

APACMED CODE OF ETHICAL CONDUCT FOR INTERACTIONS WITH HEALTH CARE PROFESSIONALS Q&A

APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (**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 harmonisation. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, codes of ethics, and to share best practices.

APACMed's Code of Ethical Conduct for Interactions with Health Care Professionals (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 (Members) and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Asia Pacific (HCPs), and healthcare, medical, or scientific organisations which may have direct or indirect influence on the purchase or acquisition of medical technology (Healthcare Institutions). Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in the Code.

APACMed recognises that collaborative interactions between Members 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.

Revisions to the Code

In February 2017, to 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.

This Q&A provides Members with guidance on how these changes to the Code will be implemented. It intends to help Members better understand what the revisions mean in practice, and these messages can be used to help inform stakeholders about the changes.

Q&A OVERVIEW

- About the Code
- About the Code Revisions
- Satellite Symposia
- Travel and Logistics Arrangements
- Member Organised or Supported Medical Technology Training and Education
- Further Information

THIS DOCUMENT IS INTENDED FOR REACTIVE USE ONLY, TO ANSWER QUESTIONS OR GUIDE CONVERSATIONS, AND SHOULD THEREFORE NOT BE SHARED EXTERNALLY



ABOUT THE CODE

1. What is the Code?

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

2. What is the purpose of the Code?

The purpose of the Code is to facilitate ethical interactions between its 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 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 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.

4. Does the Code apply to Members' distributors and other third party intermediaries?

Yes. This requirements of the Code extend to all Members' distributors and 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.

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 particular situation, Members should follow the more restrictive provision.

ABOUT THE CODE REVISIONS

6. There are some revisions to the Code effective 1 January 2018 – what are those revisions?

The Board of APACMed agreed to revise the Code to eliminate direct sponsorship of individual HCPs to Third Party Educational Events that will occur on or after 1 January 2018.

7. 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 healthcare, and organised by a Professional Association, Healthcare Institution, or by a *bona fide* medical or other professional education provider.

8. What is the impact of the Code revisions?

For Third Party Educational Events that will occur from 1 January 2018, Members will no longer be permitted to 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 shall Members be permitted to select – or influence the selection of – any individual HCP to attend a Third Party Educational Event, whether as a delegate or as faculty.



Members will also no longer be permitted to make logistics arrangements for individual HCPs attending or speaking at Third Party Educational Events.

These new restrictions apply to all Third Party Educational Events occurring in 2018 and beyond, regardless of when the arrangements are made.

9. What is the rationale for the Code revisions relating to direct sponsorship?

The revisions to the Code are an important step to align the APACMed Code with international best practices that preserve and enhance the independence of HCPs' decision-making.

Direct sponsorship of individual HCPs to Third Party Educational Events is not currently permitted in a number of Asia Pacific countries or in the United States. Moreover, direct sponsorship of individual HCPs to Third Party Educational Events will not be permitted by members of MedTech Europe and AdvaMed in China, effective 1 January 2018.

The revisions to the APACMed Code 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.

10. Is there a transition period or is there an immediate cessation of direct sponsorship on 1 January 2018?

The APACMed Board has determined that the date of implementation is 1 January 2018. This means that Members may not directly sponsor individual HCPs to Third Party Educational Events occurring on and after 1 January 2018, regardless of when the support was originally offered or solicited. As a result, arrangements occurring now for Third Party Educational Events in 2018 are subject to the new restrictions.

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

The principal impact of the Code revisions is that Members will no longer be able to select and directly sponsor - or influence the selection of - an individual HCP to attend or speak at a Third Party Educational Event. However, Members may continue to support HCP education in other ways.

On and after 1 January 2018, Members will continue to be able to provide educational grants to:

- the organiser 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
- a Healthcare Institution to support attendance of HCPs at a Third Party Educational Event, and/or
- a Professional Association to support attendance of HCPs at a Third Party Educational Event.

In addition, Members may continue to support Third Party Educational Events by providing funding to the Third Party Educational Event organisers, Healthcare Institutions, and Professional Associations for the following purposes:

- advertising and leasing of booth space for displays and promotional activities
- satellite symposia.



Members may also provide educational grants to the Third Party Educational Event organisers, Healthcare Institutions, and Professional Associations to cover the costs associated with HCPs' attendance at Third Party Educational Events. These costs may include reasonable travel and modest accommodation expenses where out-of-town travel is required, registration fees, and incidental meals and refreshments.

PLEASE NOTE THAT MEMBERS ARE NOT PERMITTED TO SELECT - OR INFLUENCE THE SELECTION OF - AN INDIVIDUAL HCP TO RECEIVE THESE BENEFITS.

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

Yes. However, Members are not permitted to seek to inappropriately influence the programme content, selection of faculty, educational methods, or materials at the Third Party Educational Event.

13. What impact do the Code revisions have on Members' own training and education programmes?

The Code revisions will 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 see also the responses to Questions 14 to 17 below.

SATELLITE SYMPOSIA

14. What are "satellite symposia" as referred to under Section 3.5(b) of the Code?

Satellite symposia are events that are held alongside a Third Party Educational Event. Satellite symposia can be sponsored by a Member, and are included in the official agenda of the Third Party Educational Event. They are generally organised by Members that have a presence at (e.g., a booth), or that have otherwise supported, the Third Party Educational Event.

15. Can a Member select faculty for a satellite symposium? Yes.

16. Can a Member pay honoraria and expenses of faculty to participate in a satellite symposium?

Yes. Members may pay honoraria to faculty members to provide *bona fide* services at a satellite symposium in accordance with Section 2 of the Code.

If the faculty only attends the satellite symposium, then the Member may pay the travel expenses and any accommodation and meal costs associated with the faculty's attendance at the satellite meeting.

If the faculty attends the Third Party Educational Event associated with the satellite symposium, 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 and any accommodation and meal costs directly associated with the satellite symposium.



17. Can a Member pay the expenses of individual HCPs to attend a satellite symposium?

If an HCP is already attending a Third Party Educational Event, Members may pay the additional local travel expenses and associated accommodation and meal costs of HCPs to attend the satellite symposium.

TRAVEL AND LOGISTICS ARRANGEMENTS

18. 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. For Third Party Educational Events on or after 1 January 2018, 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 the organiser of the Third Party Educational Event, Healthcare Institution, or Professional Association to support the attendance of HCPs at the Third Party Educational Event.

MEMBER-ORGANISED OR SUPPORTED MEDICAL TECHNOLOGY TRAINING AND EDUCATION

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

Yes. The revision to the Code only impact Third Party Educational Events. Refer to Section 4 of the Code.

20. Are Members permitted to organise training and education events in conjunction with Healthcare Institutions, and Professional Associations and select and meet the costs of attendance of HCPs at those events?

Yes. The revision to the Code only impact Third Party Educational Events. Refer to Section 4 of the Code.

21. 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 programmes organised by Members.

22. Are Members permitted to organise training and education events together with a Healthcare Institution utilising the facilities of the Healthcare Institution?

Yes. This is Member-organised training, which is permitted under Section 4 of the Code.

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

Yes. However, such events must be arranged and conducted in accordance with the letter and spirit of the Code; Members are not permitted to organise their own training and education events to, in effect, directly sponsor individual HCPs to Third Party Educational Events.

FURTHER INFORMATION

- 24. How can I find out more about the Code and the revisions to it?
 - In the first instance you should contact your legal/compliance team.
 - Over the coming months, APACMed will be releasing additional information concerning the Code revisions. Please visit the APACMed website (www.apacmed.org) for updates.