JOINT GUIDANCE FOR MEDICAL DEVICE AND DIAGNOSTICS COMPANIES ON ETHICAL THIRD PARTY SALES AND MARKETING INTERMEDIARY ["SMI"] RELATIONSHIPS

Version July 10, 2014

1. ***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 companies ("Companies") to engage third party intermediaries to assist 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 these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives ("Third Party SMIs").

Regardless of the form of entity or the particular terminology used by individual Companies, this document is intended to cover those Third Party SMIs that market, sell or otherwise bring to end-users Companies' products or services. It is essential that Companies' interactions with Third Party SMIs, as well as Third Party SMIs' behaviour on a Company's behalf (including Third Party SMI interactions with Health Care Professionals ("HCPs") and governmental officials) are conducted pursuant to all applicable legal and ethical principles that comply with standards equivalent to those in our organizations' individual Codes of Ethics[1] ("Codes"). Collectively, these legal standards and ethical principles, as well as Company anti-corruption policies based on them, are referred to below as "Applicable Laws, Principles and Company Policies."

[1] See, 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; MTAA Medical Technology Code of Practice, http://www.mtaa.org.au/code-of-practice/overview; MTANZ Code of Practice, http://mtanz.org.nz/Professional-Development/Code-of-Practice-6440.htm; and MEDEC Code of Conduct, http://www.medec.org/code. Terms used in this document, not defined above, should be construed in accordance with the AdvaMed, Eucomed, MTAA, MTANZ, and MEDEC Codes.

Further to the Codes, the AdvaMed and Eucomed May 4, 2010 Joint Statement on Ethical Interactions between Medical Technology Companies and Healthcare Professionals and to our joint commitment to provide guidance to the medical technology industry at large on ethical business conduct, AdvaMed, Eucomed, MTAA, MTANZ, and MEDEC recognize that joint, harmonized, ethical guidance with respect to Company interactions with Third Party SMIs can be helpful to ensure integrity in medical decision making[2].

2. ***Guidance***

AdvaMed, Eucomed, MTAA, MTANZ, and MEDEC encourage Companies to adopt a Third Party SMI Management Compliance Program in addition to an overall (HCP) compliance program, applicable to all relevant personnel, including a Company's senior leadership. Taking into account a variety of risk-based factors, as well as local applicable laws; such programs may include the following elements:

A. Written Policy/Procedure. Adopt a compliance policy banning all forms of bribery[3] by any person or entity acting on the Company's behalf including Third Party SMIs. Such policies may include more detailed implementing policies for common risk areas (for example, travel, gifts, hospitality, entertainment, grants or donations, research, capital equipment).

B. Risk Assessment. Evaluate the risk profile for proposed and utilized Third Party SMI arrangements, including, for example, assessing:

1) Risk in country/geography through information such as, but not limited to, the Transparency International "Corruption Index" as well as specific risk profiles of planned or utilized Third Party SMIs;

2) Information concerning local market legal requirements;

[2] The AdvaMed Code currently provides guidance respecting United States agency and distribution arrangements. See AdvaMed Code FAQ 14.

[3] As used in this Guidance, the term "bribery" refers to transfers of something of value to government officials, health care providers or others that may violate applicable laws, principles or company policies. *See also*, OECD Anti-Bribery Convention definition, http://www.oecd.org/dataoecd/4/18/38028044.pdf at p 7.

3) Information from the Third Party SMIs for potentially unusual arrangements (unusually high commissions, high degree of interaction with government officials, marketing budgets, off shore payment accounts, etc.); as well as

4) Information available from public sources or employees for potential issues associated with the Third Party SMIs. The Risk Assessment can inform the application of other elements of this Guidance.

C. Diligence Program. Establish a risk-based pre-engagement and renewal due diligence program to identify, prevent and mitigate risks relating to the market in which the Third Party SMI is engaged to operate, as well as any specific activities the Third Party SMI deploys on behalf of the Company.

D. Written Contract. Encourage contract terms that require adequate controls and implementation of the Company's anti-corruption policy, such as the following:

- Compliance with Applicable Laws, Principles and Company Policies;
- Right to conduct independent audits, including where possible access to relevant books and records;
- Rights for early termination for failure to comply with Applicable Laws, Principles and Company Policies; and
- Diligence rights upon renewal.

E. Training and Education. Establish initial and regular training and education for Third Party SMIs and relevant Company personnel who manage Third Party SMI relationships on Applicable Laws, Principles and Company Policies. Where practical, training should be done in local language.

F. Monitor/Audit. Consider (and exercise reasonable efforts in) risk-based, routine monitoring, auditing or other assessment of Third Party SMI relationships for compliance with Applicable Laws, Principles and Company Policies and relevant contract terms; and regular certification of Third Party SMI personnel on compliance

with Applicable Laws, Principles and Company Policies and relevant contract terms.

G. Appropriate Corrective Action. Reserve and undertake necessary and appropriate corrective measures, consistent with applicable local laws if a Third Party SMI fails to comply with Applicable Laws, Principles and Company Policies and relevant contract terms or engages in other impermissible conduct.

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About AdvaMed, Eucomed, MTAA, MTANZ, and MEDEC

AdvaMed, Eucomed, MTAA, MTANZ, and MEDEC 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. For more information on AdvaMed's Code of Ethics and compliance programs and guidance, see:*

  http://www.advamed.org/MemberPortal/About/code/

- *About Eucomed. Eucomed represents the medical technology industry in Europe. Eucomed's mission is to make modern, innovative and reliable medical technology available to more people. For more information on Eucomed's Code of Ethical Business Practice and compliance programs and guidance, see:*

  http://www.eucomed.be/ethics.aspx

- *<u>About MTAA</u>. MTAA is the national association representing companies in the medical technology industry of Australia. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. For more information on MTAA's Medical Technology Code of Practice and compliance programs and guidance, see:*

  http://www.mtaa.org.au/code-of-practice/overview

- *<u>About MTANZ</u>. MTANZ is the leading industry body representing medical technology manufacturers, importers and distributors of medical devices in New Zealand. For more information on MTANZ's Code of Practice and compliance programs and guidance, see:*

  http://mtanz.org.nz/Professional-Development/Code-of-Practice-6440.htm

- *<u>About MEDEC</u>. MEDEC is the national association created by and for the Canadian medical technology industry. MEDEC is the primary source for advocacy, information and education on the medical technology industry for members, the greater healthcare community, industry partners and the general public. For more information on MEDEC's Code of Conduct and compliance programs and guidance, see:*

  http://www.medec.org/code