

2015 APEC Business Ethics for SMEs Forum

Medical Device Sector Workshop

19 August 2015 | Manila, Philippines



Ms. Lynn Costa

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The United States

Participant Introductions & Status Updates by Associations

SESSION ONE

The Value of High-Standard Ethics – An SME's Perspective

Session One: The Value of High-Standard Ethics – An SME's Perspective

Moderator: Mr. Stephan Ekmekjian, MEDEC (Canada)

Panelists:

- 1. Mr. Mario Mongilardi, President, COMSALUD (Peru)**
- 2. Ms. Zhang Beibei, CCCMHPIE (China)**
- 3. Ms. Johanna Gulle, PAMDRAP (Philippines)**

SESSION TWO

Best Practices for Low Cost Implementation of your Code of Ethics

Session 2: Best Practices for Low Cost Implementation of your Code of Ethics

**Campbell Clark, Medtronic; Thomas Hsu, Edwards;
David Rosenzweig, Abbott; Michelle Wagner, J&J**

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Session Two: Best Practices for Low Cost Implementation of your Code of Ethics

Objective: Strategies for associations and companies, in particular small and resource-constrained enterprises, on how to implement high-standard codes at little or no cost.

This session will provide practical evidence and examples to reject perceptions that implementing ethical practices is too costly or time consuming for organizations.

Structure: Breakout Team Exercise.

Output: Module/Toolkit of resources for medical device companies, particularly SMEs, which demonstrates the value of high-standard ethics and best practices for low cost implementation of a code of ethics.



Session Two: Best Practices for Low Cost Implementation of your Code of Ethics

Why is a Code of Ethics Necessary?

- Anti-corruption laws and enforcement of those laws is becoming more aggressive.
- Violating current anti-corruption laws could lead to:
 - governmental investigations
 - civil lawsuits
 - financial costs associated with investigations, litigation and government oversight
 - reputational harm and public embarrassment, leading to loss of competitive advantage and consumer trust
 - disruption and loss of business



Session Two: Best Practices for Low Cost Implementation of your Code of Ethics

Why is a Code of Ethics Necessary? (cont.)

- Civil/criminal penalties, include:
 - jail sentences
 - loss of profits (disgorgement)
 - loss of contracts, permits or licenses
 - exclusion from government-run tenders
 - assignment of compliance monitors

Session Two: Best Practices for Low Cost Implementation of your Code of Ethics

Benefits to SMEs of Ethical Behaviour

- Meets legal and regulatory expectations
- Protects company from legal/financial harm
- Creates a productive corporate culture
- Enhances employee morale, productivity and retention
- Competitive advantage
- Creates foundation for long term corporate sustainability
- Reduces cost of capital
- Increases shareholder value
- Attracts customers and institutional investors
- Protects company reputation

Session Two: Best Practices for Low Cost Implementation of your Code of Ethics

Output from Session Two

A “toolkit” comprising the following material:

1. Third party due diligence checklist to enable this work to be “in-sourced”
2. Speaking up policy
3. “Decision tree”
4. “Tips and tricks” on how to establish the “Tone from the Top” in the SME context
5. A communication strategy around ethics and compliance and the adoption of the code, together with communication materials

Session 2: Best Practices for Low Cost Implementation of your Code of Ethics

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LUNCH BREAK

(Luzon Room – Upstairs)

12:00 – 13:00

SESSION THREE: **ASSOCIATIONS AS AGENTS** **OF CHANGE FOR MEMBERS** **& NON-MEMBERS**

Session Three: Associations as Agents of Change for Members & Non-Members

Leads:

- **Ms. Nancy Travis, AdvaMed (United States)**
- **Ms. Andrea Perez, AMID (Mexico)**

Background

- The *Advanced Medical Technology Association (AdvaMed)* has a Code of Ethics, which each member of the Board of Directors has pledged to uphold.
- The AdvaMed Code provides member companies with guidance on their interactions with Health Care Professionals (HCPs) to ensure that collaborative relationships meet the highest ethical standards, and medical decisions are based on the best interests of the patient.
- It covers a wide variety of interactions, including consulting arrangements, training & education, meals & travel, and provision of educational items & demonstration products, requiring a legitimate business justification for the interaction and a fair market value limitation to the exchange.
- The Code is in part based on U.S. Government guidance and has been recognized by federal and state government officials, including in the Massachusetts, Connecticut, & Nevada medical device marketing law requirements.

Case Study

- Members of the U.S. Congress grew concerned about potentially inappropriate payments to doctors in the healthcare sector
- In 2008 Congress held a hearing to determine whether manufacturers & distributors of medical devices, drugs, biologicals and medical supplies should track and report payments and transfers of value provided to physicians and teaching hospitals.

Questions

- What risks are there in releasing such data to the public?
- How can companies and the association use the code of ethics to mitigate those risks?

Background

- *The Mexican Association of Innovative Medical Devices Industries (AMID)* has a Code of Ethics and a Code of Interaction with Healthcare Professionals. Companies are required to comply with these Codes in order to retain their membership or to become a member of the association.
- Each company has their own Code of Ethics which is aligned with both Codes of AMID.
- All distributors from each member company have to Comply with both Codes of AMID.
- The Company *Pharmaceutical Alfa* is member of AMID.
- The Company *Laboratories Beta* is a local company with more than 50 years of operations in the country and aiming to become the leading distributor of *Pharmaceutical Alfa*.
- *Laboratories Beta* is not member of AMID

***The costumers/clients represents more than 40% of the total sales of each Company.**

Case Study

Pharmaceutical Alfa and *Laboratories Beta*, both received requests from their major customers/clients (i.e. Hospitals, Doctors, Clinics, etc.)* asking to the commercial team for “obligatory contributions” in cash or payments in kind in order to carry out all sort of social events or holiday celebrations. In both cases, the distributors of these companies have also received the same requests. The customers/clients mentioned if the companies grant this “obligatory contributions” they will have a preferential treatment, otherwise payments will be retained.

Questions

- How do you think *Pharmaceutical Alfa* decided to solve the situation?
- How do you think *Laboratories Beta* decided to solve the situation?

Breakout Session

**MEDICAL DEVICE SECTOR WORKSHOP
19 AUGUST 2015**

***Session Three: Associations as Agents of Change for
Members & Non-Members***



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Solution

Pharmaceutical Alfa

- Decided to communicate and escalate the situation to AMID. Therefore, AMID in compliance with its Code of Ethics and the Code of Interactions with HCPs, formulated a letter supported by all associated companies which expressed the impossibility of giving any gift in cash or payment in kind. The letter was circulated among all associated companies which, at the same time, circulated it to all its customers/clients in order to let them know the position of the industry.

Results

- The business relationship was not affected
- Background and precedents of good practice where established among member companies and the industry.
- Established foundations of a strong culture of compliance and fair competition in the market.
- No further requests of this nature where asked.



Solution

Advanced Medical Technology Association

- Working with member companies, developed a robust advocacy campaign to convey the benefits for innovation of collaboration between companies and healthcare providers
- In meetings with lawmakers and regulators:
 - Used the Code of Ethics as a tool to educate members on the value of this collaboration for product development and improvement
 - Highlighted the Code of Ethics as a guide to ensure these relationships are conducted in the appropriate manner
 - Built confidence in the good will of the industry and the association through the Code of Ethics



Timeline of AdvaMed's Sunshine Engagement

Dec '07

- Advocacy work to shape legislation

Feb '08

- Testimony before Senate Special Committee on Aging

Mar
'08-10

- AdvaMed approval of consensus Sunshine positions

Apr '10

- Formation of Interdisciplinary Working Group to prioritize implementation issues; develop policy recommendations

Mar '11

- Participation in CMS Special Open Door Forum

Apr '11

- Meeting with CMS to discuss Recommendations

Jul '11

- Letter to CMS setting out AdvaMed's Consensus Sunshine Implementation Recommendations

Oct '11

- Submission of interstakeholder letter to HHS Secretary Sebelius (raised delayed implementation)

Nov '11

- Communications with Senate staff regarding "costs" of delayed regulatory guidance & proposed implementation postponement

Dec '11

- Submission of written testimony to Committee members for Senate Special Committee on Aging Hearing, "Parting the Clouds"

Feb '12

- Submission of comments in response to Proposed Rule

Apr-Jun
'12

- Meetings with CMS & Senate Staff

Aug '12

- Letter to CMS urging publication of Final Rule (in conjunction with other industry associations)

Sep '12

- Written testimony for Senate Aging Roundtable on Sunshine Implementation



The Device Industry Difference

Physician-Industry Interactions: A Pathway to Innovation

Collaboration

with Health Care Professionals is Necessary for
Patient Safety and **Medical Innovation**

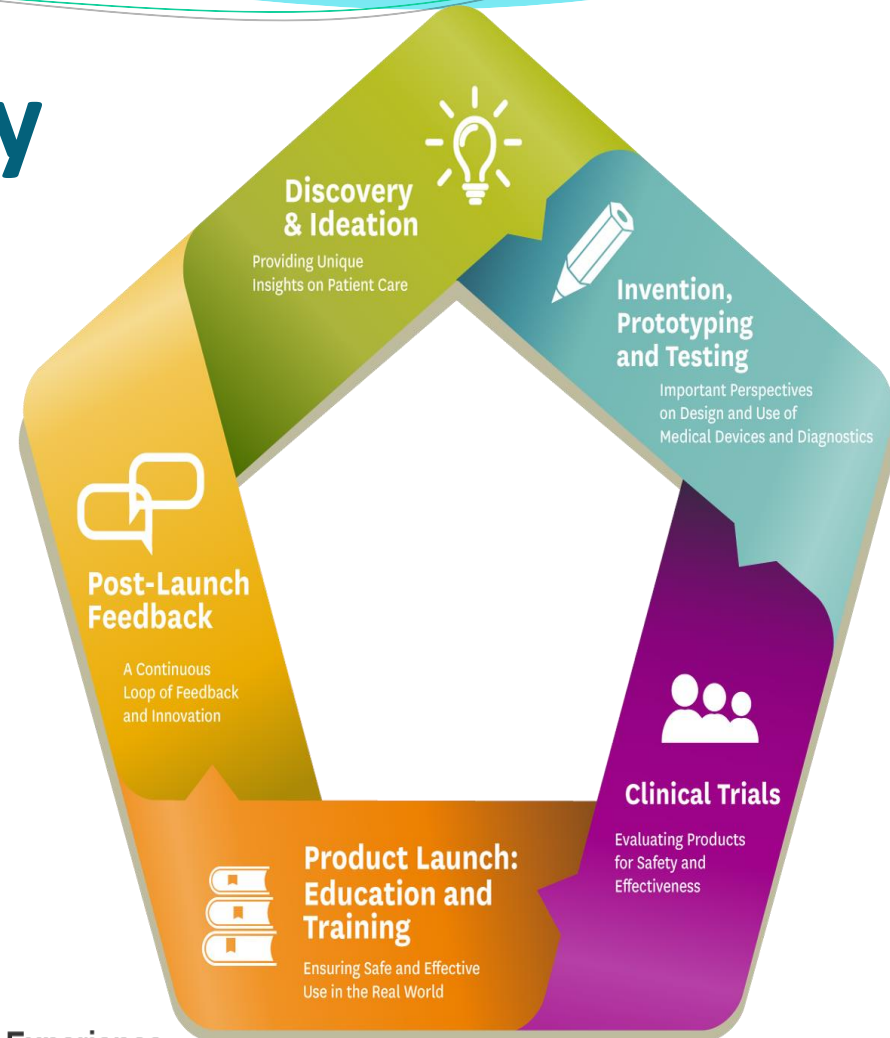


Hands-On Training Required

Re-Training

Short Life Cycles

HCPs bring **Practical Field Experience**
vital to continued development and
improvement of medical technology



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The AdvaMed Code as a Tool to Support Innovation

Sections of the AdvaMed Code

- I. Preamble: Goal and Scope of the AdvaMed Code
- II. Code of Ethics Compliance
- III. Company-Conducted Product Training and Education
- IV. Supporting Third-Party Educational Conferences
- V. Sales, Promotional, and Other Business Meetings
- VI. Consulting Arrangements with Health Care Professionals (HCPs)
- VII. Prohibition on Entertainment and Recreation
- VIII. Modest Meals Associated with HCP Business Interactions
- IX. Educational Items; Prohibition on Gifts
- X. Provision of Coverage, Reimbursement & Health Economics Info
- XI. Research and Educational; Grants and Charitable Donations
- XII. Evaluation and Demonstration Products



Results

Patient Protection and Affordable Care Act (PPACA) signed into law in 2010

- Includes many of AdvaMed's recommendations
- Requires medical device manufacturers to report "payments or other transfers of value" to "covered recipients"
 - Payments or other transfers of value means a transfer of anything of value. Certain identified payments/transfers excluded, e.g., those less than \$10/\$100 annual aggregate, certain educational materials, in-kind items for charity care
 - Covered Recipients are limited to physicians and teaching hospitals
 - Reportable information includes name and address of covered recipient, amount + date of payment, form of payment (e.g., cash, stock), nature of payment (e.g., consulting fees, gift, entertainment)



SESSION FOUR: **BEST PRACTICES FOR** **ASSOCIATIONS IN HELPING** **MEMBERS IMPLEMENT THE CODE**

Sample Code of Ethics based on the Kuala Lumpur Principles

Integrity means dealing honestly, truthfully, and fairly with all parties.

Independence means that Healthcare Professionals' interactions with Companies should not skew the Healthcare Professional's medical decision making from the best interest of the patients.

Appropriateness means that arrangements conform to proper commercial standards, are accurate and free from corrupt purposes.

Transparency means that Companies and Healthcare Professionals are open regarding significant financial relationships between the parties.

Advancement means that relationships are intended to advance medical technology innovation and patient care.

The safe and effective use of Medical Technologies, and the continuing advancement of Medical Technologies, requires collaborative interactions between Companies and Healthcare Professionals. However, when interactions are not conducted in accordance with appropriate ethical standards, they pose a risk of inappropriately influencing the decision-making of Healthcare Professionals. Even appropriate interactions may undermine the public's confidence if they appear to be intended as an inappropriate inducement.¹ Collaborative interactions between Companies and Healthcare Professionals should preserve independent decision-making by Healthcare Professionals and public confidence in the integrity of patient care, treatment and product selection. Companies and Healthcare Professionals should avoid interactions that could improperly influence a Healthcare Professional's purchasing or medical decision-making or appear to do so.

The above guidelines and principles apply to all interactions between Companies and Healthcare Professionals. They supplement and are subject to, the laws of each country, province or region in which a Company conducts business and Companies are responsible for knowing and complying with those laws. The additional principles set forth below are intended to supplement, not to replace, the general provisions above.

2. Consulting Arrangements.

Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may compensate consultants at fair market value for performing these types of services, provided they are intended to fulfill a legitimate business need and do not constitute an undue inducement.

¹ Inappropriate inducement means a remunerative arrangement intended to inappropriately influence a Healthcare Professional's medical decision and product selection.

Sample Medical Device Association Code of Ethical Conduct for Interactions with Healthcare Professionals (Based on the APEC Kuala Lumpur Principles)¹

This Code of Ethical Conduct ("Code") is effective as of [date]. Company certifications should be submitted no later than the first of [month] of each year, beginning in [year]. [Association name] will publish the certification form that Companies should use on its website at [association web site].

1. Purpose of Code & General Provisions

[Association name] recognizes that ethical interactions between the medical device and diagnostics industry and healthcare professionals advance Medical Technologies and ensure public confidence in the Medical Device and Diagnostics industry. The purpose of this Code is to facilitate ethical interactions between companies that develop, produce, manufacture and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in [APEC Member Economy] ("Companies") and those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in [APEC Member Economy] ("Health Care Professionals").

Interactions with Health Care Professionals. Ethical interactions between Companies and Healthcare Professionals enhance patient access to the safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by Companies. Ethical interactions also promote innovation and the ongoing development of advanced Medical Technologies through legitimate and transparent collaboration between Healthcare Professionals and Companies. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies to participate in global markets.

Ethical interactions ensure that medical decision-making is made in the best interest of the patient. To ensure that relationships meet this standard, interactions between Companies and Healthcare Professionals should be conducted in accordance with the following principles: **Integrity, Independence, Appropriateness, Transparency and Advancement:**

¹ The APEC Kuala Lumpur Principles, endorsed by APEC Ministers in 2011, can be accessed here:

http://apec.apec.org/Documents/2011/MM/3MEMM/11_3memm_009.pdf

² The term "Healthcare Professionals" includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Companies' medical technology products. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

Medical Technologies is not covered by this section and should be evaluated under the provisions of Section 2.

10. Ensuring Effective Code Implementation

In order to ensure effective implementation of Code principles, each [Association name] Member Company should take the following concrete steps:

- Appoint a senior executive responsible for oversight of the Company's compliance with this Code.
- Adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with the Code.
- Provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance.
- Ensure that senior management and the company's board of directors or other governing body have expressly committed to support the Code.
- Institute appropriate internal monitoring and auditing mechanisms.
- Create safe mechanisms for, and encourage, employees who raise concerns.
- Require that third party intermediaries (including consultants, distributors, sales agents, and brokers) that may interact with Healthcare Providers in connection with Company Medical Technologies agree to comply with this Code; and
- Provide a certification to [Association name] that the Company has signed onto the [Association name] Code of Ethical Conduct, so those Member Companies can be publicized.



Sample Code of Ethics Training Slide Deck

The APEC Model Code

Sections of the Code

Rational for having Codes of Practice

- Provide basic ground rules for data

The Code of Practice is NOT intended:

The Medical Device Industry Dilemma

Close and ongoing collaboration between medical professionals and medical technology necessary for patient safety and medical advancement.

- Medical technologies require hands-on training to assure safe and effective use and retraining as technologies undergo repeated changes.
- Physicians bring practical field and other knowledge to the development and improvement of medical technology.



APEC Model Code Training

Implementation and Evaluation

Improve patient care by providing access to HCPs free of charge for educational purposes, provided that the information is not given or intended as an advertisement.

Information should be appropriately disclosed. All Companies should ensure the information is retrieved or returned if not

Sample Code of Ethics Comprehension Quiz

Courtesy of MEDEC, Canada's Medical Technology Companies



MEDEC Code of Conduct Quiz on New Code

- Q.1 What does a code of Conduct stand for?
- Q.2 How long have we had a Code of Conduct for our industry?
- Q.3 Why do we need a Code of Conduct?
- Q.4 What group of individuals may have material influence over purchasing decisions?
- Q.5 Are Codes of Conduct found exclusively in the healthcare industry?
- Q.6 Why was the code revised and restated?
- Q.7 In which provinces can a Code of Conduct be used?
- Q.8 Is a Code of Conduct a new requirement by government?
- Q.9 Which customers does a Code of Conduct typically apply to?
- Q.10 Who developed MEDEC's Code of Conduct?
- Q.11 Who will monitor adherence to the industry's Code of Conduct?
- Q.12 If a Canadian company has its headquarters in the US or Europe, does the company refer to AdvaMed's or Eucomed's Code of Conduct?



- Q.13 In a membership driven association, who is guided by a Code of Conduct?
- Q.14 Does a Code offer legal advice?
- Q.15 What are some major revisions to the 2012 MEDEC Code?



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Sample Certification Form

[Insert Association Logo Here]

Code of Ethics
Certification [YEAR]
CHECKLIST

Medical technology companies may participate in this certification program. The certification affirms that the company has agreed to abide by the [Insert Association Name] Code of Ethics on Interactions with Health Care Professionals [Name of Code] and further that they have implemented policies and procedures to implement the [Name of Code] as part of an effective compliance program. The Certifications and the Logo License Program operate on a Calendar Year basis and both are now being accepted for [year].

A New Certification requires (Attachment A):

Two Signatures

☐ the signature of the Chief Executive Officer or other senior individual with equivalent responsibilities (CEO); and
☐ the signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO).

☐ the signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO), to attest that their company has previously certified and that the company continues to abide by the [Name of Code]

Compliance Contact Information for posting on the [Insert Association Name] website with either:

☐ Compliance Contact (Individual or Dept. Name) + Telephone and/or Email Address (Compliance Hotline Optional)

- OR -

☐ Compliance Hotline

Electronic Submission:

☐ Please transmit a PDF electronic copy via email to: [Insert Email Address]

☐ Please email a graphic file of your Company's logo to: [Insert Email Address]

[Name of Code] Logo License Agreement (Optional)

[Insert Association Name] has developed a distinctive Code of Ethics Supporter Logo ("Logo") for medical technology manufacturers that have executed the Certification of Adoption of the [Name of Code] of Ethics ("Certification") and wish to use the Logo.

A New Participant in the Logo Program requires:

☐ A Completed Certification or Renewal Certification form (meeting the requirements noted above)

☐ A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to [Insert Email Address].

☐ Contact information to receive the invoice for the Royalty Payment ([Insert Payment Amount]/ year prorated)

A Renewal Certification requires (Attachment B):

One Signature

☐ the signature of the Chief Compliance Officer or other senior individual with equivalent responsibilities (CCO), to attest that their company has previously certified and that the company continues to abide by the [Name of Code]

Updated Compliance Contact Information:

☐ Update Compliance Contact Information if it has changed from the previous certification

Electronic Submission:

☐ Please transmit a PDF electronic copy via email to: [Insert Email Address]

For Question re: the Certification, Renewal Certification, or the Logo Supporter Program, contact:
 [Insert Contact Information]

A Renewal Participant in the Logo Program requires:

☐ A Completed Certification or Renewal Certification form (meeting the requirements noted above)

☐ A completed Logo License Agreement Form (Attachment C) with the signature of the CCO emailed to [Insert Email Address].

☐ Updated Contact information, if it has changed, to receive the invoice for the Royalty Payment ([Insert Payment Amount]/ year prorated)

Renewal
 Certification of Adoption of the [Name of Code] of Ethics

[Insert Association Logo Here]

RE-CERTIFICATION OF ADOPTION OF THE [ASSOCIATION NAME] CODE OF ETHICS

Pursuant to the [Name of Code] of Ethics on Interactions with Health Care Professionals ("[Association Name] Code"), medical technology companies, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the [Name of Code] as part of an effective compliance program. This renewal certification requires a company's Chief Compliance Officer (CCO) or other senior individual with equivalent responsibilities to sign and affirm that their company has previously certified and that the company continues to abide by the [Name of Code]. [Association Name] will list the certifying company on the [Association Name] website in [year]. (see [insert website])

[Insert Association Logo Here]

[NAME OF CODE] LOGO LICENSE SUPPLEMENT

[Association Name] has developed a distinctive Code of Ethics Supporter Logo ("Logo") for medical technology manufacturers that have executed the Certification of Adoption of the [Name of Code] of Ethics ("[Name of Code] Certification") and wish to use the Logo. The Logo is intended to provide a visible symbol of the medical technology company's commitment to the ethical standards embodied by the Code and to raise awareness about the [Name of Code] among industry, health care professionals, and the general public.

Companies seeking to use the Logo must sign the following nonexclusive license provision. [Association Name] retains the right to revoke this License for a Company's failure to abide by the terms of this Logo License Supplement.

I, [Name of Company], of [Company Name] (hereinafter "Company"), I agree to abide by the following terms of the License. The License is a revocable, non-transferable, nonassignable, non-exclusive license to use an unaltered version of the Logo on marketing materials, business cards, and displays at meetings and conferences, and stationary. The Logo may not be used on any product.

The licensee acknowledges and agrees that the right to use the Logo, as well as the actual use of the Logo, is not an endorsement by [Association Name].

The right to use the Logo is subject to the licensee's annual completion of the [Association Name] Certification and payment of a royalty (\$300 / year prorated), which royalty may be adjusted by [Association Name] from time to time; and

The royalty payment is made solely in exchange for the use of the Logo, and such payment does not entitle the licensee to any other benefit or service from [Association Name].

Signature: _____ Date: _____
 Chief Compliance Officer (or Equivalent)
 Name: _____
 Title: _____

Please email the invoice for the royalty payment to:

Name: _____ Use PO or Reference#: _____
 Email: _____

Please email the confirmation of payment receipt and the logo file to:

Name: _____
 Email: _____

[Name of Company] ("Company"). I certify that, to the best of my knowledge, the Company and its subsidiaries:

that we will abide by the [Name of Code], and that we have implemented the [Name of Code] as part of an effective compliance program.

Company's most recent certification, there have been no material changes in this regard.

CONTACT INFORMATION ON [ASSOCIATION NAME] WEBSITE:

Hotline Number: _____
 - OR -
 Email: _____

The certification will be posted to: [insert website here].



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Sample FAQs

Courtesy of the Advanced Medical Technology Association

FREQUENTLY ASKED QUESTIONS REGARDING ADVA MED'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and "hands on" nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 Who are "Health Care Professionals"? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?

The phrase "Health Care Professionals" is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician's practice managers and management within group purchasing organizations ("GPOs").

Q3 Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside

Any relationship between a Health Care Professional and a Company where services provided to the Company by the Health Care Professional are considered to constitute consulting or consulting arrangement and should comply with Section VI. Examples of consulting arrangements include providing education and training, speaking engagements, presenting and participating, software center or center of excellence arrangements, participating in advisory boards or focus groups, medical technology development and research services arrangements (such as joint research arrangements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Research and educational grants are not considered consulting arrangements. They are addressed in Section VI.

Q5 Can the derivation of a consultant include his or her experience, usage or familiarity with a specific Company Medical Technology?

Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It provides that these qualifications could include experience with usage of a familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be based on usage or familiarity with a specific Medical Technology.

Q6 How are Clinical Study Agreements treated under the Code?

Arrangements that result in the provision of clinical research services by a Health Care Professional to a Company are not considered consulting or consulting arrangements and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written service agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should be for a legitimate research purpose.

A Clinical Study Agreement typically is entered into between a Company and a Health Care Professional that is a Health Care Professional, or a group, and compensation for the clinical research services is paid to that entity. An individual Health Care Professional may act as a study investigator for the clinical research services to be provided to the individual entity that is a study investigator for the clinical research services. The clinical study agreement (i.e., protocol development). In that case, it may be appropriate to enter into a separate consulting arrangement with that Health Care Professional.

Q7 How are a Company methods that "fair market value"?

There are different valuation methods that may be used to establish fair market value. In all instances, a Health Care Professional should be compensated on the basis of fair market value for the services provided. The method or methods used by a Company should be documented.

Q8 What is considered a "legitimate need" to engage a Health Care Professional as a consultant?

A legitimate need arises when a Company requires the services of a Health Care Professional to achieve a specific business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly

(1) Revised and Restated Code of Ethics
Effective July 1, 2009

(2) Revised and Restated Code of Ethics
Effective July 1, 2009

(3) A Company or its representative provides a gift to a recipient in a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or to serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement and are not provided to recognize a significant life event.

Q9 May a Company offer an item during a sales presentation, such as a meal or a gift, to a Health Care Professional?

No. A Company may not offer or give away any item to a Health Care Professional under Section IX.

Q10 What types of items are considered to be for the benefit of patients or to serve a genuine educational function for the Health Care Professional?

Items intended for the benefit of patients could include, for example, "flower," "candle," and other items for the benefit of patients. With respect to items for the benefit of patients, a Company engaged in the provision of such items to ensure they are intended for the benefit of patients.

Q11 It is appropriate to determine that a Health Care Professional is an "efficient means"?

It may be appropriate for Companies to provide access to services and resources associated with the use of their information. A Health Care Professional's information is a valuable asset to the Company, and it is appropriate to determine that a Health Care Professional is an "efficient means" for the Company.

Q12 May a Company make an educational grant to a Health Care Professional?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately advise any physician to report for enhancement purposes.

Q13 May a Company make an educational grant to a Health Care Professional?

The following is a general listing of programs which will be allowed. A Company may not use the provision of an inducement.

Q14 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q15 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q16 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q17 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

from Health Care Professionals in a health care provider that is affiliated with the Health Care Professional is not a proper business objective. Thus, there is a legitimate need to engage a Health Care Professional only if the arrangement would have been entered into absent an opportunity to generate business directly from the Health Care Professional. The level of consulting services to be obtained from a Health Care Professional should be based on the amount that is reasonably necessary to achieve a Company's proper business objective.

SECTION VI: PROHIBITION ON ENTERTAINMENT AND RECREATION

(14) May a Company's employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?

No. The Code should be viewed as applying to a Company's employees and agents even if they pay. Depending on the circumstances, it may be appropriate for an employee or agent of a Company to engage in certain activities with a Health Care Professional if each pays his or her own way.

SECTION VII: MOST MEDICAL ASSOCIATES WITH ETHICAL CARE PROFESSIONAL BUSINESS INTERACTIONS

(15) Is a general discussion to build good business relationships a "business presentation" under the Code?

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiation. The business discussion should be based on the time spent during the meeting. Development of general goodwill and business relationships should not be the primary purpose of a business meeting, and a business meeting should not be used to entertain or recreational purposes.

SECTION VIII: EDUCATIONAL ITEMS, PROHIBITION ON GIFTS

(16) May a Company provide a gift to a Health Care Professional, such as flowers, fruit baskets, meals, or other items?

No. A Company may not provide a gift to a Health Care Professional that is not for the benefit of patients or to serve a genuine educational function for the Health Care Professional.

Q17 May a Company provide a gift to a Health Care Professional who is not affiliated with the Company?

Gifts given to the staff of a Health Care Professional should be based on the fact that they are not the Health Care Professional and are subject to all applicable provisions of the Code.

(18) Revised and Restated Code of Ethics
Effective July 1, 2009

(19) May a Company or its representative provide a gift to a recipient in a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or to serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement and are not provided to recognize a significant life event.

Q20 May a Company offer an item during a sales presentation, such as a meal or a gift, to a Health Care Professional?

No. A Company may not offer or give away any item to a Health Care Professional under Section IX.

Q21 What types of items are considered to be for the benefit of patients or to serve a genuine educational function for the Health Care Professional?

Items intended for the benefit of patients could include, for example, "flower," "candle," and other items for the benefit of patients. With respect to items for the benefit of patients, a Company engaged in the provision of such items to ensure they are intended for the benefit of patients.

Q22 It is appropriate to determine that a Health Care Professional is an "efficient means"?

It may be appropriate for Companies to provide access to services and resources associated with the use of their information. A Health Care Professional's information is a valuable asset to the Company, and it is appropriate to determine that a Health Care Professional is an "efficient means" for the Company.

Q23 May a Company make an educational grant to a Health Care Professional?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately advise any physician to report for enhancement purposes.

Q24 May a Company make an educational grant to a Health Care Professional?

The following is a general listing of programs which will be allowed. A Company may not use the provision of an inducement.

Q25 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q26 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q27 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q28 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Q29 May a Company make an educational grant to a Health Care Professional?

No. A Company may not pay for or provide indirect inducements to a Health Care Professional to attend educational events, such as gifts.

Sample Postcard on the Code of Practice for HCPs

Courtesy of the Medical Technology Association of Australia

Working with medical technology companies

What you need to know about the Medical Technology Industry Code of Practice

What to expect from companies

- Ethical behaviour
- Product education and in-service training in a learning environment
- Modest hospitality associated with product education
- Support for educational conferences but only by providing sponsorship to the conference organiser and not individual participants
- Research and educational grants but only to institutions established for that purpose
- Donations for charitable purposes and sponsorship of an event where the proceeds will go to charity

What companies may not do

- Provide direct funding to attend a conference
- Provide hospitality except in the context of product education or in-service training, or by sponsoring hospitality at an educational conference
- Pay the cost of travel, hospitality or other expenses for partners or family members
- Pay for participation in or attendance at a sporting event or other entertainment
- Provide any gift unless it benefits patients or serves an educational purpose and is minimal in value
- Provide any form of branded promotional item

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Medical Technology
ASSOCIATION OF AUSTRALIA



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Sample Brochure on the Code of Practice for HCPs

Courtesy of the Advanced Medical Technology Association

				
<p>COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION</p> <p>Because of the way medical device technologies are used, medical technology companies have a responsibility to make available to HCPs, training on the safe and effective use of their products, and education, i.e., information on the disease state and benefits of their technologies. Companies should follow the following principles when providing training and education to HCPs:</p> <ul style="list-style-type: none"> 1 Programs should be conducted in clinical or educational settings that are conducive to exchange of information, like clinical, educational or conference centers. 2 "Hands on" training should be held at facilities suitable for the type of training to be conducted, and instructors should be qualified and have the technical expertise to conduct the training. 3 Meals and refreshments may be provided only to attendees and must be modest in nature and subordinate in time and focus to the training and/or education. 4 Companies may pay for necessary and reasonable travel, and modest lodging for healthcare professional attendees only. It is inappropriate for companies to pay for meals, refreshments, travel or lodging for any person who does not have a bona fide professional reason to attend the training or education. 	<p>EVALUATION AND DEMONSTRATION PRODUCTS</p> <p>Medical Technology Companies have a unique responsibility to ensure the safe and effective use of their products and technologies. One way this can be accomplished is through the provision of reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.</p> <p>Evaluation Products: Evaluation products may be provided for HCPs to evaluate a product to determine whether to purchase that product in the future. Companies may provide single-use products only in sufficient quantity necessary for the adequate evaluation of those products, and furnish capital equipment only for a reasonable period of time sufficient for evaluation of the equipment.</p> <p>Demonstration Products: Demonstration products are typically unsolicited single use products that are used for HCP and patient awareness, education and training. Such products are not intended to be used in patient care and are typically identified as "Sample," "Not for Human Use," or other designation on the product, its packaging and/or documentation accompanying the product.</p> <p>Companies should provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.</p>	<p>CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS</p>		<p>WHY A REVISED CODE?</p> <p>AdvaMed recognizes and respects the obligation of Health Care Professionals (HCPs) to make independent decisions regarding the health care of their patients. Medical technology companies can support this obligation and serve the best interest of patients through ethical interactions with HCPs. As such, AdvaMed has revised its Code of Ethics on Interactions with HCPs – creating ethical principles that govern the interactions between medical technology companies and the individuals or entities that provide healthcare services to patients or that purchase, lease, recommend, use, or prescribe medical technologies in the United States.</p> <p>CODE OF ETHICS COMPLIANCE</p> <p>Medical Technology Companies are strongly encouraged to adopt the Code of Ethics and to implement an effective compliance program. Companies that adopt the Code are strongly encouraged to submit to AdvaMed an annual certification to that effect. Member companies shall, and non-member companies may, supply contact information to AdvaMed concerning the company's compliance department or an anonymous hotline to facilitate reporting possible violations of the Code. Companies adopting the Code shall communicate its principles to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code.</p>
<p>SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES</p> <p>Independent educational or scientific conferences impart valuable information to HCPs and promote the advancement of effective health care. Medical technology companies may support these events as follows:</p> <ul style="list-style-type: none"> 1 Grants: Companies may provide grants only to conference sponsors to reduce conference costs or to training institutions to allow attendance of HCPs in training. Grants should be paid only to reimburse legitimate expenses for the educational activity, and the conference sponsor is solely responsible for the program content, faculty, educational methods and materials. 2 Conference Meals and Refreshments: Companies may provide meals and refreshments to all attendees provided that they are open to all attendees and consistent with the standards established by the conference sponsor or the accrediting body. Meals or refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and should also be clearly separate from the education portion of the conference. 3 Faculty Expense: Companies may provide grants to conference sponsors for reasonable honoraria, travel, lodging and modest meals for HCPs who are bona fide conference faculty members. 4 Advertisement and Demonstration: Companies may purchase advertisement and lease booth space for company displays at conferences. <p>SALES, PROMOTIONAL AND OTHER BUSINESS MEETINGS</p> <p>It is appropriate for companies to conduct sales, promotional and other business meetings with HCPs to discuss product features, sales terms or contracts. These meetings typically occur close to the healthcare's place of business. Companies may pay for occasional modest meals in connection with such meetings. In addition, in cases where it is necessary to demonstrate non-portable equipment, or conduct plant tours, companies may pay for reasonable travel costs, lodging and modest meals of attendees (but not their guests).</p> <p>CONSULTING ARRANGEMENTS</p> <p>Medical technology companies may enter into consulting arrangements with HCPs to discuss product features, sales terms or contracts. These meetings typically occur close to the healthcare's place of business. Companies may pay for occasional modest meals in connection with such meetings. In addition, in cases where it is necessary to demonstrate non-portable equipment, or conduct plant tours, companies may pay for reasonable travel costs, lodging and modest meals of attendees (but not their guests).</p> <p>PROVISION ON PAYMENTS</p> <p>Companies should not enter into royalty arrangements only when HCPs make significant contributions to a product, technology, process or method. Royalties paid in exchange for intellectual property should not be conditioned upon the purchase or recommendation of the technology developed, or a requirement that the HCP market the new technology. When calculating royalties, Companies are strongly encouraged to consider the appropriateness of excluding the number of units purchased by the HCP or their staff. All royalty payments should be adequately documented.</p>	<p>REVISED AND RESTATED EFFECTIVE JULY 1, 2009</p>	<p>This brochure is intended to provide a brief overview of the Code's key messages. Please visit www.AdvaMed.org to see the full Code and related FAQs.</p>		

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

that do not take into account purchasing criteria, implement appropriate procedures to ensure that gifts and charitable donations are not used as an unlawful inducement.

Company's sales personnel may provide input about the suitability of a grant or charitable donation recipient or program, but they should not control or unduly influence such decisions.



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Sample Article

Courtesy of the Medical Technology Association of Australia

Ethical and Transparent Interactions with Industry Benefit Ostomates in Australia

Anne Trimmer, Chief Executive Officer Medical Technology Association of Australia (MTAA)

As an ostomate you will be familiar with the products that medical technology companies supply. These products help you manage your condition and improve your quality of life.

Appropriate selection of medical technology products to meet an individual patient's needs and circumstances is a decision rightly made by the treating healthcare professional, for example a GP or stomal therapy nurse. Patients expect healthcare professionals to make these decisions based on the qualities of the product and their suitability for them as the patient, not on the basis of any incentives offered to the healthcare professional by the manufacturer or supplier of the product. The Medical Technology Association of Australia (MTAA) Code of Practice supports this expectation by providing an ethical framework for medical technology companies to work within in their dealings with both healthcare professionals and consumers.

About the MTAA Code

MTAA is the national association representing companies in the medical technology industry. The MTAA Code of Practice is an industry code for medical technology companies including suppliers of stoma products. The Code of



use of products, including discussions about product features and performance. The Code permits such training but requires that it is conducted in a clinical, educational or other setting that supports effective learning.

The Code also allows companies to provide hospitality to healthcare professionals in limited circumstances – by sponsorship of hospitality at a third party conference or as incidental to the bona-fide presentation of educational material or commercial information. The hospitality must be modest in value, not include any entertainment, and take place in a setting conducive to the scientific,

Industry interactions with consumers

The MTAA Code recognises and supports relationships between the medical technology industry and health consumer organisations, e.g. Australian Council of Stoma Associations. The Code also allows companies to make educational grants to support the education of consumers or the general public about important healthcare topics.

The Code also allows companies to run competitions for consumers. However, the Code prohibits companies from making it a condition of entry into the competition that a consumer use or purchase a specific product.

Questions or complaints about the MTAA Code

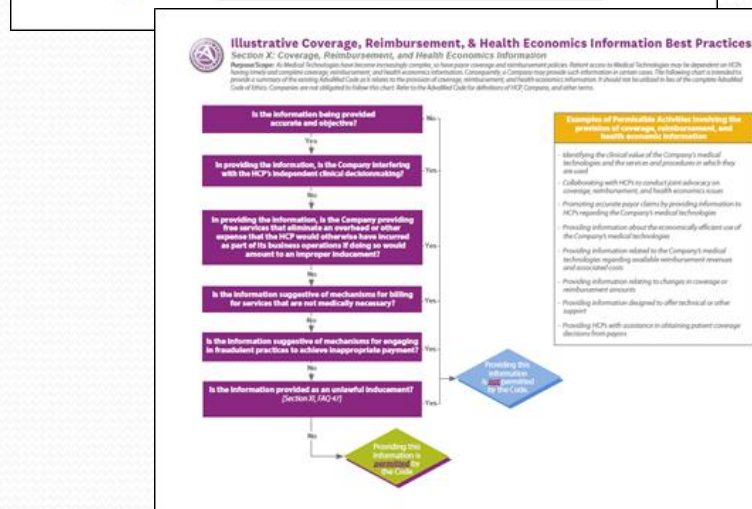
A consumer or healthcare professional who believes that a medical technology company has breached the provisions of the MTAA Code of Practice can make a complaint to the Code Complaints Committee. A consumer or healthcare professional who is considering making a complaint is encouraged to raise his or her concerns with the company first as it may have been an isolated activity that offends the company's own code of conduct.



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Courtesy of the Advanced Medical Technology Association

Courtesy of the Advanced Medical Technology Association



Sample Notice on Information Service

Courtesy of the Medical Technology Association of Australia

For further information:

Medical Technology Association of Australia



Medical Technology
ASSOCIATION OF AUSTRALIA

Level 12, 54 Miller Street
North Sydney NSW 2066 Australia

P: (02) 9900 0650

E: code@mtaa.org.au

W: www.mtaa.org.au



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Examples of Code of Ethics Logos



** In the past, MTAA offered a Code of Practice Licence to companies that demonstrated the highest level of commitment to ethical compliance. In 2014, the Licence was suspended following an external review of the Code of Practice . MTAA's Code Authority is currently developing an updated strategy to promote the program and broader awareness of the Code of Practice.*

Sample Code of Ethics App

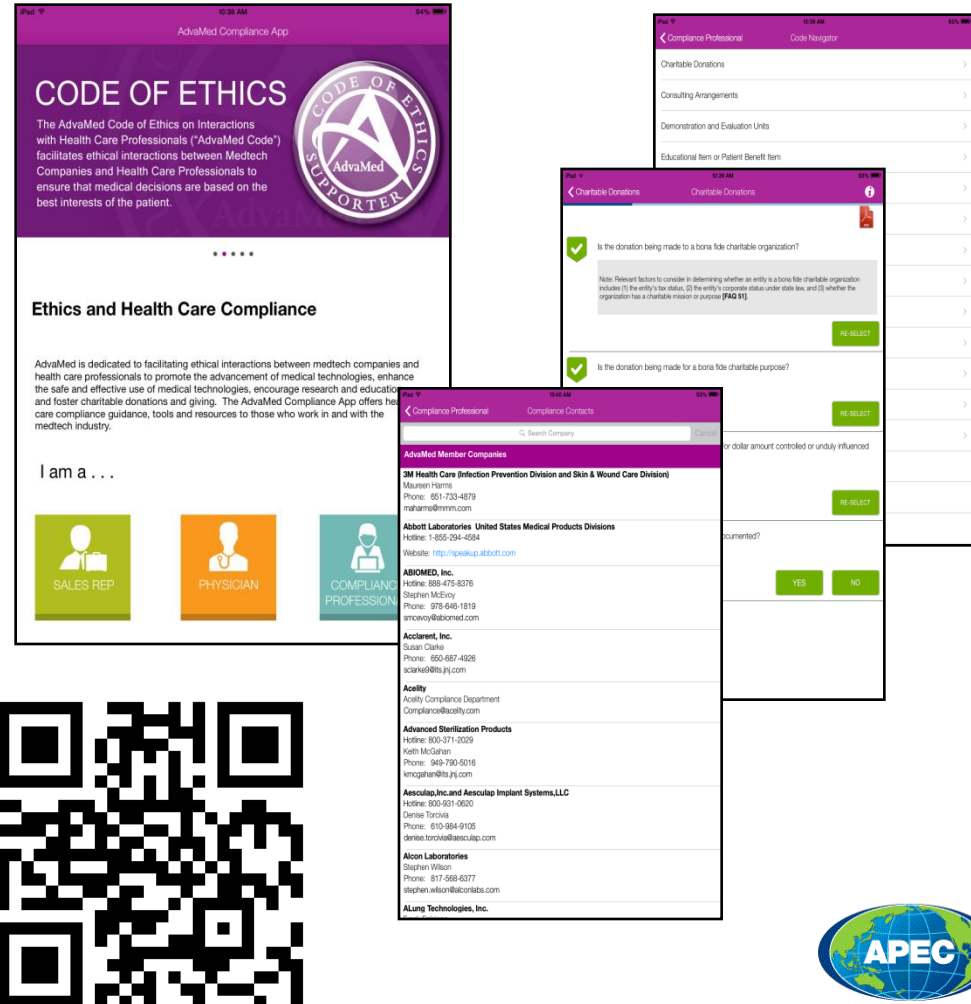
Courtesy of the Advanced Medical Technology Association



Now available for IOS devices (iPad, iPhone & iPod Touch)

AdvaMed Compliance mobile app

- ▶ **Tools** to assist in interactions and discussions with HCPs
 - Code Navigator
 - Mobile Reference
- ▶ **Global Tools**
 - Medtech Industry Codes & Crosswalks
 - Direct Sponsorship
 - SMI Compliance
- ▶ **Reference & Training Resources**
 - Compliance Contacts search
 - List of Certifying Companies
 - Code Brochure & Training Slides
- ▶ **Benchmarking Survey Tool**
- ▶ **Launched May 15** via iTunes App store for free download:
<https://appsto.re/us/Otjl7.i>



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COFFEE & NETWORKING BREAK

15:00-15:30

SESSION FIVE

Managing Third Parties – How SMEs Can Get it Right

Session Lead: Lori Reber, Smith & Nephew

SESSION SIX

How Can APEC Governments Help?

Moderator: Kathleen Hamann (United States)

Discussant: Dato' Hafsah Hashim (Malaysia)

Discussant: Dr. Marietta Baccay (Philippines)

CLOSING SESSION & WORKSHOP GROUP PHOTOGRAPH

Closing Session and Workshop Group Photograph

Remarks on Emerging Trends and Issues:

- Ms. Jane Wurth, MTAA (Australia)

Review of Plenary Session Procedures:

- Ms. Patricia Wu, C&M International (United States)

Workshop Group Photograph

Emerging issues and trends in the medical device sector

Jane Wurth

Code of Practice Manager, Medical Technology Association of Australia

APEC Business Ethics for SMEs Forum

Medical Device Sector Workshop

19-20 August 2015 | Manila, Philippines



Business Ethics for APEC SMEs Initiative

Progress so far

- As a result of the APEC initiative, codes of ethics have been adopted and are undergoing implementation by more than 65 biopharmaceutical and medical device industry associations from 19 APEC member economies, representing more than 14,000 enterprises (10,000+ SMEs).



Current issues

- Gifts
- Direct sponsorships



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Future-proofing the industry

- How can all of us champion the importance of business ethics in the APEC region?
- Where will we be 5, 10, 20 years from now?



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Closing Session and Workshop Group Photograph

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Workshop Group Photograph

2015 APEC Business Ethics for SMEs Forum

Medical Device Sector Workshop Official Photograph

19 August 2015 | Manila, Philippines



2015 APEC Business Ethics for SMEs Forum

Medical Device Sector Reception (Leyte Samar)