



ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES  
PERSATUAN INDUSTRI PERUBATAN MALAYSIA

# Codes of Ethics

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### 1 Purpose

- 1.1 The purpose of this Code is to facilitate ethical interactions between Companies and Healthcare Professionals in Malaysia.
- 1.2 Ethical interactions between Companies and Healthcare Professionals provide numerous benefits, such as:
  - (a) Ensuring that medical decision-making is made in the best interest of the patient.
  - (b) Increasing public confidence in the medical device and diagnostics industry.
  - (c) Enhancing patient access to the safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by Companies.
  - (d) Promoting innovation and the ongoing development of Medical Technologies through legitimate and transparent collaboration
  - (e) Facilitating open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies to participate in global markets.

### 2 General Principles

This Code is based upon the following general principles:

- (a) **Advancement** – Companies’ relationships with Healthcare Professionals must be for the purpose of advancing Medical Technology, innovation and patient care.
  - (b) **Integrity** – Companies must interact with Healthcare Professionals in an honest, truthful, and fair manner.
  - (c) **Independence** – Companies may not provide anything of value to improperly influence a Healthcare Professional from making medical decision that is based on the best interest of the patients.
  - (d) **Appropriateness** – Interactions must be modest and/or reflect fair market value, and be for legitimate purposes.
  - (e) **Transparency** – Companies must be open regarding significant financial relationships with Healthcare Professionals.
- 2.1 To the extent that any provision of this Code conflicts with a provision of a law, regulation, company policy, or local medical technology industry code of ethical conduct, Companies shall comply with the provision that has the strictest requirement or highest ethical standard.

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### 3 Definitions

#### 3.1 In this Code:

**Companies** means organizations that develop, manufacture, sell, market or distribute Medical Technologies in Malaysia.

**Demonstration Products** means products that are used for training of Healthcare Professionals or patient education.

**Evaluation Products** means products provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment.

**Healthcare Professionals** includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Companies' Medical Technologies. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above and anyone with material influence over purchasing decisions.

**Medical Technologies** means products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.

### 4 Consulting Arrangements with Healthcare Professionals

4.1 Companies may engage Healthcare Professionals to provide services that support research and development to advance medical science, develop new technologies, improve existing products and services, educate on the safe and effective use of company products or enhance the quality and efficacy of patient care.

4.2 Consulting arrangements between Companies and Healthcare Professionals must comply with the following:

- (a) A legitimate need and purpose for the services is identified in advance;
- (b) Only the number of Healthcare Professionals reasonably needed to perform the services are engaged;
- (c) Healthcare Professionals are selected based on their qualifications to perform the services and are not based on the volume or value of business generated or potentially generated by them;
- (d) Compensation paid to a Healthcare Professional consultant must be consistent with fair market value for the services actually performed;
- (e) Compensation is paid after the services have been performed and upon sufficient evidence of performance of services (retainer fees or other advance payments are not permitted);
- (f) Compensation is paid by cheque or electronic bank transfer. Payment must not be by cash;

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- (g) The services and compensation to be paid (if any) are documented in a written agreement in advance of the services being performed; and
  - (h) Consulting arrangements should be disclosed in advance and in writing to the Healthcare Professional consultant's institution or employer, unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations or rules.
- 4.3 When it is necessary for the Healthcare Professional consultant to travel in order to perform the services, Companies may pay for or reimburse the reasonable travel, accommodation and meal expenses, provided that:
- (a) The expenses are limited to those that are necessary for the Healthcare Professional to perform the services;
  - (b) No expenses are paid for spouses or other guests accompanying the Healthcare Professional; (An exception for spouses who worked at the same entity and assigned by the supervisor at that Healthcare Professional to join the event)
  - (c) Whenever possible, Companies make travel bookings directly on behalf of the Healthcare Professional, rather than providing reimbursement to the Healthcare Professional;
  - (d) When direct bookings are not possible, reimbursement is only made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment;
  - (e) Reimbursement is made by cheque or electronic bank transfer. Payment must not be by cash;
  - (f) Companies must not fund the Healthcare Professional consultant's vacation or other personal activities such as private side trips.

### **5 Third Party Educational Conferences**

- 5.1 A third party educational conference is a conference sponsored or conducted by or on behalf of a professional association that is independent, of an educational or scientific or policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.
- 5.2 Companies may support such conferences through grants to conference organizers, grants to institutions to support individual attendance at the conference, or other appropriate methods, provided that:
- (a) Such support should preserve the independence of medical education and should not be used as a means of inappropriate inducement;

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- (b) The grants should be made only following a written request from the conference organizer or institution, including sufficient information to allow the Company to evaluate the scientific and educational merit of the conference as well as the appropriateness of the venue and agenda;
  - (c) The conference venue and agenda do not bring the industry's reputation into disrepute;
  - (d) The support is consistent with relevant guidelines established by the conference organizer and any accrediting body,
  - (e) The conference organizer should independently control and be responsible for the selection of program content, faculty, educational methods and materials;
  - (f) The funding provided is proportionate to the overall costs of the conference;
  - (g) Companies must not directly pay for, or reimburse, the expenses of any individual Healthcare Professional delegates to attend the conference and grants must not inappropriately benefit individual Healthcare Professionals or provide for side trips, recreation, entertainment or lavish meals or accommodations; and
  - (h) All grant arrangements must be appropriately documented.
- 5.3 Where consistent with the conference organizer's guidelines, Companies may sponsor or organize appropriate meals in connection with conferences, provided that such meals are:
- (a) Modest in cost;
  - (b) Don't include entertainment or recreational activities;
  - (c) Are subordinate in time and focus to the scientific or educational purpose of the conference; and
  - (d) Only provided to Healthcare Professional attendees of the conference.
- 5.4 Companies may purchase advertisements and lease booth space for Company displays at conferences.
- 5.5 Companies may also sponsor satellite symposia at conferences and provide content and faculty for these symposia, provided that the arrangements are disclosed in writing in all materials relating to the satellite event. If Healthcare Professional consultants are engaged for these symposia, the provisions relating to Healthcare Professional consultants also apply.

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### **6 Company-Sponsored Training and Educational Meetings**

- 6.1 Companies may provide training and education of Healthcare Professionals on the safe and effective use of Company products, including “hands-on” training sessions, cadaver workshops, wet lab sessions, live surgeries, lectures and presentations.
- 6.2 Companies may provide reasonably-priced meals in connection with training and education meetings.
- 6.3 Training and education meetings must:
- (a) Be held in a location (e.g. town or city) that is logistically sensible considering the location of the majority of participants and those providing the educational learning.
  - (b) Be held in appropriate venues such as the Healthcare Professional’s premises, Company’s premises, clinical, laboratory, educational or conference facilities (including hotel meeting rooms) that enable effective learning;
  - (c) Be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise;
  - (d) Follow a robust educational agenda that limits free time to that necessary for reasonable breaks and meals; and
  - (e) Not include or facilitate entertainment or other inappropriate activities.
- 6.4 When it is impractical or inefficient to provide training at or close to a Healthcare Professional’s place of business (such as for plant tours or demonstrations of non-portable equipment), Companies may pay the reasonable travel and accommodation costs, provided that:
- (a) The costs are limited to those that are necessary for the Healthcare Professional to attend the training;
  - (b) No costs are paid for spouses or other guests that are not legitimate attendees in their own right; (An exception for spouses who worked at the same entity and assigned by the supervisor at that Healthcare Professional to join the event.)
  - (c) Whenever possible, Companies make travel bookings directly on behalf of the Healthcare Professional, rather than providing reimbursement to the Healthcare Professional;
  - (d) When direct bookings are not possible, reimbursement is only made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment; and

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- (e) Reimbursement is made by cheque or electronic bank transfer. Payment must not be by cash.
- (f) Companies must not fund Healthcare Professional's vacation or other personal activities such as private side trips.

### **7 Meals Provided During Business Meetings**

- 7.1 Company representatives may meet from time to time with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sales terms. Such meetings are subject to the following rules:
- (a) 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, provided it is conducive to the business discussion;
  - (b) Meals must be modest and incidental to the business discussion;
  - (c) Entertainment may not be provided; and
  - (d) Expenses may not be paid for spouses or other guests of Healthcare Professionals that do not have a legitimate business interest in attending the meeting. (An exception for spouses who worked at the same entity and assigned by the supervisor at that Healthcare Professional to join the event)

### **8 Educational Items**

- 8.1 Companies may occasionally provide items to Healthcare Professionals that benefit patients or serve a genuine educational function for Healthcare Professionals. Items that are capable of use by Healthcare Professionals (or their family members, office staff or friends) for non-educational or non-patient related uses are inappropriate.
- 8.2 Educational items should be modest in cost, as determined by local standards, and should not be provided with excessive frequency.
- 8.3 Certain permissible educational items, such as textbooks and anatomical models, may be higher in cost but nonetheless, they should not be extravagant.

### **9 Gifts and Entertainment**

- 9.1 Gifts are items that are provided to individual Healthcare Professionals that do not fit into any of the categories set out in this Code. Gifts include cash, gift cards, food, wine or spirits, gift baskets, flowers or any type of branded promotional items.
- 9.2 Companies must not provide gifts to Healthcare Professionals even if the item is of minimal value, except where expressly allowed by local law.

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- 9.3 Companies must not provide, organize or pay for recreational or entertainment activities for Healthcare Professionals, including (without limitation) tourist, cultural or artistic activities, or leisure activities.

### 10 Grants and Donations

- 10.1 Companies may provide research, educational and charitable grants and donations provided that the Company:

- (a) Adopts objective criteria for providing grants and donations that do not take into account the volume or value of purchase made by, or anticipated from, the grant recipient or affiliated Healthcare Professionals;
- (b) Implements appropriate procedures to evaluate grant and donation requests against those objective criteria and to ensure that they are not used as a condition of purchase of the Company's products or to improperly obtain any other form of advantage;
- (c) Ensures that sales representatives do not control or unduly influence decisions around grants and donations although they may provide input to help evaluate the suitability of a proposed program or recipient;
- (d) Does not provide grants for inappropriate activities, such as holiday parties or entertainment activities;
- (e) Does not link the grant or donation directly or indirectly to the purchase of Medical Technologies;
- (f) Provides the grant or donation in response to a written request from a bona fide organization or institution;
- (g) Provides the grant or donation to the requesting institution or organization and not to individual Healthcare Professionals; and
- (h) Documents the grant or donation provided.

- 10.2 In addition to the rules set forth above, the following rules apply to the particular types of grants and donations specified:

- (a) **Charitable Donations (monetary or in-kind):**
  - (i) Companies may make monetary and in-kind donations to support *bona fide* charitable organizations and missions and non-profit organizations for charitable purposes, such as supporting indigent care, patient education, public education or the sponsorship of events where the proceeds are intended for charitable purposes.
  - (ii) In rare instances, donations may be made to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission, but it is the obligation of the Company providing such donation to ensure that the mission is bona fide and that such



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individual will not personally benefit, directly or indirectly, from the donation provided.

**(b) Educational Grants:**

- (i) Companies may provide grants to support legitimate educational purposes, such as the medical education of Healthcare Professionals, or medical students, residents, and fellows, and education of patients and the public about important healthcare topics.
- (ii) Grants may not exceed the value necessary to achieve the educational purpose.

**(c) Research Grants:**

- (i) 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.
- (ii) Sponsored research should have well-defined objectives and milestones that are documented in a research protocol or similar document.
- (iii) Payments should only be made upon evidence of satisfactory completion of the research activities or at agreed milestones as documented in the research protocol.
- (iv) Company-initiated or directed research involving a Company's Medical Technologies is not covered by this section and should be evaluated under the provisions addressing consulting arrangements.

### **11 Demonstration and Evaluation Products**

11.1 Companies may provide Medical Technologies to Healthcare Professionals free of charge for demonstration and evaluation purposes, provided that:

- (a) They are not given or intended as an improper inducement;
- (b) Demonstration Products should be marked "not for human use" or otherwise to indicate that they are solely for demonstration purposes;
- (c) Evaluation Products are provided in quantities (or for a duration) that is reasonably determined to enable adequate evaluation by the Healthcare Professional;
- (d) Evaluation Products should be appropriately disclosed and documented; and
- (e) Companies should ensure that loaned products are retrieved or returned if not purchased at the end of the evaluation period.

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**12 Ensuring Effective Code Implementation**

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

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

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