

正本

檔 號：
保存年限：

行政院衛生署食品藥物管理局 函

機關地址：11561 台北市南港區昆陽街161-2號

傳 真：27877498

聯絡人及電話：鄒孟珍 27878000#7466

電子郵件信箱：mctsou@fda.gov.tw

10478

台北市中山區建國北路二段87號10F之1

受文者：中華民國西藥代理商商業同業公會

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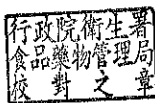
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局長 康照洲

擬：醫療院所發展委員會

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**Asia-Pacific
Economic Cooperation**

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Agenda Item: 3

The Kuala Lumpur Principles Medical Device Sector Codes of Ethics

Purpose: Consideration
Submitted by: SMEEMM Chair



**18th Small and Medium Enterprises
Ministerial Meeting
Big Sky, United States
21 May 2011**

The Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

Medical technology sector Codes of Business Ethics promote ethical interactions between medical device and diagnostics companies ("Companies") and Healthcare Professionals¹ ("HCPs"). Ethical interactions enhance patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by Companies. Ethical interactions also promote innovation and the ongoing development of advanced medical technologies through legitimate and transparent collaboration between HCPs and Companies to identify, and bring to market new products. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies, especially small and medium size 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 HCPs should be conducted in accordance with the following principles: **Integrity, Independence, Appropriateness, Transparency and Advancement:**

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

Independence means that HCP interactions with Companies should not skew the HCP's medical decision making from the best interests of the patient.

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

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

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

Accordingly, medical technology industry codes of ethics ("Industry Codes") should incorporate, but not necessarily be confined to, the following:

1. Collaborative interactions between Companies and HCPs should preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.

¹ 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.

2. Consultancy agreements between Companies and HCPs should support research and development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. Consultancy agreements should not be used as a means of inappropriate inducement².
3. Company support of HCPs' education, for example through support to third-party educational programs and educational grants, should preserve the independence of medical education and should not be used as a means of inappropriate inducement.
4. Companies may provide training of HCPs on product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by HCPs.
5. Companies should not provide entertainment and recreation to HCPs as an inappropriate inducement. Any attendance at entertainment events, consenting or agreeing to receive any gift, commission, or gratuity shall not be regarded as appropriate for nurturing appropriate business relationships.
6. Company donations for charitable or other philanthropic purposes should support *bona fide* charitable organizations and missions, and should not be a means to privately benefit an HCP.
7. Free products should not be used as a means of inappropriate inducement. However, Companies may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes.

To ensure Industry Codes are effective, they should encourage adherence to the following elements that are relevant to a Company's business:

1. Companies to appoint a senior executive responsible for oversight of the Company's compliance with the Industry Code.
2. Companies to develop or adopt practical, useful, and meaningful policies, guidance, and tools on how to implement policies consistent with the Industry Code.
3. Companies to provide effective and ongoing training and education on the Industry Code and the Company's policies consistent with the Industry Code.
4. Companies' senior management and governing body, if applicable, commit to support the Industry Code.

² Inappropriate inducement means a remunerative arrangement intended to inappropriately influence an HCP's medical decision and product selection.

5. Companies to institute appropriate internal monitoring and auditing mechanisms.
6. Companies to create safe mechanisms for, and encourage, employees who raise concerns. Companies to communicate company policies consistent with the Industry Code to their third party intermediaries with the expectation that the intermediaries will comply with the Industry Code.

In order to promote an ethical commercial environment, cooperation among multiple stakeholders is required. Therefore, it is recommended that APEC economies encourage:

Medical Device Sector

- Medical device sector industry associations and their member companies to develop and implement Industry Codes consistent with the principles set out above and to consider publicizing those members who have signed onto the Industry Codes, among other steps to encourage adoption of Industry Codes;
- Medical device sector regulators and/or anti-corruption enforcement authorities to endorse and support Industry Codes;

Healthcare Professionals

- HCPs, such as medical and academic institutions and physician groups, to develop and implement codes of ethics consistent with the above principles;
- HCPs to develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures in line with respective government policies on procurement and Industry Codes, if appropriate;

APEC Economies

- Each APEC economy to formulate and promote clear laws and regulations that are objectively applied;
- APEC economies to work to advance ethical collaborations consistent with the above principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration; and
- APEC economies to work together to ensure that the above principles and Industry Codes remain relevant and effective to address new and relevant business arrangements that may emerge.

BACKGROUND

At the 14th Economic Leaders' meeting held in Hanoi in 2006, APEC Leaders reaffirmed their high commitment to fight corruption. In 2006 APEC Ministers stressed the importance of preventive measures and integrity systems in the fight against corruption and urged member economies to adopt and implement codes or norms of conduct. In 2007 APEC Leaders endorsed anti-corruption principles for the public and private sectors, including an APEC Code of Conduct for Business.

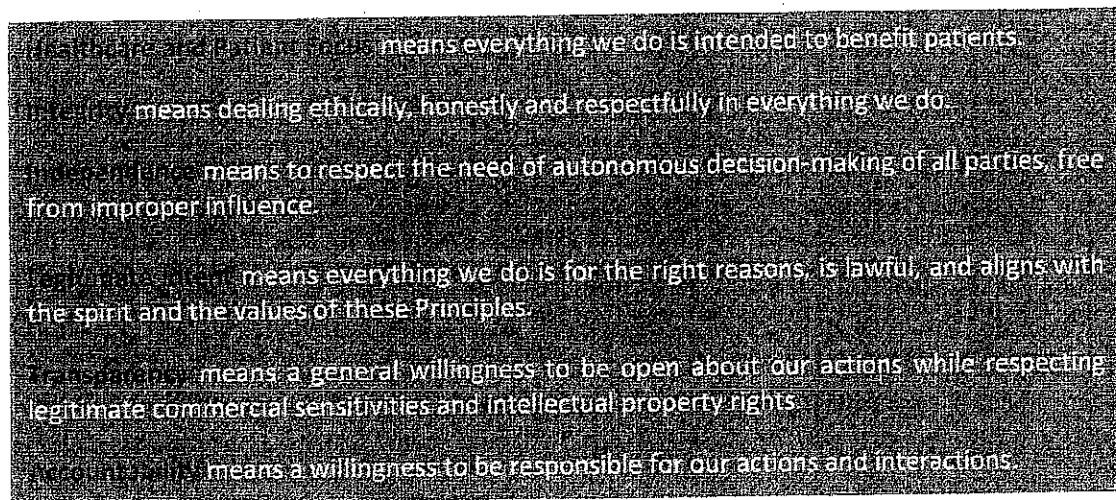
In 2010 SME Ministers issued a joint statement which called for "facilitating open and transparent business environments free from the high costs of corruption by the development of APEC codes of business ethics in sectors of export interest to APEC economies, beginning with the medical device sector." And APEC Ministers "...welcomed steps taken to improve...understanding of the ethical business practices needed to sustain participation in international trade, and look forward to the development of codes to improve and better align industry practices across APEC economies."

Following this, an Expert Working Group convened in Kuala Lumpur, Malaysia, on April 6-7, 2011, to develop a set of APEC Principles for Codes of Business Ethics to Ensure Ethical Interactions Between Medical Technology Companies, drawing upon existing best practices and voluntary codes of business ethics in APEC economies.

The Mexico City Principles

*For Voluntary Codes of Business Ethics and the
Business and Society / Sector*

Ethical interactions help ensure that medical decisions are made in the best interests of patients. For relationships with healthcare professionals and other stakeholders to meet this standard, companies in the biopharmaceutical sector¹ ("Companies") should be guided by these six principles:



Preamble

1. Companies engage in the development, manufacturing, research, marketing, distribution, and/or sale of medicines to benefit patients.
2. Ethical relationships with healthcare professionals, government officials, patients, and other stakeholders are critical to the mission of Companies to help patients by developing and making medicines available.
3. In interacting with all stakeholders, Companies are committed to following the highest ethical standards as well as all applicable laws and regulations. Companies encourage healthcare professionals, government officials, and others who work with Companies to respect these Principles and adopt consistent standards if applicable.
4. These Principles are to reinforce our intention that Companies' interactions are professional exchanges designed to benefit patients and to enhance the practice of medicine. These Principles are based on the foundation that a healthcare professional's care of patients

¹ For purposes of this document the term "biopharmaceutical sector" includes companies, regardless of ownership status, that develop, manufacture, market, or distribute pharmaceutical and/or biologic products. Such products are also referred to in these Principles as "medicines."

should be based solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

5. Companies have an obligation and responsibility to provide objective, accurate, balanced information about their medicines to healthcare professionals in order to establish a clear understanding of the appropriate use of these medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients.
6. Companies should promote, sell and distribute their medicines in a manner that is ethical, objective, balanced and accountable, and in accordance with all relevant and applicable laws and regulations. Information in promotional materials must support proper assessment of the benefits and risks of the product and its proper use.
7. Companies are committed to education and training on the safe, appropriate, and effective use of their medicines.
8. Companies are accountable for complying with relevant codes of ethical business practices. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical activities.
9. Companies will comply with relevant standards regarding the development, production, processing, distribution, commercialization and safety of medicines.
10. Companies undertake to adhere to relevant local, national, and regional industry ethics codes in both the spirit and the letter.
11. Companies will respect the independence of patient organizations.
12. Companies should ensure that all relevant personnel and agents acting on their behalf are appropriately trained in the requirements of local, national, and regional industry ethics codes.
13. Companies will respect patient privacy.
14. Companies will ensure that all personnel and third parties working on their behalf comply with these Principles and all applicable laws and regulations.

Through the promotion of these Principles, Companies and APEC economies seek to ensure that ethical practices are established.

1. Interactions with Healthcare Professionals

- A. Interactions between Companies and healthcare professionals provide valuable scientific, clinical, product, and policy information about medicines that may lead to improved patient care.
- B. Appropriate marketing helps to ensure that medicines are used correctly for maximum patient benefit. Company relationships with healthcare professionals are critical to achieving these goals because they enable Companies to:
 - 1. inform healthcare professionals about the benefits and risks of medicines to help advance appropriate patient use;
 - 2. provide scientific and educational information;
 - 3. support medical research and education; and
 - 4. obtain feedback and advice about our products through consultation with medical experts.
- C. All interactions with healthcare professionals are to be conducted in a professional and ethical manner.
 - 1. Healthcare professionals must not be improperly influenced by Companies.
 - 2. Nothing should be offered or provided by a Company in a manner that inappropriately influences a healthcare professional's prescribing practices.
 - 3. Education and promotional activities should encourage the appropriate use of medicines by presenting them objectively and without exaggerating their properties, and should be in compliance with the provisions prescribed by these Principles and applicable local, national, and regional industry codes of ethics.
 - 4. Relationships between Company personnel and healthcare professionals should encourage the development of a medical practice committed to patients' well-being and be based on truthful, accurate, and updated scientific evidence.

2. Promotional Information and Activities

- A. No medicines shall be promoted for use in a specific economy until the requisite approval for marketing for such use has been given in that economy. Promotion should be consistent with locally approved product information.
 - 1. It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material.

2. Companies commit that pertinent and appropriate information will be made available to all healthcare professionals in all economies, as permitted by applicable laws and regulations.
- B. Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable healthcare professionals to form his or her own opinion of the therapeutic value of the medicines concerned.
1. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.
 2. Promotional information should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.
 3. Companies are responsible for compliance with applicable laws and regulations, including intellectual property laws, and local, national, and regional industry codes of ethics.
 4. Clinical assessments, postmarketing surveillance and experience programmes and postauthorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.
 5. Materials sponsored by a Company relating to medicines and their uses, whether promotional in nature or not, should clearly indicate by whom they have been sponsored.

3. Safety of Medicines

- A. Medicines provided by Companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities in each economy in which they operate.
- B. Companies will report adverse events or adverse drug reactions to regulatory authorities, subject to applicable laws and regulations.

4. Symposia and Congresses

- A. The purpose and focus of all symposia, congresses and other promotional or non-promotional, scientific or professional meetings (an "Event") for healthcare professionals

organized or sponsored by a Company should be to inform healthcare professionals about products and/or to provide scientific or educational information.

- B. Company relationships with healthcare professionals are regulated by multiple entities and intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.
- C. Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, or promote any medicine.
- D. All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies should avoid using extravagant venues or resorts.
- E. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:
 - 1. to participants of the Event and not their guests; and
 - 2. is moderate and reasonable as judged by local standards.
- F. Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

5. Informational Presentations by Company Representatives

- A. In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, Company representatives may take the opportunity to present Information during healthcare professionals' working day, including mealtimes, in accordance with applicable laws and regulations.
 - 1. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business necessity to the healthcare professional as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are reasonable as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.
 - 2. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a Company is not appropriate. Offering "take-out" meals or meals to be eaten without a Company representative being present is not appropriate.

6. Entertainment

- A. Company interactions are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care.
 - 1. To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, Companies should not provide any form of entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the Company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
 - 2. No standalone entertainment or other leisure or social activities should be provided or paid for by Companies. At events, entertainment of modest nature, which is secondary to refreshments or meals, is allowed.

7. Educational Items and Gifts

- A. Payments in cash or cash equivalents (such as gift certificates) or gifts for the personal benefit of healthcare professionals should not be provided or offered to healthcare professionals.
 - 1. It is appropriate for Companies, where permitted by law or local codes of ethics, to offer items designed primarily for the education of patients or healthcare professionals if the items are of modest value and do not have value to healthcare professionals outside of his or her professional responsibilities.
 - 2. These items should not subsidize normal routine operations of a medical practice.

8. Support for Continuing Medical Education

- A. Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care and the medical practice.
 - 1. Companies should develop objective criteria for making CME grant decisions to ensure that programs funded are bona fide and quality educational programs and that financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

- B. Grants, scholarships, subsidies, support, consulting contracts, educational or practice related items should not be provided or offered to a healthcare professional in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a healthcare professional's prescribing practices. Companies should have a reasonable expectation that the grant is for the purpose of supporting legitimate education, scientific, or medical research.

9. Samples

- A. When used appropriately, samples can be an important tool for healthcare professionals and provide benefit to patient health outcomes.
- B. In accordance with local laws and regulations, samples of medicines supplied at no charge may be provided to healthcare professionals in order to enhance patient care. Samples must not be resold or otherwise misused.
 - 1. Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples while they are in possession of medical representatives.
 - 2. Samples should not be used as payment for services, return for favorable treatment, or other inappropriate inducements.

10. Consultant and Speaker Arrangements

- A. Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice to inform their efforts to ensure that the medicines they develop, produce and/or market are meeting the needs of patients. In addition, healthcare professionals participate in Company-sponsored speaking programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of medicines.
 - 1. Companies should continue to ensure that consultant and speaking arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.
 - 2. It is appropriate for consultants and speakers who provide services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting or speaking arrangement should be reasonable and based on fair market value.

3. Consulting or advisory arrangements lacking a bona fide business purpose should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses.
- B. The following factors support the existence of a bona fide consulting or speaking arrangement (not all factors may be relevant to any particular arrangement):
1. a written contract specifies the nature of the services to be provided and the basis for payment of those services;
 2. a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 3. the criteria for selecting consultants and speakers are directly related to the identified purpose, and the persons responsible for selecting the consultants and speakers have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
 4. the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
 5. the retaining Company maintains records concerning, and makes appropriate use of, the services provided;
 6. the venue and circumstances of any meeting with consultants or speakers are conducive with the primary focus of the meeting; specifically, resorts are not appropriate venues.

11. Compliance Procedures and Responsibilities

- A. It is the responsibility of Companies to ensure that internal compliance procedures exist that facilitate compliance with these Principles and the spirit they embody. These procedures should be documented and provided to employees to further enhance compliance.

12. Conduct and Training of Company Representatives

- A. Company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of medicines. These representatives often serve as the primary point of contact between the Companies who research, develop, manufacture and market medicines and the healthcare professionals who prescribe them. As such, Company representatives must act with the highest degree of professionalism and integrity.

1. Companies should ensure that all representatives who are employed by or acting on behalf of the companies, and who visit healthcare professionals, receive training about the applicable laws, regulations and industry codes of ethics that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with applicable laws and regulations.
2. Companies should provide updated or additional training in all of the areas needed for their representatives who visit healthcare professionals. Companies should also assess their representatives periodically to ensure that they comply with relevant Company policies and standards of conduct.
3. Companies should take appropriate action when representatives fail to comply with relevant Company policies that are consistent with these Principles and national and local industry codes of ethics.

13. Public Sector Relationships and Procurement

- A. The decision-making process by Companies and Governments during and including the government procurement process, through bidding or any other procedure of government procurement, must be professional and ethical. There should be no attempt to exert inappropriate influence.
- B. Companies must provide accurate and balanced information to the Government.
- C. Companies and government officials should ensure that their relationships and fee-for-service arrangements comply with government ethics rules or procedures.

14. Clinical Trials

- A. All clinical trials (phases I to IV) and scientific research involving patients sponsored or supported by companies will be conducted with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine. Companies must ensure transparency and accountability in the presentation of research and publication of study results.
- B. Clinical trials should not be used as inappropriate inducements for past or future sales.
- C. Clinical trials should be undertaken in an ethical manner, without undue influence by competitors.

15. Company Donations for Charitable Purposes

- A. As a demonstration of good corporate citizenship, Companies recognize their responsibility to support worthwhile activities both within and outside our communities
 - 1. Donations including donations in kind, may be provided to organizations and institutions involved in promoting activities such as artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities in accordance with applicable laws and regulations.
 - 2. Companies should ensure that such support is not undertaken solely for product promotional reasons, and is not directed solely for product promotion purposes.
 - 3. Funding and donations in-kind should be directed to organizations and documented in a manner that outlines the nature of the donation provided.
 - 4. Acknowledgement by the recipient organization of such support should be restricted to appropriate recognition of support.
 - 5. Companies should ensure that there are no incentives to prescribe, recommend, purchase, supply or administer a product based on financial support and that nothing should be offered or provided which would interfere with the independence of a healthcare professional's prescribing or dispensing practices.

16. Patient Organizations

- A. Companies should respect the autonomy of patient organizations and their independence.
- B. Support from Companies must not be conditional on the promotion of a specific medicine.

17. Adherence to Principles

- A. All Companies that interact with healthcare professionals, government officials, and other stakeholders should adopt procedures to assure adherence to these Principles and local, national, and regional industry codes of ethics. Healthcare professionals, government officials, and other stakeholders should respect these Principles and adopt consistent standards if applicable.

Implementation

In order to promote an ethical commercial environment, cooperation among multiple stakeholders is required. Therefore, it is recommended that Companies, healthcare professionals and APEC economies engage in the following activities:

Companies and industry associations should:

- Develop and implement codes of ethics consistent with the Principles set out above. Industry associations should consider publicizing those members who have signed onto the industry codes, among other steps to encourage adoption of industry codes.
- Make available training regarding industry codes of ethics to healthcare professionals and healthcare professional students in collaboration with recognized authorities.
- Contribute to and participate in capacity building, in particular for small and medium sized enterprises (SMEs).
- Work together to ensure that the above Principles and their industry codes of ethics remain relevant and effective to address new business arrangements that may emerge.

Healthcare Professional Organizations should:

- Respect these Principles and develop and implement codes of ethics consistent with the above principles.

APEC Economies should:

- Develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to endorse and support the above Principles and national and local industry codes of ethics, where appropriate.
- Encourage Companies to adhere to the above Principles and national and local industry codes of ethics.
- Formulate and promote clear laws and regulations that are objectively applied.
- Work to advance ethical collaborations consistent with the above Principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration.

- * Work together to ensure that the above Principles remain relevant and effective to address new business arrangements that may emerge.

Appendix

For the purpose of these Principles, the following definitions are provided:

"Congress" means an event sponsored and organized by a society, college, university or other non-Company entity for the purpose of providing medical and/or scientific information.

"Consultant" means an external, independent healthcare professional, scientist, patient association/ patient representative, public or private payer retained individually or through an entity (e.g. university, hospital or research organization) to provide advice, information or other services.

"Healthcare Professional" means a provider of medical or health services and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business, including but not limited to physicians, nurses, or pharmacists and their staff.

"Representative" means a person calling on healthcare professionals and/or their staff on behalf of a Company regarding the promotion or discussion of medicines.

