Impact of New Ethical MedTech,

APACMed & China AdvaMed Ethical Codes'

On ACCME Accredited Third-Party Organized Events

October 20, 2017

Executive Summary

New international medical technology ethical codes of conduct will be going into effect January 1, 2018, which impact the direct sponsorship and support of HCP attendance to third party events by member manufacturers. Direct sponsorship of individual HCPs will no longer be allowed, instead funding will need to occur through educational grants.

Updates to these three codes will go into effect on January 1, 2018:

- [MedTech Europe Code of Ethical Business Practice (Ethical MedTech)][1]
- [APACMed Code of Ethical Conduct for Interactions with Healthcare Professionals][2]
- [China Code of Ethics][3]

The revisions to the three codes support greater transparency and independence in medical education in Europe and Asia. Many of the principles espoused in the revised codes are echoed in the ACCME's Standards for Commercial Support: Standards to Ensure Independence in CME Activities[SM]. These Standards have been in place since 1992, and have been recognized internationally as a benchmark for independent medical education, and have been adopted by numerous other healthcare continuing education accreditors in the US and around the world.

ACCME accredited organizations can accept support for their educational activities from member manufacturing companies under the revised codes and successfully maintain independence from industry by adhering to ACCME's [Standard 3: Appropriate Use of Commercial Support][4]. The ACCME's Standard 3 allows accredited organizations to accept funds from commercial interests, with the express understanding that they will:

- Make all decisions regarding the use of the support independent of any company or companies
- Have a signed written agreement with the company that includes the specific terms and conditions of the support
- Use the funds only for the educational activity and to offset the cost of participation to the learners as a whole
- Not pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of the supported educational activity
- Disclose to learners the source and (if in-kind) the nature of the commercial support

Alignment between the revised codes and ACCME requirements can be achieved by ensuring that funds received from member manufacturing companies by the ACCME accredited organization are not used to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of the supported educational activity.

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[1] MedTech Europe Code of Ethical Business Practice, January 2016
[2] APACMed Code of Ethical Conduct for Interactions with Healthcare Professionals, 1 January 2017
[3] China Code of Ethics, AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("China Code"), 1 January 2017
[4] Accreditation Council for Continuing Medical Education (ACCME)Standard 3: Appropriate Use of Commercial Support
[5] [MedTech Healthcare Leaflet Organisations]
[6] [AdvaMed Direct Sponsorship Phase-out Brochure – English, September 22, 2017]
[7] [Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure Independence in CME Activities][SM]

Below are verbatim excerpts from these codes and accreditation rules from official resources, codes, rules, and internet sites for the various organizations and institutions.

MedTech Europe Code of Ethical Business Practice (Ethical MedTech)[1]
Introduction

Promoting an Ethical Industry
MedTech Europe recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology industry.

The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes.

Aims and Principles of the Code
The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving MedTech Europe's mission to make safe, innovative and reliable technology and related services available to more people. For example:

- Advancement of Medical Technologies
- Safe and Effective Use of Medical Technology
- Research and Education

In each such interaction Member Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:

- The Principle of Image and Perception
- The Principle of Separation
- The Principle of Transparency
- The Principle of Equivalence
- The Principle of Documentation

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[4] Accreditation Council for Continuing Medical Education (ACCME)Standard 3: Appropriate Use of Commercial Support
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Transition Period to phase out direct support for HCP attendance at Third Party Organised Educational Events and for HCP speakers at satellite symposia

After the end of the Transition Period on 31 December 2017, Member Companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium. This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events (as provided for at Chapter 2, Section 3) shall no longer be permitted under the Code.

After the Transition Period, Member Companies may provide financial or in kind support to Third Party Organised Educational Events only through Educational Grants or other types of funding in accordance with the rules of Chapter 2: Third Party Organised Educational Events and Chapter 4: Grants and Charitable Donations.

Support to Medical Education and Interactions with Healthcare Organisations, (MedTech Europe Code of Ethical Business Practice) – Leaflet[5]

A common Code of Ethical Business Practice
- The new Medtech Europe Code of Ethical Business Practice sets strict, clear and transparent rules for our industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), including company-organised events, arrangements with consultants, research and financial support to medical education.
- The new Code is common for the In Vitro Diagnostics and Medical Devices companies which are member of MedTech Europe.

Code in Brief

Sponsorship model for third-party organised events (e.g. conferences, congresses etc.):
- As of 1 January 2018, MedTech Europe members will no longer give direct financial support to individual HCPs to attend third party organised events. This will be done through educational grants provided to Healthcare Organisations (HCOs).

Transparency of educational grants:
- As of 1 January 2018, MedTech Europe members will publicly disclose educational grants provided to HCOs (e.g. support to conferences, scholarships and fellowships).

All events organised or supported by members need to comply with general criteria for events:
- For example, all events with HCPs must take place in appropriate locations and venues, with reasonable hospitality, no guests or spouses etc.

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- A broader category of sponsorship will require approval under the conference Vetting System (e.g. provisions educational grants, promotional activity -e.g. booths-, etc.).

APACMed Code of Ethical Conduct for Interactions with Healthcare Professionals[2]

APACMed MISSION: Our mission is to improve the standards of care through innovative collaborations among stakeholders to jointly shape the future of health care in Asia Pacific.

APACMed Code of Conduct: APACMed promotes ethical interactions between the medical technology industry and health care professionals to advance its mission. The purpose of APACMed's Code of Ethical Conduct for Interactions with Health Care Professionals is to facilitate ethical interactions between its Corporate Members that develop, manufacture, sell, market, or distribute medical technologies in Asia Pacific and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Asia Pacific.

Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in this Code. This Code is subject to the laws of each country, province, or region, and other codes of conduct, applicable to a Member. If a provision in law or another code of conduct applicable to a Member is more restrictive than the corresponding provision in this Code, the Member shall adhere to the more restrictive provision in the law or other code of conduct. Likewise, if a provision in this Code is more restrictive than the corresponding provision in law or another code of conduct applicable to a Member, the Member shall adhere to the more restrictive provision in this Code.

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APACMed recognizes that collaborative interactions between Members and HCPs are essential to advancing medical technology and ensuring the safe and effective use of Members' products and services.

APACMed is committed to ensuring that these interactions meet the highest ethical standards, preserve HCPs' independent decision-making, and reinforce public confidence in the integrity of patient care, treatment, and product and service selection.

APACMed Code of Ethical Conduct: Member support of Third Party Educational Events

3.1 Member support of a Third Party Educational Event shall at all times preserve the independence of medical and scientific education. A Third Party Educational Event must primarily be dedicated to promoting medical, scientific, and educational activities and discourse, and must be initiated by the Third Party Educational Event organizer.

3.2 Any Member's decision to support a Third Party Educational Event must be based on sufficient information to enable the Member to evaluate the medical, scientific, and educational merit of the Third Party Educational Event, as well as the appropriateness of the venue and agenda. Members should not seek to inappropriately influence the program content, selection of faculty, educational methods, or materials at the Third Party Educational Event.

3.3 Under no circumstances shall a Member's support of a Third Party Educational Event be to induce an HCP to use, recommend, purchase, or prescribe the Member's products and/or services. The nature of and the conditions attaching to a Member's support of a Third Party Educational Event must be properly documented in writing.

3.4 Subject to Section 8 (Research and educational grants), a Member may provide an educational grant to:

  (a) the organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational Event and/or to support attendance of HCPs at the Third Party Educational Event;
  (b) a Healthcare Institution to support attendance of HCPs at the Third Party Educational Event; and/or
  (c) a Professional Association to support attendance of HCPs at the Third Party Educational Event.

3.6 A Member may select and directly pay for the expenses of any individual HCP to attend or speak at a Third Party Educational Event ("Direct Sponsorship"). Where possible, the costs of travel, accommodation, meals and refreshments should not be reimbursed directly to individual HCPs but should be paid directly to the Third Party Educational Event organizer or qualified and reputable third party service providers. With effect from 1 January 2018, Direct Sponsorship will no longer be permitted, and this Section 3.6 shall be replaced by the following wording:

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3.6 Members shall neither:

(a) pay for, offer to pay for, or otherwise reimburse the expenses of any individual HCP to attend or speak at a Third Party Educational Event;

nor

(b) select, or influence the selection of, any HCP to attend a Third Party Educational Event, whether as a delegate or as faculty.

In accordance with Section 8 (Research and educational grants), Members may only support attendance of HCP speakers and delegates at Third Party Educational Events through provision of educational grants under Section 3.4, provided the recipient of the grant makes an independent decision on selection of the attending HCPs.

AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("China Code")[3]

The AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("China Code") facilitates ethical interactions between Medtech Companies and Health Care Professionals in China to help ensure that medical decisions are based on the best interests of the patient.

China Code Introduction
Medtech Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals (HCPs) to advance medical technologies, enhance the safe and effective use of medical technologies, encourage research and education, and foster charitable donations and giving. To ensure that these collaborative relationships meet the highest ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. The AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("China Code") [Chinese] [English] clarifies and distinguishes appropriate activity between health care professionals and representatives of AdvaMed member companies in China.

Background
AdvaMed and its members encourage ethical business practices and socially responsible industry conduct related to their interactions with health care professionals through:
- The AdvaMed China Board, which consists of AdvaMed member companies' most senior executives in China, together with the AdvaMed China Code Task Force, which consists of legal professionals and compliance offices supporting AdvaMed member companies in China, lead AdvaMed's ethics and compliance initiatives in China, including stewardship of the China Code;

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- The China Code Certification Program, which allows AdvaMed member and non-member companies to certify adoption of the China Code;
- The China Code Logo Supporters Program, which offers any medtech company that has certified to the China Code a license to display the China Code of Ethics Logo, promoting awareness of the China Code and providing a visible symbol of the company's commitment to effective compliance programming and ethical interactions with health care providers; and
- Providing contact information to health care compliance officers responsible for overseeing their company's compliance with fraud and abuse laws and implementation of China Code; and
- Hosting and facilitating educational conferences and meetings for compliance best practices exchanges and dialogue with government and industry leaders. AdvaMed seeks opportunities to communicate the importance of furthering ethical interactions between industry and health care professionals through speaking engagements and meetings with all partners in the health care continuum.
- Most recently, in furthering member companies' commitment to ethics and compliance, AdvaMed's Board voted to approved a phase-out of direct sponsorships of health care professionals (HCPs) in China to attend third party educational conferences, effective January 1, 2018. While companies can no longer directly support individual HCP attendance at these events, medical technology companies remain deeply committed to HCP education in China through educational grants/donations to conference organizers, support for HCP participation in procedural training programs, and company-conducted training on the safe and effective use of products. This revision of the China Code, described in both the pocket card and brochure materials, aligns with other medtech associations' (MedTech Europe and APACMed) phase – out of direct sponsorship both of which are also effective January 1, 2018.

Medical Technology Companies' Considerations in Funding Educational Grants/Donations[6]
The AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (AdvaMed China Code) provides compliance guidelines for medical technology companies. This includes information on how medical technology companies can support educational conferences.

Under the AdvaMed China Code, companies can provide an educational grant or donation of funds to support bona fide independent, educational, scientific, and policymaking conferences that promote scientific knowledge, medical advancement and the delivery of effective health care.

- Such educational grants/donations can be provided to (1) a Third-Party Conference Organizer or (2) another appropriate third party (such as a training institution, hospital, medical or other professional association, educational foundation, or similar entity that supports the training and education of Health Care Professionals (HCPs).
- Such educational grants/donations can be used to reduce or defray legitimate conference costs, such as the cost of modest meals, registration, venue rental, and travel and lodging, among other costs.

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- Effective 1 January 2018, AdvaMed member companies do not directly pay for individual HCPs' costs to attend a third-party educational conference. Instead, companies support educational conferences through educational grants/donations to the conference organizer or grant/donation recipient, as applicable.

Accreditation Council for Continuing Medical Education (ACCME)[7]

Since 1981, the ACCME has focused on setting and maintaining accreditation requirements that are relevant to physicians' lifelong learning needs and responsive to changes in the health care environment. The purpose of the ACCME accreditation requirements is to set expectations for accredited organizations that ensure CME is independent, based on valid content, and contributes to health care improvement for patients and their communities.

ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities[SM]
The 2004 ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities[SM] are designed to ensure that CME activities are independent and free of commercial bias. The Standards impose restrictions on CME providers' interactions with drug/device companies and other companies the ACCME defines as a commercial interest. The ACCME allows providers to accept company funding for CME activities, but prohibits any commercial influence, direct or indirect, over CME content.

The ACCME Standards for Commercial Support comprise six standards: independence, resolution of personal conflicts of interest, appropriate use of commercial support, appropriate management of associated commercial promotion, content and format without commercial bias, and disclosures relevant to potential commercial bias.

Building on guidelines that the ACCME first issued in 1987 and formally adopted in 1992, the 2004 ACCME Standards for Commercial Support added the following elements:

- CME providers must ensure that CME planning decisions are made free of the control of a commercial interest cannot take the role of a nonaccredited partner in a joint sponsorship relationship.
- Providers must be able to show that everyone who is in a position to control the content of educational activities has disclosed to the provider all relevant financial relationships with any commercial interest.
- Those who refuse to disclose relevant financial relationships are disqualified from participation in planning or delivering education.
- Providers must implement a mechanism to identify and resolve all conflicts of interest for all persons in control of content, including planners, teachers, and authors.
- The provider must have written policies and procedures governing honoraria for planners, teachers, and authors.

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When making decisions about implementing the ACCME Standards for Commercial Support, the ACCME says that CME providers must always defer to independence from commercial interests, transparency, and the separation of CME from product promotion. In other words, the purpose of CME must be to serve physicians' learning and practice needs and to promote public health.

Glossary

Accreditation Council for Continuing Medical Education (ACCME). The ACCME's mission is the identification, development, and promotion of standards for quality continuing medical education (CME) utilized by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their communities.

APACMed was founded in 2014, the Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

China Code AdvaMed and its member companies are committed to the highest ethical standards in interacting with health care professionals (HCPs) in China. The AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (China Code) provides industry-wide compliance guidance for medical technology companies' interactions with HCPs derived from best practices and global compliance trends.

Healthcare Organisation (HCO) means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services.

MedTech Europe represents the medical technology industry in Europe and is an alliance of European medical technology industry associations. The alliance was founded in October 2012 and currently has two members being the European Diagnostic Manufacturers' Association (EDMA), representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry.

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