



**ILLUSTRATIVE MEDICAL TECHNOLOGY SCENARIOS
AND COMPLIANCE PROGRAM CONTROLS FOR THIRD
PARTY SALES & MARKETING INTERMEDIARY
RELATIONSHIPS**



AdvaMed
Advanced Medical Technology Association



MedTech Europe
from diagnosis to cure

PREAMBLE

The advanced medical technology industry (the “Industry”) develops, manufactures, and markets medical products, technologies, and related services used to diagnose and treat health conditions and disabilities in order to enable patients to live longer and healthier lives. Industry understands its unique position and obligation to make ethical business practices and compliance a priority and is committed to facilitating ethical interactions between medical device and diagnostics companies (“Companies”), sales and marketing intermediaries (“SMIs”), and health care providers or professionals (“HCPs”) worldwide.

To ensure and improve patient and clinician access to innovative, reliable, and effective medical technologies, it is often necessary for Companies to engage third parties to assist in the marketing, sale, and/or distribution of the Companies’ products or services. It is essential that Companies’ interactions with SMIs, as well as SMIs’ activities on behalf of Companies (including SMI interactions with HCPs and government officials), are conducted pursuant to all applicable legal requirements and comply with ethical standards equivalent to those in the applicable Industry Codes of Ethics.¹

AdvaMed and MedTech Europe have identified and developed a range of compliance guidance and tools to offer potential best practices for Companies to consider when reducing risk associated with SMI relationships.² The *Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary [“SMI”] Relationships*, developed by AdvaMed and MedTech Europe, offers seven (7) suggested elements for Companies to consider that would contribute to a SMI management compliance program, including, (1) establishing written policies and procedures, (2) facilitating risk assessment, (3) applying a due diligence program, (4) using written contracts, (5) conducting training and education, (6) monitoring and auditing SMIs, and (7) enlisting necessary and appropriate corrective measures. In addition, this document - *Illustrative Medical Technology Scenarios and Compliance Program Controls for Third Party Sales & Marketing Intermediary Relationships* – contemplates and builds off of each of these seven elements, offering concrete scenarios to illustrate how each of these elements might impact, shape, and inform a compliance program. While this document specifically addresses the risks associated with SMIs, companies should also consider whether to scrutinize high risk third party vendors.

¹ See, AdvaMed Code of Ethics on Interactions with Health Care Professionals, [here](#).

MedTech Europe is an Alliance of medical technology associations, EDMA and Eucomed. See the MedTech Europe Code of Ethical Business Practice, [here](#)

² The Foreign Corrupt Practices Act (“FCPA”), the UK Bribery Act, and other global laws and regulations have increased the importance of Companies establishing an effective SMI compliance program. To provide training materials on effective Third Party SMI compliance programs, AdvaMed and MedTech Europe collectively offer for Companies to consider (1) Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary [“SMI”] Relationships, (2) Distributor Training Slides, and (3) a Distributor Compliance Due Diligence Resource. All can be found [here](#). These illustrative hypotheticals on managing SMI risk will be another resource available to Companies to help manage legal and ethical issues arising from the distributor chain.

DISCLAIMER

The scenarios presented herein are illustrative only. They are intended to highlight ethics and compliance risk areas that may arise in SMI relationships and identify potential compliance controls, practices, and procedures to manage select risk areas. The Companies presented in the scenarios do not represent any particular Company, nor does this document attempt to set a medical technology industry standard with regard to ethics and anti-corruption compliance. This document recognizes that practices differ across the medtech space depending on various business markets and varying company sizes. With this in mind, this document merely presents scenarios to illustrate how compliance controls might be employed to manage SMI risk.

In practice, every case is unique and a variety of risks, circumstances, and other factors influence the types of compliance controls that might be appropriate. AdvaMed and MedTech Europe provide these illustrative scenarios solely to serve as an optional resource, noting potential principles and controls that could be helpful in addressing SMI corruption risk.

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The following scenarios include examples of steps Companies might take to minimize corruption risk related to engagements with SMIs. The scenarios are not intended to reflect minimum standards or to serve as an exhaustive list of possibilities. Rather, they illustrate practical measures Companies may consider as they craft policies and procedures tailored to their unique risk profile, resources, and business structures.

Scenario A: Anti-Corruption Compliance Policy Content & Protocols Aimed at Managing SMI Relationships in High-Risk Countries

Company A found that many of its SMIs did not have anti-corruption policies and were looking for advice. Company A developed a concise anti-corruption policy for its SMIs to adopt and apply to the SMI's employees and agents who are involved in the sale and marketing of Company A's products. Company A attaches its sample SMI anti-corruption compliance policy to its agreements and requires its SMIs to adopt the policy or to have a substantially equivalent anti-corruption policy regarding the sale and marketing of Company A's products.*

In addition, as it expands its business into certain emerging markets and other higher risk markets, Company A applies additional controls to manage these relationships. Company A considers the following measures:

- Providing anti-bribery training in local languages.
- Conducting an in-person site visit to provide live training and to discuss business practices, high-risk activities, and challenges faced by the SMI.
- Requiring SMIs to seek advance approval from Company A for certain high-risk interactions with government officials or health care professionals connected to Company A's products.
- Requiring SMIs to keep adequate books and records regarding payments and other transfers of value to HCPs and customers connected to the sale and marketing of Company A's products.
- Conducting a books and records review in for-cause or high-risk situations, including reviews (either directly or through a mutually agreed upon third party) of SMI's books and records related to payments or other transfers of value to HCPs or other customers connected to Company A's products.
- Requiring SMIs to report periodically on the use of sub-distributors and other third party intermediaries involved in the sale and marketing of Company A's products and steps taken to minimize corruption risk by such entities.

* See Appendix 1 for a sample Anti-corruption Policy

- Training Company A’s local employees that manage the SMI relationships on possible corruption “red flags” and on employees’ obligation to look for and report any red flags detected.
- Requiring periodic compliance assessment and certification by Company A personnel responsible for managing the company’s relationship with the SMI.

Scenario B: Review of SMI Activity by Responsible Management

Company B uses services from SMIs such as conference organizers and travel agencies to organize various events Company B hosts in other countries, such as satellite symposia at third-party-organized conferences. Company B is considering adding language to its policies and procedures specifically related to expenses associated with SMIs, in order to help ensure effective controls. Examples of such language include:

- A description of permissible activities or services that SMIs may provide for Company B;
- Specific recordkeeping requirements for SMI activities related to Company B’s products or business;
- Procedures requiring background checks and conflict of interest checks for higher-risk SMIs;
- Procedures requiring anti-bribery training for higher-risk SMIs;
- Procedures regarding the oversight and monitoring of SMI activities related to Company B’s business, such as prior approval by Company B of certain activities by the SMI; and
- Additional financial controls prior to certain payments being made, and monitoring/auditing programs for higher-risk SMIs.

Scenario C: Creating & Evaluating Risk Profiles

Company C adheres to the following procedures in evaluating SMI risk profiles:

1. Company C completes a risk rating calculated by factoring, among other things:
 - a. Location of SMI business and territory:
 - i. Corruption perception index rating;
 - ii. Reported corruption trends and enforcement;
 - iii. Relevant health care system considerations;

1. Public or private?
 2. Who sets prices and makes product purchasing decisions?
 3. How transparent are these mechanisms?
 4. Are there clear and well-understood laws and ethical norms (such as industry codes of conduct) applicable to interactions with health care professionals and organizations?
- b. SMI profile, including years of existence, identity of principals, number of employees, and relationships of principals and key employees with government officials.
- c. Nature of SMI's business activities and compensation structure:
- i. Degree of involvement with government officials;
 - ii. Degree of involvement with health care professionals;
 - iii. Degree to which compensation depends upon SMI's ability to influence behavior of third parties;
 - iv. Use of offshore bank accounts;
 - v. Use of subagents, consultants and other third parties; and
 - vi. Amount of discount or commission relative to industry standards.
2. The Company C compliance team periodically evaluates their risk assessment metrics and updates them as needed to address emerging risks.

Scenario D: Risk Based Due Diligence

Company D's due diligence process is tiered based on the risk rating of proposed SMIs.

1. All SMIs complete an anti-corruption questionnaire, and the Company follows up on any responses/non-responses of concern, checks their references, and performs a basic reputational check (e.g., internet search).
2. For moderate-risk SMIs, a third-party background check is conducted and the report is evaluated by compliance personnel.
3. For high-risk SMIs, the Company takes additional steps tailored to the type of business and the nature of the risks. For example, it may visit the offices of targeted SMIs to verify their legitimacy, or arrange for a third party to do so. Steps taken to reduce risk

with respect to high-risk SMIs are documented and reviewed prior to approval or renewal of the SMI.

Scenario E: Adopting Contractual Provisions that Encourage Compliance

Company E created template contracts for each of its most common SMI relationships for use of these contracts in all new SMI engagements and upon renewal of existing SMI relationships. Company E's contract templates include:

- A covenant to adopt and comply with an anti-corruption policy that meets Company E's requirements;
- Provisions requiring anti-corruption training for personnel involved in activities related to Company E or its products;
- Provisions requiring adequate books and recordkeeping for transfers of value;
- Audit rights in specific cases by Company E's auditors or a mutually agreed upon independent auditor; and
- Definition of compliance requirements as material to the contract, entitling Company E to terminate the contract if it determines a breach has occurred.

In addition, based on its risk assessment, Company E has identified certain types of high-risk SMIs for which it has customized contract provisions designed to address specific needs. For example, travel agents in certain high-risk jurisdictions are required to adhere to specific provisions related to documentation of transactions and reporting use of funds, and to provide annual certifications of compliance with Company E policies.

Scenario F: Regular Training of SMIs

Company F provides a set of training materials to each new SMI so that it can provide initial training on Company F's anti-corruption policy and AdvaMed and MedTech Europe guidelines to its personnel as provided in its contract with Company F.

In addition, each Company F regional sales manager is responsible for ensuring that the SMI personnel who engage in business activities on behalf of Company F in his or her region receive annual training. When organizing annual meetings in their regions, and/or interim meetings to discuss product launches and other matters, each regional sales manager notifies Company F's compliance team, who develop appropriate training materials.* When practical, at least one

* See AdvaMed and MedTech Europe distributor training resources

member of the compliance team attends the annual training program, along with a senior executive of Company F whose presence underscores the importance of compliance and ethics to the Company's business. Each compliance session ends with a roundtable in which SMI and Company F representatives discuss compliance challenges and successes.

Each attendee signs a certification of training that is filed with the Company's compliance training records. Each regional manager works with his or her region's SMIs to ensure that SMI personnel who are unable to attend the training in person receive written training materials and certify that they have reviewed them.

Scenario G – Monitoring and Auditing

As part of its ethics and compliance program, Company G implemented a program for monitoring, auditing or other periodic assessments of SMI relationships.

- Monitoring is based on the contractual provisions in effect with SMIs and entails collection of required certifications and training records, as well as collecting and reviewing information required of specific SMIs, such as educational event materials or reports of HCP-related expenses.
- Company G implemented a multi-year monitoring and audit plan designed to balance risk with a reasonable allocation of Company G's resources. Selection of SMIs and records to be audited is based on risk assessment.
 - High-risk jurisdictions are prioritized.
 - Individual SMIs are selected based on individual risk profile.
- Monitoring may include one or more of the following protocols:
 - On-site visits of SMI offices by an audit team and/or compliance team;
 - Assessments by Company G legal or compliance personnel;
 - Creation of action plans in response to issues identified during audits or reviews;
 - Periodic review of the books and records of targeted, high-risk SMIs (using third-party auditors when necessary); and
 - When necessary, local counsel is consulted to achieve a mutually acceptable audit plan that complies with local law.

Scenario H - Corrective Action

Company H reserves the right to terminate its contract with any SMI if an ethical breach or violation has occurred.

Alleged or known breaches are evaluated by the legal and compliance teams and investigation undertaken if necessary.

When the legal and compliance team determine a breach is serious or cannot be remedied, the contract is terminated. Company H may consult with local counsel and/or the Company manager responsible for the relationship with the SMI to ensure the termination process takes into account local law as well as patient needs.

If the legal and compliance teams determine in consultation with the SMI relationship manager that the breach may be remedied, Company H may permit the SMI to take remedial action to avoid termination of the contract. For example, if Company H discovers that an SMI is not following the correct record keeping practices and procedures, and is not aware of other ethical or legal concerns, it might implement a remediation plan such as the following:

1. Company H personnel meet with SMI leadership team to discuss the issue and Company H's expectations;
2. A concrete remediation plan is established with appropriate implementation deadlines;
3. Company H offers books and records training resources to the SMI; and
4. Company H reviews the SMI at the end of the remediation period.

Company H takes steps to apply what it has learned from its remediation efforts to its interactions with other SMIs and updates its training materials as appropriate.

DEFINITIONS

The terms used throughout this document are consistent with the definitions presented in the “[Guidance](#)” and the “[Distributor Due Diligence Training Resource](#).” Please find select supplemental definitions below that should be read in conjunction with the definitions presented in those documents.

Improper Business Advantage

Any business advantage to which a Company was not clearly entitled but likely received in connection to a bribe, or bribe-like activity, by a Company employee, a sales & marketing intermediary, or any other party acting on behalf of the Company or its Third Party Intermediaries.

Sales & Marketing Intermediary (“SMI”)

An individual or entity providing services to or on behalf of a Company, including, but not limited to:

- Sales & Marketing Intermediaries
- Distributors
- Vendors
- Sales Agents
- Marketing Agents
- Customs & Regulatory Brokers
- Wholesalers
- Independent Sales Representatives
- Travel Agents
- Event Planners

Appendix 1

The example anti-corruption compliance policy below could be attached to any agreement or contract signed by an SMI to attest to their understanding and agreement to comply with a US-based Company's anti-corruption compliance policy. Please note that the anti-corruption policy below is merely a generic sample. It is not intended to serve as a template, nor does it create an Industry standard regarding how anti-corruption compliance policy documents should be drafted or what they should contain. Every Company is different and this general sample policy is not appropriate for all Companies. This sample policy should only be used to inform and guide interested parties on some of the items an anti-corruption policy could contain or address.

[Company Name] Distributor Anti-Corruption Compliance Policy

Any distributor who is a partner of [Company Name] ("DISTRIBUTOR") must observe and adhere to this [Company Name] Distributor Anti-Corruption Policy ("DACP"). This DACP forms part of DISTRIBUTOR's agreement with [Company Name] and applies to all interactions with [Company Name] customers. Further, if DISTRIBUTOR uses any sub-distributor or other similar third party ("Sub-Distributor") in the performance of its agreement with [Company Name], DISTRIBUTOR must require such Sub-Distributor in writing to comply with this DACP with respect to any actions related to [Company Name] product or services.

1. CORE POLICY

Doing business ethically supports the shared goal of DISTRIBUTOR and [Company Name] to bring life-saving

and life-enhancing therapies to patients who need them. Accordingly, DISTRIBUTOR affirms its commitment to comply with all applicable laws and regulations including, without limitation, the Foreign Corrupt Practices Act ("FCPA"), in all aspects of the performance of its agreement with [Company Name]. This means that no employee, officer or director of DISTRIBUTOR shall offer, pay, or authorize payment or the giving of anything of value to any customer, government official, or any other third party, for the purpose of obtaining any improper business advantage. "Anything of value" includes, but is not limited to:

- Cash
- Discounts
- Gifts
- Contracts
- Rebates
- Travel Lodging
- Sponsorships
- Loans

- Tickets, entertainment
- Use of materials, equipment, software, or facilities
- Employment promise
- Grants, donations, support for research

In carrying out the terms of its agreement, DISTRIBUTOR must comply with the following rules regarding transfers of value to third parties related to the sale of [Company Name] product or rendering of [Company Name] services.

2. GENERAL RULES

a) Applicability to Employees and Third Parties. If DISTRIBUTOR is restricted from making a payment by this DACP, so are its employees, even if they pay for it from their own personal funds. If DISTRIBUTOR is restricted from making a payment by this DACP, so are its sub-distributors, pursuant to DISTRIBUTOR's contract with sub-distributor. In addition, sub-distributors or other third parties may not make payments on behalf of DISTRIBUTOR, if DISTRIBUTOR would be prohibited from making those payments under law or this policy.

b) Modest Meals and Refreshments. DISTRIBUTOR may provide a modest and occasional meal to customers as business courtesy in the context of a business meeting so long as the primary purpose is a legitimate business reason, not a purely social interaction;

the meal is incidental to the business interaction; it is provided in a setting that is conducive to *bona fide* scientific, educational, or business discussions; and the DISTRIBUTOR representative personally attends the meeting.

c) Modest Lodging. DISTRIBUTOR may pay for customer lodging for a training event or other appropriate business occasion where the lodging is modest, appropriate and reasonable based upon program requirements, convenience of attendees, and reasonable cost. DISTRIBUTOR will not pay any additional costs associated with any trip or hotel extensions requested by a customer beyond the needs of the event.

d) No Subsidy of Spouses, Partners or Guests. DISTRIBUTOR may not provide meals, other hospitality, travel, lodging or other expenses for spouses, partners or guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

"Modest" means moderate in value, but may differ depending on regional differences. "Occasional" means infrequent.

3. DISTRIBUTOR SUPPORT FOR CUSTOMER EDUCATION

a) Training Organized by DISTRIBUTOR. Any physician training sessions, conferences, roundtable discussions and similar customer education events funded by DISTRIBUTOR must address appropriate scientific topics such as disease states, use of therapies, patient selection, etc. Payments to customers to conduct DISTRIBUTOR-organized training sessions and reimbursement of travel expenses must be under a written agreement in accordance with Section 5 of this policy. DISTRIBUTOR may not pay an honorarium fee for a mere attendance at a training event.

b) Support for Physician Attendance at Third-Party Congresses. Reimbursement by DISTRIBUTOR of customer expenses for attending appropriate medical conferences is permitted only where allowed under applicable law and the local codes of ethics. DISTRIBUTOR must comply with all laws regarding the disclosure or approval of such sponsorship. The amount of support may not exceed the conference registration fee and reasonable and modest travel, meals and accommodation costs relating to attendance at the event.

c) General Requirements for Educational Events. Any educational programs sponsored by DISTRIBUTOR and any support for physicians to

attend third-party conferences must meet these general requirements:

- The agenda is scientific and includes appropriate topics such as disease states, use of therapies, patient selection, etc.;
- The conference has a full agenda on each non-travel conference day (partial day agendas are acceptable for travel days at the start and end of the conference);
- The conference is in an appropriate setting and not a luxury or resort location; and
- Rules in Section 2 of this policy apply, regarding modest meals, modest lodging, no spouses or guests, etc.

4. USE OF EVENT PLANNERS

When DISTRIBUTOR uses the services of a travel agent or event planner (“Travel Agent”) to assist in arrangements for customer education programs or for customer travel or attendance at a medical conference, the following requirements apply:

- DISTRIBUTOR must require the Travel Agent to follow the substance of the DACP, including for example, the requirements of modesty and not to pay for spouses’, partners’ or guests’ travel.
- DISTRIBUTOR must require the Travel Agent to maintain detailed accounting and expense records for each individual event or travel

arrangement undertaken on behalf of DISTRIBUTOR. Such records must be available for inspection promptly upon request from DISTRIBUTOR or [Company Name].

- DISTRIBUTOR may only use Travel Agents previously approved by [Company Name].

5. SERVICES AGREEMENTS

DISTRIBUTOR may compensate individuals, including physicians or other customers or potential customers, for bona fide consulting services, where the services have value to DISTRIBUTOR and the fees are reasonable and based on the services actually provided. All such arrangements must be in writing and DISTRIBUTOR must maintain records of services and payments.

6. GIFTS

Except in the very limited circumstances below, the giving of gifts to customers is generally prohibited. DISTRIBUTOR may occasionally provide items that have a genuine educational function or benefit patients, such as textbooks or anatomical models, if they are modest in value and in accordance with the national and local laws, regulations and industry and professional codes of conduct of the country where the customer is located. Where expressly authorized under local law, DISTRIBUTOR may provide small tokens/gifts of

appreciation for specific occasions. Any such tokens/gifts must be the most modest token/gift suitable for the occasion, to ensure it is not, and will not be perceived by others to be, a potential means of corrupt influence. It is *never* appropriate to give items such as cash or cash equivalents, or valuable personal items (e.g. clothing, perfume, iPods, iPads, iPhones, tickets, etc.).

The description, amount and purpose of any such items given to customers must be documented.

7. ENTERTAINMENT

In general, it is not appropriate to pay for entertainment of customers. However, modest entertainment is allowed where expressly authorized by local laws and industry codes. Vacation trips, wine tasting, night clubs, and any kind of expensive or lavish entertainment are not allowed.

8. EDUCATIONAL AND SCIENTIFIC DONATIONS

Grants and charitable donations are permitted only if the grant or donation is intended for a charitable or other philanthropic purpose, or to support bona fide educational or research programs. Such grants or donations must not take into account the volume or value of purchases made by, or

anticipated from, the grant recipients. DISTRIBUTOR shall keep detailed records of such grants or donations.

9. SAMPLES AND FREE PRODUCTS

DISTRIBUTOR may provide a limited number of sample or free products to customers for evaluation purposes in accordance with local laws and industry codes. The provision of such products should be notified in writing to the customer institution through notation on an invoice, written agreement, or other appropriate method. DISTRIBUTOR shall keep

detailed records of its samples and free products provided to customers.

10. CLINICAL STUDIES

DISTRIBUTOR shall not conduct, fund, sponsor or support any type of clinical trial and/or studies activities involving [Company Name] products, including registries or any other type of study, whether organized or sponsored by a healthcare provider in the Territory or any other person or entity, except with a prior written approval from [Company Name].

The example anti-corruption compliance certification below could be signed by a senior employee of an SMI entity (who has authority to sign on behalf of the SMI) to attest to their understanding and compliance with anti-corruption compliance policies. Please note that the anti-corruption certification below is merely a generic sample. It is not intended to serve as a template, nor does it create an Industry standard regarding how anti-corruption compliance certification documents should be drafted or what they should contain. Every Company is different and this general sample certification is not appropriate for all Companies, nor should every Company necessarily have an anti-corruption compliance certification process in the first place. This sample certification should only be used to inform and guide interested parties on some of the items an anti-corruption certification policy could contain or address, should those interested parties want to implement this process as part of their compliance program.

[COMPANY NAME] ANTI-CORRUPTION COMPLIANCE CERTIFICATION

The undersigned, having first been duly informed and having made reasonable and good faith inquiry of my corporate organization, hereby certify as follows:

1. I confirm that:

A. [Company Name] does not pay, or offer to pay, bribes to government officials or private persons in order to obtain or retain business or to gain an improper business advantage;

B. [Company Name] does not pay bribes indirectly through agents or other third parties;

C. [Company Name] avoids the appearance of paying bribes by refraining from hosting lavish meals and entertainment, gift giving, charitable donations, or the making of facilitating payments;

D. [Company Name] maintains detailed and accurate books and records, and implements internal controls reasonably designed to prevent, detect, and impose discipline for breaches of anti-bribery laws, company anti-bribery compliance policies and pharmaceutical marketing compliance regulations;

E. [Company Name] does not pay, offer to pay or authorize bribes, but if any improper payment should somehow be made, [Company Name] does not conceal such payments by “off-the-books” arrangements or by falsifying corporate books and records or reports.

2. [Company Name] has implemented an anti-corruption (or anti-bribery) policy and procedures related to interactions with healthcare professionals, government officials and others, and to the best of my knowledge no activities or payments have taken place at the company or on the company’s behalf that would violate that policy.

3. [Company Name] has implemented operational guidance, and has provided or is in the process of providing training to all relevant personnel on the following topics:

A. Gifts;

B. Hospitality, entertainment and expenses;

C. Customer travel (e.g., promotional activities);

D. Political contributions;

E. Charitable donations and sponsorships;

F. Facilitation payments;

G. The use of agents, finders, distributors, business development consultants and other third parties whose conduct may be attributed in whole or in part to [Company Name];

H. The conduct of anti-bribery due diligence and implementation of appropriate anti-bribery controls in merger, acquisition, and joint venture activity governing documents; and

I. Segregation of duties and other financial controls to assure appropriate limits on authority as to expenditures or other dispositions of company assets or the accrual of liabilities.

4. [Company Name] has adequately-resourced Legal, Compliance, and Internal Audit functions, staffed with personnel of sufficient stature, training, and experience, and with sufficient staff to handle the compliance challenges of the organization. [Company Name] conducts annual internal audits which are reasonably designed to prevent, detect, and impose discipline for breaches of anti-bribery laws, company anti-bribery compliance policies and compliance regulations.

5. There have been no incidents in which there have been violations of [Company Name]'s anti-bribery compliance policy, any applicable anti-bribery law or regulations.

6. There have been no incidents in which there have been allegations of violations of [Company Name]'s anti-bribery compliance policy, any applicable anti-bribery law or regulations.

Acknowledged and confirmed:

[Company Name]

By: _____

Name: _____

Title: _____

Date: _____

About AdvaMed and MedTech Europe

AdvaMed and MedTech Europe represent medical technology manufacturers and innovators, and together commit to facilitate ethical business and interactions and collaborations among medical device and diagnostics companies and Healthcare Professionals in order to ensure ongoing development of advanced medical technologies and patient access to the safe and effective use of medical technologies.

About AdvaMed. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. AdvaMed promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets. More information on AdvaMed's Code of Ethics and compliance programs and guidance can be found [here](#).

About MedTech Europe. MedTech Europe is an Alliance of European medical technology industry associations (EDMA and Eucomed). MedTech Europe promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. The medical technology industry represented by MedTech Europe is committed to ensuring that its collaboration with HCPs adheres to the highest ethical and professional standards. These standards are currently encompassed in the Eucomed Code of Ethical Business Practice which can be found [here](#) along with other compliance-related documents.