

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

FREQUENTLY ASKED QUESTIONS (“FAQ”)

These FAQ provide Members and other parties who will need to apply the Code with guidance:

- on how the Code is implemented;
- on how to interpret certain of the provisions of the Code; and
- to help Members better understand what the Code means in various practical scenarios.

These FAQ will be reviewed regularly, and additional FAQ may be included to help Members in the continued interpretation, application, and implementation of the Code.

Capitalized terms used in the FAQ have the meaning specified in Appendix 1.

FAQ Overview

- A. About the Code
- B. About Section 3: Member Support of Third Party Educational Events
- C. About Section 4: Member Organized or Supported Medical Technology Training and Education
- D. About Section 8: Research and Education Grants

A. ABOUT THE CODE

1. What is the Code?

The Code is the code of ethics applicable to all APACMed Members (and their employees) and SMIs in their interactions with HCPs.

2. What is the purpose of the Code?

The purpose of the Code is to facilitate ethical interactions between APACMed's corporate members that develop, manufacture, sell, market, or distribute medical technologies in Asia Pacific and those individuals and entities that use, recommend, purchase, or prescribe such medical technologies in Asia Pacific.

3. Is it mandatory for Members to adhere to the Code?

Yes. The Code applies to all Members, and adherence to the Code is a condition of membership to APACMed. The requirement extends to all Members, their employees, and SMIs.

4. Does the Code apply to SMIs acting for Members?

Yes. Requirements of the Code extend to all SMIs engaged or appointed by the Member who may interact with HCPs in connection with the Member's medical technologies.

5. There are many different codes out there, and some seem to conflict, so how do I know which one I should follow?

APACMed Members have committed to adopting and abiding by the ethical principles outlined in the Code. However, this is subject to the laws of each country, province, or region, and other codes of conduct applicable to a Member. Where multiple laws or codes apply to a situation, Members should follow the more restrictive provision.

B. ABOUT SECTION 3: MEMBER SUPPORT OF THIRD PARTY EDUCATIONAL EVENTS

General questions

6. What is a Third Party Educational Event?

A 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 health care, and organized by a Professional Association, HCO, or by a *bona fide* medical or other professional education provider.

7. How does the Code affect the ability of Members to sponsor HCPs to attend Third Party Educational Events?

As from 1 January 2018, the Code prohibited the Direct Sponsorship by Members to support attendance by individual HCPs at Third Party Educational Events. As a result, from 1 January 2018, Members may not 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. In addition, Members may not select – or influence the selection of – any individual HCP to attend a Third Party Educational Event, whether as a delegate or as faculty. Members are also prohibited from making logistics arrangements for individual HCPs attending or speaking at Third Party Educational Events, except in limited cases discussed below regarding Satellite Symposia.

8. What is the rationale for the Code prohibition of Direct Sponsorship?

APACMed revised its Code to prohibit Direct Sponsorships in order to align the Code with international best practices that preserve and enhance the independence of HCPs' decision-making. Direct Sponsorship is not permitted in several Asia Pacific countries nor in many other regions in the world. This Code aims to promote the highest standards of transparency around our Members' interactions with HCPs, while at the same time addressing the clear need for training and education of HCPs in Asia Pacific in new medical technologies and therapies.

9. What alternative means are available for Members to support Third Party Educational Events?

Under the Code, Members may not select nor directly sponsor - or influence the selection of - an individual HCP to attend or speak at a Third Party Educational Event (with the limited exception of Member involvement in the planning and execution of Satellite Meetings, as discussed below). However, Members may continue to support HCP education in other ways. Members may provide Education Grants to:

- 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;
- an HCO to support attendance of HCPs at a Third Party Educational Event;
- a Professional Association to support attendance of HCPs at a Third Party Educational Event; and/or
- a *bona fide* administrative intermediary platform that is involved or otherwise assists in the management of medical conferences.

Such grants by Members may cover the costs associated with HCPs' attendance at Third Party Educational Events. These costs may include modest accommodation expenses

where out-of-town travel is required, reasonable travel expenses, registration fees, and incidental meals and refreshments. Members are not permitted to select – or influence the selection of – an individual HCP to receive these benefits under an Education Grant. Members may not book HCP travel or make other logistics arrangements associated with the attendance of HCPs at Third Party Educational Events, except as otherwise discussed in the Code and these FAQ. Finally, Members may continue to support Third Party Educational Events for the following purposes, in line with appropriate contractual agreements:

- advertising and leasing of booth space for displays and promotional activities; and
- Satellite Symposia.

10. Are Members allowed to propose or recommend individual HCPs as faculty to Third Party Educational Event organizers?

Yes. However, Members are not permitted to seek to inappropriately influence the program content, selection of faculty, educational methods, or materials at the Third Party Educational Event. While Members may recommend faculty for the main agenda of a Third Party Educational Event, the ultimate decision of which faculty to invite must remain with the organizer of the Third Party Educational Event. Note that as discussed below, when a Member is sponsoring a Satellite Symposium as part of the program at a Third Party Educational Event, the Member may select the speakers, panelists, or other faculty at the Satellite Symposium.

11. Are Members permitted to arrange or pay for travel for an individual HCP to attend a Third Party Educational Event, either as faculty or as a delegate?

No. Members are not permitted to arrange, directly pay for, or reimburse the expenses of any individual HCP to attend or speak at a Third Party Educational Event. However, a grant may be provided to appropriate organizations to support the attendance of HCPs at the Third Party Educational Event and as discussed in Questions 16 to 19, Members may support certain expenses associated with individual HCP participation as faculty at Member-organized Satellite Symposia.

12. Can Members engage an HCP as a consultant to speak at an international Third Party Educational Event and pay their associated expenses?

Members must not arrange, directly pay for, nor reimburse to individual HCPs the costs of travel, accommodation, nor meals and refreshments. In addition, Members must not influence the selection of faculty. As outlined under Question 11, Members shall make all payments directly to the organizer of the Third Party Educational Event or to qualified and reputable third party organizations specified under Question 9.

13. What impact does the Code have on Members' own training and education programs?

The Code's prohibition of Direct Sponsorship does not affect Members' ability to train and educate HCPs on product-specific technology deployment, use, and application to facilitate the safe and effective use of medical technologies. Members may continue to provide or support education to HCPs on topics concerning or associated with the use of their medical technologies. Please refer to the answers to Questions 20 to 32.

14. I am a conference organizer and I am organizing a Third Party Educational Event for HCPs at a resort location overseas. Can Members sponsor this event?

The appropriateness of the geographic location applies irrespective of who organizes the event and Members should take this into account when making the decision to support an event. Members' primary consideration must be the agenda and the quality of the education that will be provided. Members may of course decline to sponsor a conference if they consider that, on balance, the event does not meet these criteria. Many Members also have their own internal guidelines which prohibit them from sponsoring events at resort locations. APACMed is aware of other codes of ethics that expressly prohibit their members' support of third party conferences at resort locations. In Asia Pacific, however, there are suitable conference venues termed "resorts" that nevertheless for cost reasons, proximity to the proposed attendees, and ease of travel to and from the location are suitable for Third Party Educational Events. Where, however, a resort location is selected by the Third Party Educational Event organizer by reason of the available recreational amenities, and for no other obvious reason, then Members should express their concerns to the organizers about the choice of location and decline to support the Third Party Educational Event.

15. As part of a Member's financial support of a Third Party Educational Event, the organizer has offered several sponsorship benefits, including a golf foursome and several additional badges to secure entry into the Third Party Educational Event. Can the Member invite an HCP to join the golf foursome, and can the Member give one of the badges to an HCP?

No. A Member should not pass along to an HCP any benefits that the Member receives in exchange for its financial support, including for educational and charitable programs. Members should consider the image that may be projected to the public when deciding whether to support a conference which involves recreational aspects, such as a golf foursome. See also the answer to Question 14.

Satellite Symposia

16. What are "satellite symposia" as referred to under Section 3.5(b)?

Satellite Symposia are generally organized by Members that have a presence (e.g., a booth) at, or that have otherwise supported, the Third Party Educational Event. Although the Member is responsible for the content of the Satellite Symposium, these programs may be subject to the Third-Party Educational Event organizer's application and approval process. While Satellite Symposia are generally included on the agenda of the Third-Party Educational Event and associated promotional materials, these are Member-conducted events. Members should be transparent in promoting these as such.

17. Can a Member select faculty for a Satellite Symposium or a booth presentation at a Third Party Educational Event?

Yes.

18. Can a Member pay the honorarium and expenses of a faculty member to participate in a Satellite Symposium or a booth presentation?

Yes. A Member may pay honoraria to faculty members to provide *bona fide* services at a Satellite Symposium or a booth presentation in accordance with Section 2. Where payment of a registration fee is required for speakers to access the Satellite Symposium, the Member may also pay for the registration fee. The registration fee must, where possible, be prorated to the actual attendance required to deliver the required services. For example, if the Satellite Symposium is held on a single day of a three-day Third Party Educational Event, and it is possible to choose a one-day registration, that option should

be selected. If the faculty only attends the Satellite Symposium and not the remainder of the Third Party Educational Event, then the Member may pay for reasonable travel expenses and any modest accommodation and meal costs associated with the faculty's attendance at the Satellite Symposium. However, if the faculty also attends the main Third Party Educational Event associated with the Satellite Symposium, then the Member is not permitted to pay any associated travel expenses, with the exception of local transportation between the Third Party Educational Event and the Satellite Symposium if they do not take place at the same location, and any accommodation and meal costs directly associated with the Satellite Symposium and not with the Third Party Educational Event.

19. Can a Member pay the expenses of individual HCPs to attend a Satellite Symposium?

No. A Member generally draws its audience for a Satellite Symposium from the attendees of the related Third Party Educational Event. The Code prohibits Members from directly paying for the travel, lodging, or registration fees for HCPs to attend a Third Party Educational Event, including Satellite Symposia held at such Third Party Educational Events. Members can, however, pay for reasonable meal costs and additional ground transportation costs associated with the HCP's attendance at the Satellite Symposium.

This prohibition does not preclude a Member from paying for HCPs' modest and reasonable travel and lodging expenses to attend a separate, unrelated, organized training or educational session or Member-conducted consultant meeting such as Advisory Board, as described in Sections 2 and 4. However, this should not be used as a mechanism to in effect subsidize the attendance of the HCP at a Third Party Educational Event held proximately to the Member's meeting or event.

C. ABOUT SECTION 4: MEMBER-ORGANIZED OR SUPPORTED MEDICAL TECHNOLOGY TRAINING AND EDUCATION

General Questions

20. Are Members permitted to organize their own training and education events and select and meet the costs of attendance of HCPs at those events?

Yes. The Code's prohibition of direct HCP sponsorships only impacts Third Party Educational Events. Refer to Section 4.

21. Are Members permitted to organize training and education events in conjunction with HCOs and Professional Associations and select and meet the costs of attendance of HCPs at those events?

Yes. A Member-organized training and education event may be co-sponsored or jointly organized with an appropriately qualified organization such as an HCO, Professional Association, or *bona fide* training provider. Contributions and costs should be shared fairly and equitably between the parties organizing the event.

22. Are Members permitted to organize training and education events together with an HCO utilizing the facilities of the HCO?

Yes. This is Member-organized training, which is permitted under Section 4. Any charges of the HCO for using its facilities for *bona fide* activities must be in accordance with FMV and strictly related to the specific training event. Costs or expenses the HCO would have incurred in any event and irrespective of the training at its premises may not be paid by a Member.

23. What are some of the main characteristics of a Third Party Procedure Training?

Third Party Procedure Training consists of practical, hands-on training, generally involving more than one provider/manufacturer/sponsor, enabling all HCPs to actively participate. This must be evident in the agenda of the Third Party Procedure Training. The program, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the HCPs' skills in minimally invasive surgery; orthopedic trauma surgery; or the implantation of cardiac rhythm devices; etc. The program must also include practical demonstrations (and/or actual live surgeries, where permissible). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers, skin models, synthetic bones, cath labs; etc.

Third Party Procedure Trainings are typically organized in a clinical environment, as opposed to a classroom setting for example. For the avoidance of doubt, "clinical" includes places suitable for the simulation of medical procedures, rather than just hospital environments. Examples of suitable "clinical environments" include, of course, hospitals and clinics where medical treatment on patients may be undertaken, but also conference rooms which are appropriately arranged to enable medical procedures to be simulated.

Examples of Third Party Procedure Trainings include where medical technologies are used on cadavers, skin models, synthetic bones, etc., or incorporating augmented reality technologies in the delivery of the program. Third Party Procedure Trainings must be organized as a "stand-alone" event and not as part of a Third Party Educational Event. Where most of the training is not provided in a clinical environment, for example, where the training is organized in connection, adjacent to or at the same time as a larger Third

Party Educational Event, then the clinical training will not be regarded as a Third Party Procedure Training under the Code.

24. Is it permissible for a Member to seek accreditation by a third-party association for its own product or procedural training?

Yes. The Code does not place any restrictions on engaging third parties to accredit training and education programs organized by Members.

25. A Member would like to arrange a visiting surgeon program. The program would involve surgeons visiting another surgeon who has experience with Member's technology to view the use of the technology in live procedures. Is such a program permitted under the Code?

Yes. Section 4 applies to Member-organized or supported medical technology training and education. Under Section 4, Members may fund reasonable travel, modest accommodation and incidental, modest meals and refreshments for HCPs attending the demonstration, but excluding service fees or similar payments.

26. Can a Member pay the host surgeon under such a program?

Yes. Members may engage a host surgeon as a consultant. Section 2 allows not more than FMV compensation to be paid for consulting services.

27. Are ski resorts and tropical islands out of bounds for Member-organized or supported training and education for HCPs?

The Code requires that Member organized or supported medical technology training and education is 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. The venue must not be selected because of its entertainment, leisure, or recreational facilities.

28. Can Members conduct Member organized training and education at a resort or 5 star restaurants if all other venues are booked out?

It is not acceptable to book a venue that is not consistent with the Code on the basis that all other venues were booked out. Members need to plan and book early enough to avoid placing themselves in such a situation.

Member-organized training and education that coincide with or is adjacent to a Third Party Educational Event

29. Are Members permitted to organize their own training and education events which coincide, as to time and place, with a Third Party Educational Event?

Yes. Members may at times wish to realize economies and logistical benefits by organizing meetings such as advisory boards or clinical investigator meetings, or procedural training workshops, to occur when groups of HCPs and Member personnel will already be in the same location to attend a Third Party Educational Event. This will generally be appropriate so long as the Member-organized training and education event or meeting is not simply a "workaround" to the prohibition on Direct Sponsorship. It would constitute a Code violation if a Member was to in effect subsidize an HCP's attendance at the Third Party Educational Event by meeting the HCP's expenses to travel to the location of the Member-organized event (if the HCP was to attend the Third Party Educational Event).

30. Can a Member pay honoraria and expenses of faculty to participate in their own training and education events that coincide with or are adjacent to Third Party Educational Events?

A Member may only pay for the contractual remuneration and expenses agreed for the provision of the services by the HCP at the Member-organized meeting, calculated in accordance with FMV. Under no circumstances may a Member pay for the incremental costs relating to the HCP's attendance at the Third Party Educational Event.

31. Can a Member pay the expenses of individual HCPs to attend a Member-organized training and education event that coincides with or is adjacent to a Third Party Educational Event?

A Member may not generally pay the travel expenses of any HCP to attend the Member-organized training and education event if that HCP will also be attending the Third Party Educational Event. The only exception will be in the case of an HCP who needs to extend their stay in the meeting location in order to attend the Member-organized meeting and can demonstrate appropriate and documented incremental flight, hotel, and/or meal costs that will result from the extended stay. In such cases, the Member may pay for the incremental costs. The Member should, as a matter of best practice, document the extent of the incremental costs being paid and the fact that the Member is not directly sponsoring the HCP's costs to attend the associated Third Party Educational Event.

The overriding principle is that all Member-organized or supported training and education events must be arranged and conducted in accordance with the letter and spirit of the Code; Members are not permitted to organize their own training and education events to, in effect, directly sponsor individual HCPs to Third Party Educational Events.

D. ABOUT SECTION 8: RESEARCH GRANTS AND EDUCATION GRANTS

32. Do the general requirements for Education Grants in Section 8 allow fellowship grants to be given by Members to hospitals?

Yes. Fellowship grants given by Members under Section 8 to support specialty education are a form of Education Grant. They must comply with the general requirements for Education Grants specified in Section 8.

33. Can Member companies support the participation of poster or abstract presenters at Third Party Educational Events?

Poster or abstract presenters at Third Party Educational Events are not to be considered as speakers or faculty. If Members wish to support their participation at a Third Party Educational Event, such support may be provided through an Education Grant, but Members are not permitted to select, or influence the selection of, an individual HCP to receive these benefits under the Education Grant.