

APACMED CODE OF ETHICAL CONDUCT FOR INTERACTIONS WITH HEALTH CARE PROFESSIONALS

APACMed Mission:

Our mission is to improve the standards of care through innovative collaborations among stakeholders to jointly shape the future of health care in Asia Pacific

Note:

- *Definitions of key terms are provided in Appendix 1*
- *Further information about the Code is provided in Appendix 2*
- *Further guidance is provided in the separate FAQs document*

A. PURPOSE AND APPLICABILITY OF CODE

This Code is effective as of 1 January 2016.

- First amendment: incorporated 23 February 2017, effective 1 January 2018
- Second amendment: effective 1 July 2020

APACMed promotes ethical interactions between the medical technology industry and HCPs to advance the APACMed Mission. The purpose of this Code is to facilitate ethical interactions between Members and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Asia Pacific.

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 each country, province, or region 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 under the law or other code of conduct. Likewise, if a provision in this Code is more restrictive than the corresponding provision in law or other 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 APACMed 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 APACMed 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 an HCP to use, recommend, purchase, or prescribe the Member's products and services. HCPs shall be compensated at not more than the FMV for the services provided in the jurisdiction in which the HCP regularly conducts their practice, irrespective of where the consulting service takes place. Any expenses paid or benefits provided to an 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 Event shall always 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 enough 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 must 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 as an inducement to 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 Grants and Education Grants), a Member may provide an Education Grant to:

- (a) the organizer of a 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) *bona fide* and reputable organizations, which may or may not be affiliated with a Third Party Event Organizer, HCO, or Professional Association, that provide Education Grant administration services;
- (c) an HCO to support attendance of HCPs at the Third Party Educational Event; and/or
- (d) a Professional Association to support attendance of HCPs at the Third Party Educational Event.

In all cases, the Education Grant recipient must fully respect the terms of this Code regarding Member provision of Education Grants.

3.5 Without limiting Section 3.4, a Member's support of a Third Party Educational Event 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 that 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) arrange, 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 Grants and Education Grants), Members may only support attendance of HCP speakers, poster or abstract presenters, and delegates at Third Party Educational Events through provision of Education 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).

3.8 A Member may purchase a satellite symposium package at a Third Party Educational Event and provide presentations on subjects that are consistent with the overall content of the Third Party Educational Event. A Member may determine the content of the satellite symposium and be responsible for speaker selection. A Member may have corporate branding incorporated in such a Satellite Symposium and can promote the Satellite Symposium to its customers. A Member may select faculty members, consultants, or its employees to speak at or to facilitate the Satellite Symposium. Any meals or hospitality provided must comply with the provisions of Section 3.5(e).

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, who may include Members' employees with appropriate technical expertise or personnel of a reputable 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 HCPs' 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.

- 4.3 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 must not provide, pay for, or arrange recreation activities or entertainment for participating HCPs, nor shall Members provide, pay for, or arrange travel, accommodation, meals, or refreshments for spouses or other guests of participating HCPs.
- 4.4 As a limited exception to Section 3.6, which is the general prohibition against direct sponsorship of HCPs to Third Party Educational Events, a Member may support an HCP's attendance at a Third Party Procedure Training either:
- (a) by selecting the HCP and directly covering the costs of their attendance;
 - (b) *via* an Education Grant to the HCO which employs the HCP selected by the Member; or
 - (c) *via* an Education Grant to the HCO to cover the costs of one or more of its employed HCPs to be selected by the HCO to attend the Third Party Procedure Training.

Members providing support to enable an HCP to attend a Third Party Procedure Training under the options listed in this Section 4.4 shall do so strictly in accordance with the following:

- (i) For option (a), the Member shall directly pay for registration, travel and hospitality, in accordance with its policies and procedures, and Section 3 of this Code.; and
- (ii) Education Grants must be provided in accordance with Section 8, except that Members may propose to HCOs the participation of individual HCPs to attend a Third Party Procedure Training, in accordance with option (b) above.

The Member must apply the requirements governing conduct, attendance, and relevance for the HCP's professional practice at the Third Party Procedure Training in accordance with the rules of the country of the practicing HCP and comply with all applicable laws and codes of conduct applicable in the country where the training is being conducted. Before supporting the attendance of an HCP at a Third Party Procedure Training, the Member must familiarize itself with FAQ 24 and be satisfied that such support does not result in a breach of Section 3.6, being the general prohibition against direct sponsorship of HCPs to Third Party Educational Events.

5. Prohibition on gift giving and entertainment

Gifts may never be given to an HCP, directly or indirectly, including gifts of cash, cash equivalents such as gift cards/certificates, tobacco, or alcohol. Members must neither provide nor arrange recreation activities or entertainment for HCPs. Recreation activities and entertainment include 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 Evaluation Product, Samples, and Demonstration Product covered in Section 7 (Evaluation Product/Sample/Demonstration Products).

6. Educational support items

Members must ensure that sales of products and services are never made based on an

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 Product/Samples/Demonstration Product

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 Grants and Education Grants

A Member may provide Research Grants and Education Grants provided that the Member:

- (a) adopts objective criteria for providing the Research Grants and Education Grants;
- (b) implements appropriate procedures to ensure that Research Grants and Education 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 a Research Grant or Education Grant makes an independent decision on application of the Research Grant or Education Grant and/or the selection of any beneficiary thereof.

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. Education 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 Charitable 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 Charitable Donation is prohibited under applicable laws 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 an HCP using, recommending, purchasing, or prescribing a Member's products or services. All Charitable Donations shall be appropriately documented.

10. Technical support in the clinical setting

Member representatives may play an important role in the clinical setting by providing technical support on the safe and effective use of their medical technologies and products. For example, Member representatives may need to explain how a product's unique settings and technical controls function and may make recommendations to HCPs responsible for patient care. Member representatives may also assist HCPs and HCOs in a clinical, operating room, laboratory, or other setting to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with medical technologies and products that involve multiple devices and/or accessories.

All interactions by Member representatives with HCPs and HCOs must comply with all applicable laws, regulations and local industry codes. In addition, when providing technical support to HCPs and/or HCOs in all settings, Members and their representatives should:

- (a) enter and be present in a clinical or other patient care setting only at the request of and under the supervision of HCPs or other HCO personnel;
- (b) be transparent that they are acting on behalf of the Member in a technical support capacity;
- (c) adhere to applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements; and
- (d) not compromise or interfere with an HCP's independent clinical decision-making.

11. Third party sales and marketing intermediaries (SMIs)

To ensure and improve ongoing patient and clinician access to innovative, reliable, and effective medical technologies, it is often necessary for Members to engage SMIs to assist in the marketing, sale, and/or distribution of the Member's products or services.

It is essential that a Member's interactions with SMIs, as well as SMIs' conduct on the Member's behalf (including the SMI's interactions with HCPs or governmental officials) are conducted pursuant to all applicable laws and ethical principles, and the provisions of this Code.

Members are encouraged to adopt compliance measures for management of SMIs as part of their overall compliance program. Considering various risk factors, as well as local applicable laws, regulations or professional codes, where relevant, such measures may include the following:

- (a) a written policy/procedure on engaging SMIs;
- (b) risk assessments;
- (c) due diligence;
- (d) written contracts;
- (e) training and education;
- (f) audit and monitoring; and
- (g) taking appropriate corrective action as warranted.

C. EFFECTIVE CODE IMPLEMENTATION

To ensure effective implementation of these Code principles, each Member shall:

- (1) appoint a senior executive responsible for oversight of the Member's compliance with this Code;
- (2) adopt practical, useful, and meaningful policies, guidance, and tools intended to ensure compliance with the Code;
- (3) provide effective and ongoing training and education on the Code and on ethical conduct for interactions with HCPs;
- (4) ensure that senior management and the Member's board of directors or other governing body have expressly committed to support the Code;
- (5) institute appropriate internal monitoring and auditing mechanisms;
- (6) create safe mechanisms for, and encourage, employees to raise concerns; and
- (7) require that SMIs agree to conduct their interactions in accordance with applicable laws and ethical principles at least as restrictive as those contained in this Code.

APPENDIX 1: DEFINITIONS

“**APACMed**” means the Asia Pacific Medical Technology Industry Association.

“**Code**” means this *APACMed Code of Ethical Conduct for Interactions with Health Care Professionals* (including the Appendices).

“**Charitable Donation**” means the provision of cash, equipment, Member or third party product for exclusively charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made:

- on an unrestricted basis; and
- to *bona fide* charities or other non-profit entities or bodies.

In the case of the latter, the charity/non-profit entity/body must have genuine charitable or philanthropic objectives and/or purposes.

“**Demonstration Product**” or “**Demos**” means either single-use or multiple-use products provided free of charge by or on behalf of a Member to HCOs or HCPs who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples;
- Evaluation Products;
- products provided at no charge as part of a Charitable Donation or as part of a Research Grant or Education Grant; or
- products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

“**Direct Sponsorship**” means the practice of a Member supporting attendance by an individual HCP selected by that Member at a Third Party Educational Event. As from 1 January 2018, this practice has been prohibited under this Code.

“**Education Grant**” means the provision by a Member of funding or product (including third party product) or other in-kind support to:

- an HCO by or on behalf of a Member on a restricted basis;
- a Professional Association;
- the organizer of a 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; and/or
- *bona fide* and reputable organizations, which may or may not be affiliated with an HCO, Professional Association, or a Third Party Event Organizer, that provide Education Grant administration services.

In all cases, the Education Grant must be provided solely for the support and advancement of continuing medical education of HCPs, patients, and/or the public. Such education must be on clinical, scientific, and/or health care-related topics relevant to the therapeutic areas in which the Member is interested and/or involved.

“**Evaluation Product**” means either single-use or multiple-use product and/or equipment provided free of charge to an HCO by or on behalf of a Member for the purpose of obtaining

user feedback over a defined period of use when used within the scope of the intended purpose, strictly in accordance with any necessary authorization in the jurisdiction where the Evaluation Product is used. Evaluation Products do not include the following:

- Demos;
- Samples;
- product provided free of charge as a Charitable Donation, Research Grant, or Education Grant; or
- product provided free of charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as replacement product supplied pursuant to a warranty agreement.

“**FMV**” means the fair market value for engaging the services of an HCP or other third party.

“**Grant**” means either an Education Grant or a Research Grant, or both.

“**HCO**” means “healthcare organization,” being a body or legal entity that is a health care, medical, or scientific organization or institution which may have direct or indirect influence on the purchase or acquisition of medical technology, products, and/or services.

“**HCP**” means “health care professional” and includes any individual who recommends, prescribes, procures, supplies, administers, uses, or determines the purchase or lease of (directly or indirectly) medical technologies, products and/or related services. HCP includes any individual who may have a clinical or non-clinical role, may be a government official, or employee or representative of a governmental or quasi-governmental agency, or other public or private sector organization. Examples of HCPs include physicians, nurses, midwives, pharmacists, dentists, technicians, laboratory scientists, researchers, research coordinators, or procurement professionals.

“**Member**” means a company and/or a corporate member that develops, manufactures, sells, markets, or distributes medical technologies and or products within Asia Pacific which has joined and is part of APACMed.

“**Professional Association**” means a regional, national, or specialty clinical or other professional body representing HCPs.

“**Research Grant**” means the provision by or on behalf of a Member of funding, products/equipment, and/or in-kind services to any organization that conducts research. The grant must be made for the sole, restrictive purpose of supporting the development or furtherance of *bona fide*, scientifically valid and legitimate research by the recipient. The purpose of the grant must be to advance medical, scientific, and health care knowledge, medical technologies, and/or clinical techniques designed to improve patient outcomes.

“**Sample**” means single-use or multiple-use products provided free of charge by or on behalf of a Member to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarize themselves with the products in clinical use. Samples do not include the following:

- Demos;
- Evaluation Products;
- products provided at no charge as part of a Charitable Donation, Research Grant, or Education Grant; or
- products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g., as part of an agreed discount arrangement or as replacement products supplied pursuant to a warranty agreement.

“Satellite Symposium” means a Member-organized and sponsored program that is held at a Third Party Educational Event, which is included in the official agenda of the Third Party Educational Event.

“SMI” means a third party sales and marketing intermediary, being individuals or organizations engaged by a Member to assist them in the marketing, sale and/or distribution of their products or services. They may include distributors, logistics providers, wholesalers, distribution or sales agents, marketing agents, consultants, brokers, commissioner commercial agents, and independent sales representatives with which the Member has a direct contractual relationship. They are not employees of a Member.

“Third Party Educational Event” means a conference, gathering, 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 health care, and organized by a Professional Association, HCO, or by a *bona fide*, certified medical or other professional education provider.

“Third Party Procedure Training” means a type of Third Party Educational Event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- specific therapeutic, diagnostic, or rehabilitative procedures, namely clinical courses of action, methods, or techniques; and
- practical demonstrations and/or training for HCPs, where most of the training program is delivered in a clinical environment.

The singular includes the plural and vice versa, unless the context plainly requires otherwise.

APPENDIX 2: ABOUT THE APACMED CODE

Founded in 2014, APACMed is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional, and local government bodies to shape policies, demonstrate the value of innovation, and promote regulatory harmonization. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, codes of ethics, and to share best practices.

The purpose of the Code is to facilitate ethical interactions between Members and HCOs and HCPs. Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in the Code.

APACMed recognizes that collaborative interactions between Members and HCOs and HCPs must 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.

All interactions with HCPs must be:

- conducted in compliance with applicable laws and codes of conduct;
- based on the best interests of the patient; and
- appropriately documented.

The Code has been under regular review since the first version came into force on 1 January 2016. In February 2017, the APACMed Board revised the Code to no longer permit Members' direct sponsorship of individual HCPs to Third Party Educational Events as of 1 January 2018, and the Code was amended accordingly. In light of recent amendments to the AdvaMed Code, the MedTech Europe Code, and other codes of ethics that apply to many Members both within Asia Pacific and globally, the APACMed's Legal/Ethics & Compliance Committee formed a Code Revision Subcommittee in 2019 to review developments globally, review the current Code, and recommend to the APACMed Board amendments to the Code. This resulted in a revised Code being adopted by the APACMed Board in July 2020.

This version of the Code, effective on 1 July 2020, includes further clarification around Satellite Symposia (Section 3.8), and three new provisions concerning:

- Member support of Third Party Procedure Training (Section 4.4);
- Technical support in the clinical setting (Section 10);
- Third party sales and marketing intermediaries (SMIs) (Section 11).

Included in the Code are expanded FAQs. The Code Revision Subcommittee will continue to monitor global trends in HCP codes of ethics globally and be responsive to developments in the industry and particularly in Asia Pacific.