



Guidance On The Application Of The APACMed Code Of Ethical Conduct To Virtual Events

The APACMed mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.



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INTRODUCTION

The Covid-19 pandemic has led to the imposition of restrictions on travel and in-person gatherings around the world. These limits have affected many of the interactions at the core of our Members' businesses, involving stakeholders such as healthcare professionals (HCPs), hospitals, clinics and other customers, distributors and other third party sales and marketing intermediaries, patients, and others. Of necessity, many interactions involving product marketing, medical education, procedure training, proctoring, and more, have moved online.

Such "virtual" interactions include (i) chat communications using SMS, instant messaging or messaging applications (eg WeChat, WhatsApp, Line, Zalo), or (ii) video conferencing applications (eg Zoom, MS Teams). Virtual interactions can take the form of Member-organized webinars and other online training and educational programs that allow for the transmission of either live or recorded lectures and discussions and the display of written and video content. Third party educational conferences and congresses have moved online as well, using platforms that seek to replicate the "real world" experiences of large lectures, panel discussions, poster presentations, and exhibit halls and booths. Medical device training and proctorships that previously involved in-person, hands-on procedures are also taking advantage of technologies that allow for teachers and trainees to be in different locations, using video and data feeds between remote locations to allow for the necessary supervision and education.

These and other types of virtual interactions are becoming increasingly common and appear likely to continue after the current pandemic is under control.

This APACMed Guidance is intended to assist Members in ensuring that these virtual interactions comply with the letter and spirit of the APACMed Code of Ethical Conduct (the Code), with due consideration for other local codes and regulations. This Guidance does not change the Code or the Code's FAQs. Members are expected to apply the Code to their respective dealings and interactions with HCPs and healthcare organizations (HCOs). The Guidance does, however, highlight issues that Members should consider in applying the Code to these online activities.

APPLICATION OF OTHER CODES AND REGULATIONS

The Code specifies that “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.” This principle of overlapping codes and laws, and the requirement to follow the most restrictive rule applicable to a given situation, applies fully to virtual events.

Members should consider that the cross-border nature of many virtual events may complicate the question of what rules apply to a given interaction. For example, determining what rules apply to an online product detailing meeting with a small group of HCPs in a single city may be relatively straightforward, requiring consideration of the Code and any other codes and laws applicable in the country where all of the participants in the activity reside.

But for a cross-border educational webinar with speakers and attendees located in multiple countries, the analysis may be considerably more complicated. In the case of such cross-border virtual events, Members should consider the applicability of codes and laws in all countries where participants will be located. In the event that rules from different jurisdictions conflict or appear to impose inconsistent obligations or requirements, Members should consult with legal counsel and other experts for guidance on the most appropriate course of conduct.

GENERAL PRINCIPLES APPLICABLE TO VIRTUAL EDUCATIONAL EVENTS

As noted above, the Code applies in full to virtual events just as to events conducted face-to-face. Some aspects of virtual events, however, including those mentioned below, involve issues that merit special consideration. This Guidance is intended to raise issues for Members to consider as they organize or participate in virtual events. For any specific events or interactions, each Member should make its best choices, guided at all times by the Code's requirement that "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." (Code Section 1.2).

Regulatory framework for virtual events

Members should consider the application to virtual events of restrictions on the marketing of medical devices in countries where they have not been approved for sale. Where a product has been approved for different uses in different markets, considerations of off-label promotion can also arise in cross-border programs.

For events involving participants from multiple countries, Members should consider whether disclaimers or warnings about unapproved products or uses are appropriate. In addition, Members should consider whether some country regulations might make it inappropriate to permit HCPs from those countries to attend a program.

Data privacy considerations

Nearly all countries now have some form of data privacy legislation or regulation governing the collection, processing, use, disclosure, transfer, storage, and disposal of personal information. Such laws may impose obligations on Members or service providers supporting virtual events to obtain consents from HCPs and other attendees to use their personal information for educational, marketing, or other purposes. For cross-border events, Members may want to consider whether conflicting requirements in different countries require different disclosure and data handling processes for different participants. Other data privacy standards should also be considered and followed.

Engagements of HCPs to perform services in connection with virtual events

Section 2 of the Code (Consultancy agreements) applies with full effect to engagements of HCPs to provide services in connection with virtual events. The qualifications of HCP service providers should be commensurate with the services to be provided and the number of HCPs engaged should be no more than is reasonably necessary. For panel discussions with multiple speakers and chairs or moderators, the amount of time spent by each participant actively participating in the discussion would be a factor in assessing the reasonableness of the number of service providers.

Fair market value for HCP services

As with any in-person service arrangement, compensation should be limited to the fair market value for the services provided in the jurisdiction in which the HCP regularly conducts their practice, irrespective of where the consulting service takes place. HCP service providers may be compensated for actual time performing services and for time reasonably spent preparing to perform those services. As noted above, all arrangements should ultimately be judged against the Code's overarching commitment to Member interactions with HCPs being held to the highest ethical standards, preserving HCP independence, and reinforcing public confidence in the integrity of patient care, treatment, and product and service selection.

Controlling access to virtual events

Members and other organizers of virtual events should consider whether the technologies and platforms used allow for sufficient control over access to the programs and verification that those attending are allowed to participate. Member employees should refrain from joining competitor virtual events without explicit permission.

Recording of events

Before recording any virtual event for future playback or distribution, Members should consider the need for disclosures to participants, obtaining consent, and appropriate privacy protections. Heightened care should be taken before recording any program involving disclosure or discussion of patient records or procedures

Provision of meals to participants in virtual events

Members may provide reasonable hospitality for participants in virtual events, subject to any restrictions in local codes and regulations. Any such hospitality should be timed to coincide with the virtual program. It will generally be more appropriate to provide meals to groups of HCPs gathered together at a location to participate in the virtual event than to send meals to individual HCPs, although hospitality for individuals may be appropriate under exceptional circumstances. Members should develop procedures to track the delivery of HCP meals and confirm attendance of the HCPs at the virtual program.

The delivery of meals to HCPs at home and the use of prepaid vouchers or meal cards will rarely if ever be appropriate, and is strongly discouraged.

PRINCIPLES APPLICABLE TO VIRTUAL PROCEDURE TRAINING EVENTS

The Code permits and even encourages Members to provide procedure-based training for HCPs in the safe and effective use of their medical technologies. Code Section 4. The Code also recognizes that Member personnel can play important roles in providing technical support services relating to Member products in the clinical setting. Code Section 10. During this period of pandemic-related travel restrictions and limitations on access to hospitals and other clinical settings, the need has arisen to provide such training and technical support remotely, using virtual technologies.

The Code does not prohibit such long-distance, virtual training and technical support. Members should, however, carefully consider the strengths and limitations of virtual solutions in such applications. Issues to consider include:

Privacy and patient consent issues

Members should pay special attention to ensuring that they or their third party service providers (eg HCOs, HCPs, etc...) obtain informed consent from patients to a virtual treatment setup and to any collection, use, and transfer of patient personal and medical data.

Written agreements and liability considerations

Members should enter into written agreements with HCPs, HCO, and any third party service providers that detail the roles and responsibilities of each party in connection with virtual training and technical support activities. Such agreements should address the obligations of each party and any agreements as to allocation or limitation of liability on the part of any party.

Recordings

Members should ensure that the appropriate patient consent has been obtained in case medical procedures are recorded. Any storage, further use, distribution, or sharing of such recordings should be authorized in advance by the patient and other relevant stakeholders.

Internet connectivity and connection stability

Especially in any remote training or technical support case involving live patient care, extra care should be given to ensuring that any required Internet connection will have sufficient bandwidth and stability to minimize the likelihood that a remote trainer will be disconnected mid-procedure from the site with the trainee HCP and patient. Backup connection options should be considered. While less critical than during patient procedures, connectivity should also be considered in connection with non-patient training and support activities in order to avoid inefficiencies and wasted time.

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Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚太医疗技术协会) is the 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 convergence.

Learn more about the association at www.apacmed.org



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