

ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES (AMMI)
CODE OF ETHICAL CONDUCT
FOR INTERACTIONS WITH HEALTH CARE PROFESSIONALS

A. PURPOSE AND APPLICABILITY OF CODE

This Code of Ethical Conduct (“**Code**”) is effective as of 1 January 2018.

The Association of Malaysian Medical Industries (“**AMMI**”) promotes ethical interactions between the medical technology industry and health care professionals. The purpose of this Code is to facilitate ethical interactions between its corporate members that develop, manufacture, sell, market, or distribute medical technologies in Malaysia (“**Members**”) and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Malaysia (“**HCPs**”).

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

B. ETHICAL PRINCIPLES

1. Collaborative interactions to preserve independent decision-making and public confidence

1.1 AMMI recognizes that collaborative interactions between Members and HCPs are essential to advancing medical technology and ensuring the safe and effective use of Members’ products and services. Ultimately, such interactions are to the benefit of patients.

- 1.2 AMMI is committed to ensuring that these interactions meet the highest ethical standards, preserve HCPs' independent decision-making, and reinforce public confidence in the integrity of patient care, treatment, and product and service selection.
- 1.3 All interactions with HCPs must be:
- (a) conducted in compliance with applicable laws and codes of conduct;
 - (b) based on the best interests of the patient; and
 - (c) appropriately documented.
- 1.4 In promoting or advertising their products and services to HCPs, Members must ensure that they comply with applicable laws and codes of conduct. All statements must be true, accurate, and substantiated.

2. Consultancy agreements

Members may engage HCPs to provide *bona fide* services to the Member or on behalf of the Member, examples of which include clinical research, research and development, participation on advisory boards, and training and education of other HCPs on the safe and effective use of the Member's products and services or associated procedures. The selection of HCPs shall be based on relevant expertise, and shall not be used to induce a HCP to use, recommend, purchase, or prescribe the Member's products and services. HCPs shall be compensated at not more than fair market value for the services provided in the jurisdiction in which the HCP regularly conducts its practice, irrespective of where the consulting service takes place. Any expenses paid or benefits provided to a HCP shall be reasonable and appropriately documented in a written consultancy agreement specifying all services to be provided under the engagement.

3. Member support of Third Party Educational Events

- 3.1 Member support of a Third Party Educational Event¹ shall at all times preserve the independence of medical and scientific education. A Third Party Educational Event must primarily be dedicated to promoting medical, scientific, and educational activities and discourse, and must be initiated by the Third Party Educational Event organizer.
- 3.2 Any Member's decision to support a Third Party Educational Event must be based on sufficient information to enable the Member to evaluate the medical, scientific, and educational merit of the Third Party Educational Event, as well as the appropriateness of the venue and agenda. Members should not seek to inappropriately influence the program content, selection of faculty, educational methods, or materials at the Third Party Educational Event.
- 3.3 Under no circumstances shall a Member's support of a Third Party Educational Event be to induce an HCP to use, recommend, purchase, or prescribe the Member's products and/or services. The nature of and the conditions attaching to a Member's support of a Third Party Educational Event must be properly documented in writing.
- 3.4 Subject to Section 8 (Research and educational grants), a Member may provide an educational grant to:
- (a) the organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational Event and/or to support attendance of HCPs at the Third Party Educational Event;
 - (b) a Healthcare Institution² to support attendance of HCPs at the Third Party Educational Event; and/or
 - (c) a Professional Association³ to support attendance of HCPs at the Third Party Educational Event.

¹ **Third Party Educational Event** is a conference or meeting that is of a medical, scientific, and/or educational nature, intended to promote scientific knowledge, medical advancement, and/or the delivery of effective healthcare, and organized by a Professional Association, Healthcare Institution, or by a *bona fide* medical or other professional education provider.

² **Healthcare Institution** is a body or legal entity that is a healthcare, medical, or scientific organization which may have direct or indirect influence on the purchase or acquisition of medical technology.

³ **Professional Association** is a regional, national, or specialty clinical or other professional body representing HCPs.

3.5 Without limiting Section 3.4, Member support of Third Party Educational Events shall be limited to funding:

- (a) the purchase of advertising and leasing of booth space for displays and promotional activities at the Third Party Educational Event;
- (b) the holding of satellite symposia at the Third Party Educational Event;
- (c) registration fees to the Third Party Educational Event;
- (d) reasonable travel to, and modest accommodation at, the Third Party Educational Event where out-of-town travel is required; and
- (e) incidental meals and refreshments, provided the meals and refreshments are modest in value and are subordinate in time and focus to the educational purpose of the Third Party Educational Event.

3.6 Members shall neither:

- (a) pay for, offer to pay for, or otherwise reimburse the expenses of any individual HCP to attend or speak at a Third Party Educational Event; nor
- (b) select, or influence the selection of, any HCP to attend a Third Party Educational Event, whether as a delegate or as faculty.

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

3.7 Nothing in this Section 3 applies to Section 4 (Member organized or supported medical technology training and education).

4. Member organized or supported medical technology training and education

4.1 Members may provide or support training and education to HCPs on product-specific technology deployment, use, and application to facilitate the safe and effective use of medical technologies. Members may also provide or support education to HCPs on topics concerning or associated with the use of their medical technologies. Examples of training and education programs include “hands-on” training sessions,

workshops, lectures, and product presentations. Training and education shall be conducted by qualified personnel, which may include Member personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party.

- 4.2 Training and education programs shall be conducted in venues that are conducive to the transmission of education and training and are selected based on their suitability for the proposed program and for the convenience of attendees. Appropriate venues may include the HCP's premises, the Member's premises, or other clinical, laboratory, educational, or conference training facilities (including hotel conference rooms), depending on the nature of the program. The venue must not be selected because of its entertainment, leisure, or recreational facilities. To assist HCPs attending training and education programs, Members may fund the costs of individual HCPs' reasonable travel, modest accommodation, and incidental, modest meals and refreshments. Members shall not provide, pay for, or arrange for recreation or entertainment for participating HCPs, nor shall Members provide, pay for, or arrange for travel, accommodation, meals, or refreshments of spouses or other guests of participating HCPs.

5. Prohibition on gift giving and entertainment

No gifts may ever be given to a HCP, directly or indirectly, including gifts of cash, cash equivalents such as gift cards/certificates, tobacco, or alcohol. Members should not provide, nor arrange, entertainment or recreation to, or for, HCPs. Entertainment or recreation includes, for example, theatre, sporting events, golf, skiing, hunting, and leisure or vacation trips. This Section 5 is not intended to address the legitimate practice of providing educational support items covered in Section 6 (Educational support items) and appropriate sample products and opportunities for product evaluation covered in Section 7 (Evaluation/sample/demonstration products).

6. Educational support items

Members must ensure that sales of products and services are never made on the basis of a HCP receiving anything of value from a Member. Members may occasionally provide to HCPs branded or non-branded items of minimal value, in addition to medical textbooks, medical journals, and anatomical models. These items must serve a genuine educational function relating to the HCP's practice or otherwise benefit patients.

7. Evaluation/sample/demonstration products

A Member may provide medical technology products to HCPs free of charge for evaluation and demonstration purposes, provided that:

- (a) they are not given or intended as an improper inducement;
- (b) only reasonable quantities of evaluation products are supplied to HCPs to familiarize them with the products and enable them to gain experience with the products in their practice;
- (c) they are only provided in quantities and/or for a duration that is reasonably determined to enable adequate evaluation by the HCP;
- (d) they are appropriately documented and accounted for by the Member, including to minimize any risk of the HCP being able to financially benefit from the products; and
- (e) if not meant for human use or diagnostics purposes, they are marked "Not for human use" or "Not for diagnostic purposes" or with similar language to indicate that the products are solely for demonstration purposes and that they cannot be sold or used for human clinical studies or routine patient management.

8. Research and educational grants

A Member may provide research and educational grants provided that the Member:

- (a) adopts objective criteria for providing the grants;
- (b) implements appropriate procedures to ensure that grants are not conditional on the use, recommendation, purchase, or prescription of the Member's products and services; and

- (c) ensures that the recipient of the grant makes an independent decision on application of the grant and/or selection of any beneficiary of the grant.

Research grants may only be used to support independent medical research with scientific merit or health care policy development, provided that such activities have well-defined objectives and milestones. Educational grants may only be made to advance patient care, for medical education of medical students, residents, fellows participating in fellowship programs, or other medical personnel, or for educating the public on health care issues.

9. Charitable donations

Members may make donations of money, products, or services for charitable or other philanthropic purposes, or sponsor events where the proceeds are intended for charitable purposes, unless the donations are prohibited under applicable laws and/or codes of conduct. Charitable donations shall be made to bona fide non-profit entities, charitable organizations, missions supporting charitable projects, and to other organizations supporting charitable projects. A charitable donation must not be targeted to HCPs, nor used as encouragement or as a reward for a HCP using, recommending, purchasing, or prescribing a Member's products or services. All charitable donations shall be appropriately documented.

C. EFFECTIVE CODE IMPLEMENTATION

In order to ensure effective implementation of these Code principles, each Member shall:

- (a) appoint a senior executive responsible for oversight of the Member'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 ethical conduct for interactions with HCPs;
- (d) ensure that senior management and the Member'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 to raise concerns; and
- (g) require that third party intermediaries (including consultants, distributors, sales agents, and brokers) appointed by the Member who may interact with HCPs in connection with the Member's medical technologies agree to conduct their interactions in accordance with applicable laws and ethical principles at least as restrictive as those contained in this Code.

First amendment: effective 1 January 2018