-if-ethics>

Eucomed Code of Business Practice
www.eucomed.org/key-themes/ethics

Eucomed Third-Party Management Webpage
<http://eucomed.org/key-themes/ethics/third-party-management>

Resource Guide to the U.S. FCPA
<http://www.justice.gov/criminal-fraud/fcpa-guidance>

The Bribery Act 2010 Guidance
<http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf>

OECD Anticorruption Guidance
<http://www.oecd.org/corruption/keyoecdanti-corruptiondocuments.htm>

Industry Codes of Conduct

Many national medical technology trade associations have implemented codes of conduct on interactions with HCPs. These codes offer practical guidelines based on local law and industry norms. If such codes do not exist in your country, or do not apply, you may wish to refer to the AdvaMed Code of Ethics or the Eucomed Code of Business Practice.

ETHICAL INTERACTIONS with HEALTH CARE PROFESSIONALS and GOVERNMENT OFFICIALS

Compliance Guide for Medical Technology Sales & Marketing Intermediaries (SMIs)

The Medical Technology industry is committed to ethical interactions with health care professionals and government officials, and to compliance with all applicable laws. This commitment extends to the SMIs that represent our industry, wherever they do business. This guide is intended to provide Medical Technology SMIs with an overview of relevant anticorruption laws, as well as best practices to ensure ethical business operations. Your commitment to compliance can enhance your Company's reputation and grow your business with global partners.



What is Bribery?

Bribery is offering or paying something of value to a person in order to secure an improper business advantage.

Bribery may take the form of cash, disguised consulting or other fees, gifts, entertainment, travel, free goods or services or any other benefit provided or offered in order to influence someone to improperly exercise their influence or decision-making authority.

Public-sector bribery is bribery of public officials, government employees, or employees or representatives of political parties, quasi-governmental bodies and state-run companies. This includes bribery of **health care providers** in public health care systems or institutions or that are reimbursed by public funds.

Private-sector or commercial bribery is bribery of individuals in private organizations or companies (including private health care providers).

Why is Avoiding Bribery Important?

Bribery is illegal. Companies that manufacture or distribute medical technologies face significant legal penalties if they or their business partners engage in bribery.

Bribery is unethical. Bribery hurts competition, and makes goods and services more expensive. In the health care sector, bribery can impair medical judgment, and directly harm patients.

Interacting with Health Care Providers (HCPs)

The term **Health Care Providers** or **HCPs** means physicians, nurses, pharmacists, biologists, technicians, hospitals, clinics, hospital administrators and staff, and anyone involved in the decision or recommendation to buy, lease, use or reimburse medical technology products.

It is expected that you regularly interact with HCPs for the purpose or promoting, demonstrating and selling medical devices and related products. When engaging in business discussions or providing product training, it may be appropriate to provide modest meals and necessary travel and accommodation to achieve the legitimate purpose.

Whenever such benefits are provided, they must comply with applicable laws and industry codes, be properly documented and transparent (for example, through notification to the HCP's employer).

Interacting with Government Officials

Gift-giving may be a customary business practice in your country. However, gifts can create the appearance of improper influence. It is best to avoid them. If you do give gifts, ensure that they are permitted by local law and local industry codes and do not provide lavish gifts, cash or cash-equivalents (e.g., gift certificates), entertainment or leisure activities. Even modest gifts must not be provided for the purpose of improperly influencing a government official.

Facilitation payments (payments made to individuals to expedite routine government action) are illegal in most countries and OECD guidance recommends discouraging or prohibiting these payments, even where they are legal.**

**Working Group on Bribery, *2009 Recommendation of the Council for Further Combating Bribery of Foreign Public Officials in International Business Transactions*, at § VI. <http://www.oecd.org/daf/anti-bribery/44176910.pdf>

How Can I Prevent Bribery?

- State clearly to all your employees, agents and representatives that bribery is not permitted, even if others consider it to be an acceptable business practice in your market.
- Provide training and guidance to your employees, agents and representatives so that they know the rules, and can seek your support when in doubt or when facing a difficult situation.
- Ensure that all transactions are truthful, transparent and properly documented.
- Keep accurate books and records and avoid practices that limit transparency, such as transferring money from business accounts to personal accounts.
- Take extra care in high risk situations, such as consulting arrangements, high commission rates, cash/per-diem payments, use of third parties, etc. Ensure appropriate levels of review and oversight.
- Review consulting arrangements carefully to ensure the services are necessary, legitimate, fairly compensated and there is evidence of the services performed.
- If you have questions, seek appropriate guidance or ask your company business partner.

What Laws Prohibit Bribery?

Most countries' laws prohibit **public-sector bribery**. Many countries have also banned private-sector or **commercial** bribery.

The following are examples of laws that prohibit bribery **anywhere in the world**:

- U.S. Foreign Corrupt Practices Act (FCPA)
- UK Bribery Act of 2010
- Brazil Clean Companies Act
- China Anti-Bribery Laws

You should assume that, wherever you do business, bribery is **illegal** and **unethical**.