For Interactions With Health Care Professionals

6. Educational support items

5. Prohibition on gift giving and entertainment

- For evaluation and demonstration purposes, provided that:
  - A genuine educational function relating to the HCP's practice or otherwise benefit medical textbooks, medical journals, and anatomical models. These items must serve to provide to HCPs branded or non-branded items of minimal value, in addition to leisure or vacation trips. This section is not intended to address the legitimate practice of providing, nor arrange, entertainment or recreation to, or for, HCPs. Entertainment cash equivalents such as gift cards/certificates, tobacco, or alcohol. Members should commit to adhere to this standard by adopting and abiding by the ethical standards, preserve HCPs' independent decision-making, and reinforce public confidence in the integrity of the medical profession. Ethical interactions between the medical technology industry and health care professionals to advance the APACMed Mission. The purpose of this Code is to facilitate ethical interactions between its corporate members that develop, manufacture, sell, market, or distribute medical technologies. Members may include the HCP's premises, the Member's premises, or other clinical, laboratory, educational, and research facilities. Members may purchase advertisements and lease booth space for company displays at medical associations or institutes or by bona fide medical education providers.

- A Member may provide research and educational grants provided that the Member:
  - A) adopts objective criteria for providing the grants;
  - B) adopts the corresponding provision in this Code, the Member shall adhere to the more restrictive another code of conduct applicable to a Member is more restrictive than the application of the grant and/or selection of any beneficiary of the grant.
  - C) is transparent in its decision-making process and discloses all relevant information to the HCP.
  - D) they are appropriately documented and accounted for by the Member;
  - 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 make it clear that they are not intended for human use in medical practice or diagnosis.
  - F) they are appropriately documented and accounted for by the Member;
  - G) they are specifically intended for educational or training purposes, not as a means of inducements, incentives, or rewards, and are not used for support of the HCP or for patient recruitment.
  - H) require that third party intermediaries (including consultants, distributors, sales representatives, and others) are used to provide educational or training support on behalf of the Member to the HCP or for the HCP's education or training.

9. Charitable donations

- Charitable donations shall be made to bona fide non-profit entities, for philanthropic purposes, or sponsor events where the proceeds are intended for charitable purposes.
- Members should not influence the selection of the program content, faculty, or the application of the grant and/or selection of any beneficiary of the grant.
- Members commit to adhere to this standard by adopting and abiding by the ethical standards, preserve HCPs' independent decision-making, and reinforce public confidence in the integrity of the medical profession.

C. EFFECTIVE CODE IMPLEMENTATION

- 1.1 APACMed recognizes that collaborative interactions between Members and HCPs shall:
  - A) conducted in compliance with applicable laws and codes of conduct;
  - B) based on the best interests of the patient;
  - C) conducted in a manner that is consistent with the Member's ethical conduct for interactions with HCPs;
  - D) require that third party intermediaries (including consultants, distributors, sales representatives, and others) are used to provide educational or training support on behalf of the Member to the HCP or for the HCP's education or training.

- 1.2 Members shall:
  - A) comply with the Code and any other applicable laws and regulations;
  - B) implement procedures to monitor and ensure compliance with the Code;
  - C) provide training and education to employees who interact with HCPs.

- 1.3 All interactions with HCPs must be:
  - A) bona fide education and training of individual HCPs, including the conference organizer or qualified and reputable third party service providers.
  - B) based on the best interests of the HCP;
  - C) conducted in compliance with applicable laws and codes of conduct.

- 1.4 In order to ensure effective implementation of these Code principles, each Member shall:
  - A) adopt practical, useful, and meaningful policies, guidance, and tools intended to facilitate ethical conduct for interactions with HCPs;
  - B) adopt practical, useful, and meaningful policies, guidance, and tools intended to facilitate ethical conduct for interactions with HCPs.
  - C) adopt practical, useful, and meaningful policies, guidance, and tools intended to facilitate ethical conduct for interactions with HCPs.

- 1.5 Members should not influence the selection of the program content, faculty, or the application of the grant and/or selection of any beneficiary of the grant.

- 1.6 Members shall:
  - A) ensure that they comply with applicable laws and codes of conduct. All statements and representations made by Members shall:
  - B) be true, accurate, and substantiated.
  - C) not be deceptive or misleading in any way.
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

A. PURPOSE AND APPLICABILITY OF CODE

This Code of Ethical Conduct for Interactions with Health Care Professionals (“Code”) is effective as of 1 January 2016.

The Asia Pacific Medical Technology Industry Association (“APACMed”) promotes ethical interactions between the medical technology industry and health care professionals to advance the APACMed Mission. The purpose of this Code is to facilitate ethical interactions between its corporate members that develop, manufacture, sell, market, or distribute medical technologies in Asia Pacific (“Members”) and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Asia Pacific (“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 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 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 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 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 conferences
Member support of HCPs’ education through grants to, or other support of, third party educational programs shall preserve the independence of medical education. Members may support conferences organized by national, regional, or specialty medical associations or institutes or by bona fide medical education providers. Members may purchase advertisements and lease booth space for company displays at such conferences. Conferences must primarily be dedicated to promoting objective medical, scientific, and educational activities and discourse and must be initiated by the conference organizer. Any Member’s decision to support must be based on sufficient information to evaluate the medical, scientific, and educational merit of the conference, as well as the appropriateness of the venue and agenda. Conference support shall not be used as a means of inappropriate inducement, and the nature and conditions of support must be appropriately documented.
Support by Members can include funding the reasonable costs associated with:
(a) bona fide education and training of individual HCPs, including the conference registration fees, where the funding is provided to the conference organizer;
(b) individual HCPs’ reasonable travel and modest accommodation, where there are objective reasons to support the need for out-of-town travel; and
(c) incidental, modest meals and refreshments during the course of the conference, provided the meals and refreshments are modest in value and subordinate in time and focus to the educational and/or training purpose of the conference.

Where possible, the costs of travel, accommodation, meals and refreshments should not be reimbursed directly to individual HCPs but paid directly to the conference organizer or qualified and reputable third party service providers.

Members should not influence the selection of the program content, faculty, educational methods and materials, and preferably also not the selection of the HCPs attending the conference.

While APACMed remains committed to supporting HCPs’ access to needed medical education, APACMed recommends to its Members to phase out direct payment to individual HCPs of any costs referred to in this section regarding travel, accommodation, meals and refreshments, as well as to phase out the ability to influence the selection of HCPs attending any conference referred to in this section. APACMed will work with its Members to revise this Code accordingly and to set a date by which such activities will be prohibited under this Code.

4. Member organized or supported medical technology training and education
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.
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 an 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, theater, sporting events, golf, skiing, hunting, and leisure or vacation trips. This section is not intended to address the legitimate practice of providing educational support items covered in section 6 below and appropriate sample products and opportunities for product evaluation covered in section 7 below.

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.

Adopted by the APACMed Board of Directors on December 8, 2015
A Member may provide medical technology products to HCPs free of charge for medical textbooks, medical journals, and anatomical models. These items must serve as sample products and opportunities for product evaluation covered in section 7 below. Members must ensure that sales of products and services are never made on the basis of 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 leisure or vacation trips. This section is not intended to address the legitimate practice of hosting HCPs at company sites for the purpose of training and education. It is essential to advancing medical technology and ensuring the safe and effective application of the grant and/or selection of any beneficiary of the grant. The venue must not be selected because of its entertainment, leisure, or recreational facilities. To assist HCPs attending training depend on the nature of the program. The venue must not be selected because of 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 this Code.

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 other 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 this Code. Likewise, if a provision in this Code is more restrictive than the corresponding provision in the law or other code of conduct. APACMed remains committed to supporting HCPs' access to needed medical technologies in Asia Pacific ("APAC") and those individuals and entities that participate in fellowship programs, or other medical personnel, or for educating the public on health care issues.