



Third Party Sales and Marketing Intermediary Compliance Diligence Resource

Terms of Use

Further to the 2012 AdvaMed-Eucomed Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (“SMI”) Relationships¹, this document includes a compilation of Third Party Sales and Marketing Intermediary compliance diligence questions, example certification, and an example compliance diligence privacy notice for AdvaMed and Eucomed Member Companies’ (“Companies”) consideration when engaging Third Party SMIs. The use of questions and forms within this resource is entirely voluntary. AdvaMed and Eucomed provide this resource with the express understanding that AdvaMed and Eucomed are not providing legal advice. The user should seek legal advice from expert legal counsel when assessing Third Party SMI compliance with anti-corruption laws and other relevant legal standards.

For convenience, questions are arranged within the structure of an example compliance questionnaire. However, not all questions may be relevant to a particular arrangement, and each Company should consider which questions are most applicable in each case. Further, the questions within this resource should not be used as the sole basis for determining SMI compliance with anti-corruption laws. Companies should carefully assess which questions are applicable based on the specific risks relevant to the Company’s business and operations (such as regional or business risk) as well as the existing contractual obligations or other legal requirements. Therefore, Companies may add, omit, or tailor questions as needed to address these specific risks and to ensure consistency with national and local laws applicable to their business. Further, some of these questions are overlapping or examples of different ways to obtain the same information. Last, Companies should consider the applicability and content of any compliance diligence certification and privacy notice.

¹See “Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary [‘SMI’] Relationships”:
<https://docs.google.com/a/legal.advamed.org/viewer?a=v&pid=sites&srcid=bGVnYWwuYWR2YW11ZC5vcmd8YWR2YW11ZGxlZ2FsfGd4OjE2YTnkMzEwOTkwYzVhMDI>

Preamble

To ensure and improve ongoing patient and clinician access to innovative, reliable, and effective medical technologies, it is often necessary for medical device and diagnostics manufacturers to engage SMIs to assist, among other activities, in the marketing, sale, and/or distribution of the Companies' products or services. The form of, and terminology used by Companies to describe relationships with SMIs varies, but may include dealers, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents, independent sales representatives as well as travel agents and meeting planners.

It is essential that Companies' interactions with SMIs, as well as SMIs' behavior on a Company's behalf (especially SMI interactions with Health Care Professionals ("HCPs") and Foreign Governmental Officials ("GOs")) are conducted pursuant to all applicable legal and ethical principles that comply with standards equivalent to those in our organizations' individual Codes of Ethics ("Codes")² and supported by internationally accepted standards. AdvaMed and Eucomed recognize that joint, harmonized ethical guidance on Company interactions with SMIs may be helpful to ensure integrity in medical decision making. AdvaMed and Eucomed offer this resource to assist Companies in addressing global corruption risks.

²See, AdvaMed Code of Ethics on Interactions with Health Care Professionals, <http://www.advamed.org/MemberPortal/About/code/>; Eucomed Code of Ethical Business Practice, <http://www.eucomed.be/ethics.aspx>. Terms used in this document, not defined above, should be construed in accordance with the AdvaMed and Eucomed Codes.

Key Terms

Defined below are terms and abbreviations used throughout the resource. These terms and others are defined in greater detail in the Codes. *Note that individual Company policies may provide further definitional guidance that might differ from those below.*

Company

The medical device or diagnostics manufacturer for which the SMI entity may perform SMI services.

Facilitation Payments

The FCPA (defined below) defines a facilitating payment as, “a facilitating or expediting payment to a foreign official, political party, or party official the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or political official.” The FCPA defines routine governmental action as, “an action which is ordinarily and commonly performed by a foreign official in: (i) obtaining permits, licenses, or other official documents to qualify a person to do business in a foreign country; (ii) processing governmental papers, such as visas and work orders; (iii) providing police protection, mail pick-up and delivery, or scheduling inspections associated with contract performance or inspections related to transit of goods across country; (iv) providing phone service, power and water supply, loading and unloading cargo, or protecting perishable products or commodities from deterioration; or (v) actions of a similar nature.”

Family Members

Any of the following relationships constitute family members: mother, father, spouse, civil union partner, sister brother, son, daughter, grandchild, grandparent, any of the preceding who, where applicable, are “step” relatives, mother-in-law, father-in-law, sister-in-law, brother-in-law, son-in-law, and daughter-in-law.

Foreign Corrupt Practices Act (FCPA)

A U.S. law that is applicable globally, and makes it unlawful for an U.S. person or a company to give or offer anything of value, directly or indirectly, to a foreign government official to influence any act or decision by that official for the purpose of obtaining or retaining business. Other countries have similar anti-corruption provisions such as the UK Bribery Act.

Foreign Government Official (GO)

- Health Care Professionals employed by or acting on behalf of a health care entity owned or controlled by a government body, such as a public hospital or a state university.

- Any employee, manager, director, office holder, or official of a non-U.S. government entity, or government-controlled entity (e.g., government-owned hospitals, healthcare centers, pharmacies or university hospitals; or any business owned or controlled by any national, provincial or local government);
- Any person who is a member of the military or holds a legislative, administrative, or judicial position of any non-US national, provincial or local government;
- Any employee, office holder, candidate, or elected or appointed official of a non-U.S. political party;
- Any employee or official of a public international organization such as the World Bank, the International Monetary Fund, the United Nations, the International Committee of the Red Cross, the Asian Development Bank, or the European Union.

Health Care Professional (HCP)

An individual or entity involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' medical technology.

Key Personnel

- All owners with over 5% ownership.
- All members of the board of directors (if any).
- Key management (including, but not limited to, the CEO, CFO, the Head of Sales, the Head of Sales in the Medical Division/Department etc.).
- Other key persons who have a role in sales, distribution or marketing of Company products.

You

The corporate officer or executive completing a compliance questionnaire and signing a certification on behalf of the SMI entity.

Your Company

The SMI entity completing a compliance questionnaire.

Example Questions for Potential Inclusion Within an SMI Compliance Questionnaire

Please complete the following questions as completely and thoroughly as possible. **All questions must be completed** or a written response of “not applicable” must be provided.

SMI Information

1. SMI Name
2. Has your company or any of your company’s principals done business with our Company in the last 10 years? If so, under what names³?
3. Has your company or any of your company’s principals done business in a similar field in the last 5 years? If so, under what names⁴?
4. Your Name and Title
5. Full Address
6. Telephone
7. Fax
8. Email
9. Your Company Website

³ Please list in English and the local language.

⁴ Please list in English and the local language.

SMI Profile

1. Please indicate your company's form of organization.

- Corporation
 Partnership
 Sole Proprietorship
 Other _____ (please identify)

a. Is your company a publicly traded company?

- Yes No

b. If so, on which exchange?

2. *Related Entities* – list names and addresses of:

a. Your company's parent company name, address and contact person.

b. Does your company have any subsidiaries and/or affiliates? If so, please list the subsidiaries and/or affiliates' names here.

- Yes No

c. Any other companies or entities in which you or your company has a controlling ownership interest.

3. Does your company have any alternative trade or business names? If so, please list these names.

- Yes No

4. *Key Personnel* – Identify by full name, including middle name, (if applicable):

a. Employees who will oversee your company's services for our Company.

b. Owners, principals, and/or board members of your company or your parent company.

c. Other employees who control your company's key decisions.

5. Please list the name and address of the bank that maintains your company's primary business account.

6. Please indicate your company's total number of employees.

7. Please indicate the number of your company's employees directly or indirectly involved in marketing, distributing, and/or selling our products.

8. When was your company incorporated, established, or founded?

9. Please provide your company's registration and tax number.

10. How long has your company been providing services to our company (if applicable)?

11. Does your company represent any other companies in the medical device, in vitro diagnostics (IvD), pharmaceutical or biotech industries? If so please list them.⁵

Yes

No

12. Please attach the following documentation if possible:

- a. a copy of your company's commercial registration,
- b. articles of incorporation or corporate charter,
- c. business license,
- d. an annual report or similar publication describing your company's business.

SMI Services

1. Please list all the countries in which your company conducts business.

-
-
-
-
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⁵ As noted in the *Terms of Use* set out on Page 1, each example question should be evaluated for conformance with any binding contractual obligations, among other legal requirements.

2. Please list all countries in which your company will conduct business on our behalf or distribute our products.

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-
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3. Describe the nature of the services you and your company provide/will provide for our Company.

4. Describe your company's experience and qualifications in the field of the required services.

5. Is your company dedicated solely to medical technology/life-science services or is your company a multi-industry dealer?

- Medical device, in vitro diagnostics (IvD), pharmaceutical and biotech only
- Multi-Industry (please list which industry)

SMI Anti-Corruption Compliance

1. Are you familiar with the following:

- a. The FCPA; Yes No
- b. The UK Bribery Act; Yes No
- c. Local anti-corruption laws in countries in which you operate?⁶ Yes No

2. Does your company have a code of ethics and/or anti-corruption policy? If so, please attach. Yes No

3. If you answered yes to question 2 above, does your company train personnel on your anti-corruption policy? If so, how often? Yes No
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-

4. Does your company provide periodic anti-corruption, anti-bribery training to your company's employees and relevant contract personnel on the following:

- a. Your Company Code of Ethics Yes No
- b. the FCPA Yes No
- c. the UK Bribery Act Yes No
- d. Other anti-corruption laws Yes No

5. (if applicable) Does your company train your employees on our Code of Conduct and our anti-corruption policies?⁷

⁶ Companies may wish to reference specific anti-corruption laws and standards applicable to the contemplated arrangement.

⁷ If yes, please attach a copy of training material.

Company Practices

1. Does your company permit any of the following:

- | | | |
|--|------------------------------|-----------------------------|
| a. Gifts or other items of value to HCPs, GOs, prospective customers or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Cash payments to HCPs, GOs, prospective customers or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Facilitation Payments ⁸ ? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Financial support of third party congresses or of HCPs going to third party congresses? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Financial support of training (including proctoring)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Charitable donations to HCPs, GOs, prospective customers, or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Political contributions to HCPs, GOs, prospective customers, or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Provision of entertainment to HCPs, GOs, prospective customers, or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| i. Provision of meals to HCPs, GOs, prospective customers, or other customers? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

⁸ See the definition under “Key Terms” on Page 3.

2. Does your company cover travel expenses for HCPs, GOs, prospective customers, or other customers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Does your company provide funding for research (clinical or other)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Does your company make any transfers of value to HCPs, GOs, prospective customers, or other customers (other than those described above)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. If you answered Yes to any question above, please explain.		

Penalties, Sanctions, Other Findings, Determinations and Filings

1. Has your company or any of your affiliates or key personnel ever:		
a. Been charged with a criminal offense?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. Declared bankruptcy or insolvency?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. Been excluded or disbarred?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. Been sued for fraud?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

e. Been accused or found guilty of money laundering?

Yes

No

f. Been subject to any administrative sanction or penalty?

Yes

No

g. Been accused of or found guilty of bribery or corruption?

Yes

No

h. If you answered Yes to any question above, please explain providing dates and company name concerned.

2. Have your company's or any of your affiliates' books and records ever been reviewed in any governmental audit and/or investigation for compliance with anti-corruption laws? If yes, please explain providing dates and company name concerned.

Yes

No

3. Does your company or any of its affiliates have any pending or threatened claims, litigation, or investigations that have not yet been resolved or closed? If yes, please explain providing dates and company name concerned.

Yes

No

Relationship with Foreign Government Officials

1. Are any of your company's key personnel or family members of key personnel or consultants a current or former:

a. Government official?

Yes

No

b. Government employee?

Yes

No

c. Political candidate?

Yes

No

d. If you answered Yes to any question above, please explain providing names of key personnel or family members or consultants.

2. Does your company conduct business with:

a. Government officials?

Yes

No

b. Government departments or agencies?

Yes

No

c. If you answered Yes to any question above, please explain.

3. Please indicate the percentage (%) of your sales that are derived from government contracts.

SMI Use of Other Parties

1. Does your company use any other party or person to distribute product on your company's behalf? If so, please indicate whom [if applicable].

Yes No

2. Will your company use or does your company plan to use any other party or person to perform the required services on behalf of our Company?

Yes No

3. Please detail the services and the percent of duties any other party or person provides with regard to our products.

4. If applicable, please identify the full name and address of any other party or person who will provide any work on behalf of your company.

5. Does your company require anti-bribery related terms (e.g., promises to not engage in bribery, termination rights of noncompliance, audit rights) in contracts with other parties or persons?

Yes No

6. Will any other party or person interact with HCPs or GOs on our behalf? If so, and if applicable, please identify the name and address of any other such party or person.

Yes No

7. Will any other party or person generate half⁹ or more of your company's annual revenue?

Yes No

⁹ Companies may tailor based on Company preference and assessment.

Books, Records, & Payment Practices

1. Is your company required to maintain detailed and accurate financial books and records in accordance with your country's accounting standards or applicable internationally accepted accounting standards? Please explain and specify the national or international standards to which your company's books are maintained. Please attach a copy of your records for your company's audited accounts (most recent year available).

Yes No

2. What method/type of payment will your company request under the prospective agreement?

3. In what country/ies will payments be made under the prospective agreement?

-
-
-

4. Please list the countries in which your company has bank accounts.

Example Self Certification¹⁰

The undersigned, being duly authorized by [name of your Company] to respond to this questionnaire and to certify as to the matters set forth below, hereby certifies as follows:

(a) To the best of my knowledge, all information set forth in this compliance questionnaire is correct and complete.

(b) I will notify [insert Company contact person] immediately in writing of any change in the information set out in this compliance questionnaire.

Name of your Company (Print): _____

Name (Print): _____

Position/Title: _____

Email: _____

Signature: _____

Date: _____

¹⁰ This form is to serve only as an example. AdvaMed and Eucomed member companies should confer with their legal counsel on the value and content of a certification.

***EXAMPLE¹¹* PRIVACY NOTICE**

Certain data collected in an SMI compliance diligence questionnaire may be “personal information” subject to local data protection laws and authorities. For this reason, Companies should seek legal advice from their internal data protection officer(s) and/or expert legal counsel when developing an SMI compliance diligence questionnaire to ensure compliance with applicable data protection regulations and internal company policies, including relevant notification obligations to Data Protection Authorities (DPA).

This privacy notice is intended to serve only as an example to state that information is collected for defined legitimate purposes only and is used accordingly, outlining as well the rights of the individuals whose data is collected. The use of this sample privacy notice is entirely voluntary.

As a prospective SMI to perform services on behalf of [name of the Company, referred here below as “the Company”], you are being asked to participate in a compliance due diligence review. The purposes of the review are to ensure that the SMI has the appropriate experience and qualifications and will comply with applicable anti-corruption laws and Company policies. This process requires relevant personal information about your management, key staff, agents and other individuals, which may include their names, job titles, criminal and judicial background and connections to government officials, as permitted by applicable law. Where necessary or appropriate, information you provide may be combined with other information provided. Your provision of personal information about individuals is voluntary and in compliance with applicable laws and regulations, but failure to provide requested information may be considered in our Company’s evaluation to conduct business with your company.

The information in this questionnaire will be documented in paper and/or electronic reports which will be stored at our Company. The storage and retention of this information will be carried out in accordance with the Company’s policies and procedures.

As part of its review and approval process, the Company may make the information available to authorized employees of the Company [if applicable: “or other affiliated companies (listed at)“]. Personal information may also be made available to external due diligence providers. In addition, personal information may be disclosed to a governmental authority, as required by applicable laws, regulations or court orders or pursuant to a valid request.

Please note that personal information may be transferred to countries that may have different privacy or data protection regimes than in your country.

¹¹ This form is to serve only as an example. AdvaMed and Eucomed member companies should confer with their legal counsel on the value and content of a notice.

For those SMIs that are engaged, any personal data collected will be retained for five (5) years after the business relationship ends in order to comply with legal obligations relating to anti-corruption and potential enforcement actions or inquiries. For those SMIs that are not engaged, any personal data collected will be retained for 12 months. After the above retention periods have expired, the Company will delete the stored personal data and will retain only a subset of information, including the name and location of the SMI, date the due diligence review was completed, date the SMI was trained by the Company and if relevant, the reason for not engaging a SMI (e.g., business or due diligence reasons).

Individuals may ask that the Company provide access to, rectify or update information that the Company holds about them, and that such information be deleted if it is inaccurate or irrelevant. Individuals who wish to exercise their rights or who have questions should contact [Name of the contact person in the Company].

Questionnaire Complete