



MMDA Code of Ethics (Version 0.0) January 2013



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1.0 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.

This was later referred to as "Kuala Lumpur (KL) Principles" for medical devices sector 'Code of Ethics'.



MMDA been a member of the APEC Expert Working Group (EWG), MMDA President endorsed the KL PRINCIPLES - MEDICAL DEVICE SECTOR CODES OF ETHICS at the 18th APEC SME Ministerial Meeting in Kuala Lumpur in June 2011.

Following that MMDA President issued an email communication dated June 20, 2011 to MMDA member's highlighting the recommendation made for the medical device industry associations of respective APEC economies to develop and implement Industry Codes consistent with the KL Principles.

Beside the industry stakeholder, the medical device regulators would endorse and support the Industry Codes in order to promote an ethical commercial environment.

During the 8th Committee Meeting (2011/2013 Term) it was unanimously agreed it was timely that MMDA establish a formal of Code of Ethics to voluntarily secure the acceptance and adoption of KL Principles, among its members which totaled 222 as of 31 December 2012.

2.0 Objectives

MMDA Codes of Ethics promote ethical interactions between medical device and diagnostics companies ("Companies") and Healthcare Professionals ("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.

- 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.



3.0 Scope

Should incorporate but not necessarily be confined to, the following:-

- 3.1. 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.
- 3.2. 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 inducement.
- 3.3. 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.
- 3.4. 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.
- 3.5. 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.



- 3.6. 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.
- 3.7. 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.

4.0 Responsibility

To ensure MMDA Codes of Ethics are effective, MMDA members should encourage adherence to the following elements that are relevant to its Company's business:-

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



- 4.5. Companies to institute appropriate internal monitoring and self-inspection procedures.
- 4.6. Companies to create safe mechanisms for, and encourage, employees who raise concerns.
- 4.7. Companies to communicate company policies consistent with the Code to their third party intermediaries with the expectation that the intermediaries will comply with the Code.

5.0 Effective Date

MMDA Code of Ethics (“Code”) is effective as of 1 April 2013.

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

6.0 General Principles

6.1 Method of Promotions

Method of promotions or marketing must not be such as to incite unfavorable comments or bring discredit upon, or reduce confidence in the medical devices industry.



6.2 Basis of Interactions

Members of MMDA relationship with HCP are intended to enhance patient access to the safe and effective use of medical technologies. Ethical interactions also promote innovation and the ongoing development of advanced medical technologies.

6.3 Independence of Healthcare Professionals

No financial benefits or benefits-in-kind may be provided or offered to HCP in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Ethical interactions ensure that medical decision-making is made in the best interest of the patient.

6.4 Pre-Approval Communication & Off-Label Use

No medical devices shall be promoted in Malaysia until the requisite approval for marketing has been granted by health authority.

However, it is not intended to restrict the right of scientific communities and the public to be fully informed concerning scientific and medical discoveries and progress.



7.0 Guidelines

7.1 Standard of Promotion

7.1.1. Printed Promotional And Advertising Materials

- 7.1.1.1 Promotional And Advertising Materials should be accurate, fair, objective and presented in a manner as to conform to legal/regulatory requirement, of ethical standard and in good taste. Claims should not be overstated beyond the scientific evidence and every effort should be made to avoid ambiguity and doubt.
- 7.1.1.2 Promotion should be capable of substantiation either by reference to approved labeling or by scientific evidence. Such evidence shall be made available to HCP upon request.
- 7.1.1.3. Brand names of products of other companies should not be used unless prior consent of the proprietors has been obtained.
- 7.1.1.4. Substantiated comparative claims inviting fair comparisons with a group of products or with other products in the same field are permissible, provided that such claims are not presented in a way which is likely to mislead by distortion, undue emphasis or otherwise.
- 7.1.1.5. All printed promotional and advertising materials should include name and address of the business responsible for the sales of the products and where possible date of production of the printed promotional and advertising materials.



Note: Same requirement shall apply to electronic and audio-visual promotional type.

7.1.2. Demonstration

7.1.2.1. Companies can improve patient care by providing Medical Technologies to Healthcare Providers free of charge for demonstration and evaluation purposes. Companies may provide reasonable quantities of Medical Technology products and equipment to Healthcare Professionals at no charge for evaluation and demonstration purposes, provided that such products are not given or intended as an inappropriate inducement.

7.1.2.2. These should be marked “not for human use” or otherwise to indicate that they are solely for demonstration purposes.

7.2 Company Organized Education & Training

7.2.1. Companies may provide training of Healthcare Professionals on product specific device deployment, use and application to facilitate the safe and effective use of medical technologies by Healthcare Professionals. Companies may also provide education to Healthcare Professionals on topics concerning or associated with the use of their Medical Technologies.



- 7.2.2. Training and Education programs include “hands-on” training sessions, workshops, lectures and presentations. Training and Education should be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise.
- 7.2.3. Training and Education programs should be conducted in venues that are conducive to the transmission of learning and are selected based on their suitability for the proposed program and their convenience for attending trainees. Appropriate venues may include the Healthcare Professional’s premises, the Company’s premises, or other clinical, laboratory, educational or conference facilities (including hotel conference rooms) depending on the nature of the program.
- 7.2.4. When it is impractical or inefficient to provide training at or close to a Healthcare Professional’s place of business, Companies may pay the reasonable travel and lodging costs of the attending Healthcare Professional incurred solely for the purpose of attending the program.
- 7.2.5. Companies may provide reasonably-priced meals in connection with training and education programs. Companies should not provide recreation, entertainment or lavish meals or accommodation, and should not pay or arrange for meals, accommodation or travel of spouses or other guests of participating healthcare professionals.



7.3. Sales & Promotional Meetings

It may be appropriate for Company representatives to meet from time to time with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sales terms.

7.3.1. Such meetings should generally occur at or near the Healthcare Professional's place of business, although occasionally such discussions may take place at another mutually convenient location.

7.3.2. It is appropriate to pay for reasonable travel and lodging costs of attendees when travel is necessary, for example for plant tours or demonstrations of non-portable equipment. Companies may provide reasonable meals in connection with such meetings in a venue that is conducive to the exchange of information.

7.3.3. Companies should not pay for or invite spouses or guests of Healthcare Professionals to participate in business meetings or meals

7.4 Medical/Sales/Technician Representatives

7.4.1. Medical/Sales/Technician representatives must be adequately trained and possess sufficient medical and technical knowledge and competency to present/repair/commission and decommission company's products/services in an accurate and responsible manner.

7.4.2. They should require to be trained in the Code.

7.4.3. MMDA member will assume responsibilities for taking corrective and preventive action for breaches of the Code resulting from misconduct or mis-presentation of the fact by any representatives.

7.5 Evaluation Products, Samples or Educational Items

7.5.1. Giving away of samples as an inducement to purchase is discouraged.

7.5.2. Evaluation products, either as free samples of single-use products, or loans of reusable products or capital equipment. Because evaluation products are intended for human use, they may constitute a financial benefit to Healthcare Professionals. Therefore, Companies should only provide evaluation products in quantities (or for a duration) that are reasonably calculated to permit adequate evaluation by the Healthcare Professional.

7.5.3. Evaluation products should be appropriately disclosed and documented to minimize the risk that they will provide a financial benefit to any individual Healthcare Professional, and Companies should ensure that loaned products are retrieved or returned if not purchased at the end of the evaluation period.

7.5.4. Companies may occasionally provide items to Healthcare Professions that benefit patients or serve a genuine educational function for Healthcare Professionals. Companies should not provide items that are capable of use by Healthcare Professionals



(or their family members, office staff or friends) for non-educational or non-patient related items.

7.6 Hospitality Level & Payment To Speaker & Presenter

7.6.1. Hospitality Level

The level of hospitality should be appropriate and not out of proportion to the occasion. Its cost should not exceed the level which the recipient might normally adopt when paying for themselves.

7.6.2. Payment To Speaker & Presenter

Payment of reasonable expenses such as cost of air travel, meals and lodging may be provided to healthcare professionals as invited guest speaker or presenter. An honorarium may be given. If the guest speaker or presenter is from overseas, then members are advised to check with the speaker or presenter's home country code and apply accordingly.

7.7 Charitable Donations, Education & Research Grants

7.7.1. Charitable Donations

Companies may make monetary and in-kind donations to support *bona fide* charitable organizations and missions, provided that the donation is not intended as an inappropriate inducement and does not privately benefit a Healthcare Professional. Donations should be made only in response to written requests and should be



evaluated against objective criteria adopted by the Company. Donations should be made only to healthcare institutions and nonprofit organizations and should not be paid or provided to individual Healthcare Professionals. Donations should be documented appropriately and care should be taken to ensure that local laws and transparency requirements are respected.

7.7.2. Educational Grants

Companies may provide grants for legitimate educational purposes. These include grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, and grants to support the education of patients and the public about important healthcare topics. Companies may also make educational grants to sponsors of third-party educational conferences. Educational grants should not be paid to individual Healthcare Professionals and care should be taken to avoid making grants that may provide an inappropriate benefit to individual Healthcare Professionals.

7.7.3. Research Grants

Companies may provide research grants to support independent medical research with scientific merit for the purpose of advancing scientific and clinical information, improving clinical care, promoting improved delivery of healthcare, or to otherwise benefit patients. Sponsored research should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.



7.8 Valid Patent Rights

All valid patent rights of products and processes must be respected by MMDA members.

7.9 Operations of The Code

In order to ensure effective implementation of Code principles, each MMDA Member Company should take the following concrete steps.

- 7.9.1. Appoint a senior executive responsible for oversight of the Company's compliance with this Code.
- 7.9.2. Adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with the Code;
- 7.9.3. Provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance;
- 7.9.4. Ensure that senior management and the company's board of directors or other governing body have expressly committed to support the Code;
- 7.9.5. Institute appropriate internal monitoring and auditing mechanisms;
- 7.9.6. Create safe mechanisms for, and encourage, employees who raise concerns;



- 7.9.7. 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
- 7.9.8. Provide a notification to MMDA that the Company has signed onto the MMDA Code of Ethics, so those Member Companies can be publicized.

7.10 Handling Members Dispute

- 7.10.1 In the events that there is a dispute, the complainant company must first initiate contact with the company alleged to be in breach, in order to discuss the issue and endeavor to settle the dispute/disagreement among themselves first. (This is to encourage companies to talk to one another, in order to attempt to amicably settle any issues.)
- 7.10.2 If the dispute could not be settle amicably, the complainant company may forward the matter to MMDA in writing for further deliberation.
- 7.10.3 The complainant must provide proof or evidence that the parties concerned have communicated but were unable to resolve the matter, when lodging a formal complaint to MMDA. The official complaint must be submitted by CEO or equivalent top management position of that company.



- 7.10.4 MMDA Committee Members shall meet soonest after the receipt of the complaint and decided if there is a case for the subject company to answer.
- 7.10.5 In the event that the MMDA Committee Members decide there is a case to be answered, the committee may call for both the Plaintiff and Defendant to a review meeting for further discussion.
- 7.10.6 The company judged to be in the breach of the Code, will be asked to discontinue the offending materials or practices. In additions, the company may be required to issue a retraction statement, details of which will be determine by MMDA. MMDA may at its discretion notify the relevant health authority and/or Medical Device Authority (MDA) for further consultation and advice.
- 7.10.7 MMDA will not disclose any decisions to the public, however MMDA may inform members of the findings together with the name of the company involved.
- 7.10.8 Appeal can be made on the merits of the case and should be made within two weeks of receipt of formal notice from MMDA, after which the company concerns, losses the right to appeal.

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