HKAPI Guidance on Virtual Engagements with HCPs

Effective from 1st December 2020

The COVID-19 pandemic has led to new ways of working for biopharmaceutical companies, which have replaced in-office visits and face-to face congresses with virtual engagements to maintain dialogue and scientific exchange with the medical community while protecting the health and safety of patients, healthcare professionals and their own employees. Even as economies open, it is anticipated that virtual engagements will continue.

It is important for member companies to maintain high standard of integrity and compliance during virtual engagements. Therefore, HKAPI is providing additional guidance on virtual engagements with HCPs, including hospitality for "Virtual Events" (defined hereinafter under Section 1.1 of this guidance) as well as the dissemination of promotional materials and scientific information (non-promotional) through electronic tools.

Member companies should adhere to the requirements established by their own companies and HKAPI Code of Practice (hereinafter, the "Code"). Unless otherwise defined under this guidance, capitalized words in this guidance shall have the meaning attributed to the in the Code. In the event of a conflict between the provisions of company requirements, the Code, and this guidance, the more restrictive of the conflicting provisions should apply.

Purpose

The purpose of this guidance is to provide additional interpretation in relation to the relevant provisions of the Code. This guidance must be read with the spirit of the Code in mind and always in accordance with applicable laws and regulations. The intention of the guidance is for the interactions between member companies and HCPs to always be based on high ethical standards.

Guidance

1. Hospitality Provided at Virtual Events

1.1. "Virtual Event(s)" refers to sponsored Events (as defined by Section 5.1 of the Code) or company-initiated Events organized in the format when participants and speakers (when applicable) are present in different physical locations and utilize audio and/or video to communicate online, allowing the individuals to share data and information in real-time.

1.2. Hospitality (as defined by Section 5.3(f) of the Code) can be provided to HCPs attending a Virtual Event individually only in the presence of a member company staff (whether physically or virtually). Maximum at HKD200 (excluding service and delivery charges) per person per meal and the meal should be delivered to the HCP's workplace (i.e. clinics or hospitals).

1.3. Hospitality during sales calls, detailing and/or scientific information exchanges conducted in the virtual format is disallowed.

1.4. Hospitality should not be provided to HCPs at their own home or outside the workplace.

1.5. Other than those mentioned above, all other types of engagement with HCPs could be assimilated to a face-to-face meeting and shall follow Section 5 and Appendix 2 of the Code.

2. Promotional Materials and Scientific Information (Non-Promotional) Provided via Electronic Tools

2.1. Member companies may provide promotional materials and scientific information (non-promotional) to HCPs via electronic tools only when these are complied with the relevant sections of the Code, including but not limited to Section 4 and Section 5.1(c) of the Code.

2.2. Member companies should establish processes and controls to:

2.2.1. Verify HCP identification to ensure that digital materials will be provided to the specific recipients (refer to Section 4.4 of the Code);

2.2.2. Obtain necessary consent from the recipients before sending digital materials;

2.2.3. Offer opt-out right to recipients;

For Virtual Events:

2.2.4. Verify HCP identification at Event registration; and

2.2.5. Clearly state any product promotional materials apply to Hong Kong only and inform HCPs to refer to the prescribing information from their home country/location as this may vary depending on local approvals in each country/location.

2.3. Where the intended recipients of the relevant materials or target audience or participants of the Virtual Events involve non-local HCPs, the Joint Guidance on Virtual International Medical Congresses impacted by COVID-19 in the Annexure shall apply.

2.4. Member companies should ensure that any personal data collected, processed, used or stored for the virtual engagements must comply with all applicable laws and regulations on data protection, including but not limited to the Personal Data (Privacy) Ordinance (Cap 486).

Annexure

Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19

https://www.ifpma.org/wp-content/uploads/2020/07/COVID_eBIC-guidance_Virtual-International-Congresses.pdf

Joint Guidance on

Virtual International Medical Congresses Impacted by COVID-19

by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA)

The COVID-19 pandemic has led to new ways of working for biopharmaceutical companies, which have replaced in-office visits and face-to face congresses with virtual engagements to maintain dialogue and scientific exchange with the medical community while protecting the health and safety of patients, healthcare professionals and their own employees. Even as economies open, it is anticipated that virtual meetings and congresses will continue.

The IFPMA's Ethos and Code of Practice set global standards for industry business practices, which must be maintained in the virtual setting. In response to Company and Association questions, IFPMA, EFPIA and PhRMA are issuing this guidance on Virtual International Medical Congresses impacted by COVID-19, which will be in effect until December 31, 2020. This provisional guidance may be amended to take into consideration experience in the coming weeks/months. Companies should adhere to the requirements established by their country's applicable laws, regulations, or industry codes of practice. In the event of a conflict between the provisions of the applicable laws, regulations, and codes, the more restrictive of the conflicting provisions should apply.

Scope of the Guidance

This guidance applies to all International Congresses organized by medical associations/societies involving HCPs from multiple countries, and activities organized by Companies at these congresses (e.g. exhibition stands, satellite symposia, poster sessions) that have been moved to a purely virtual format, and that are taking place between July 1 and Dec 31, 2020. The document additionally provides considerations for International Congresses scheduled after December 31, 2020. Specifically, this guidance sets out factors IFPMA/EFPIA/PhRMA member companies and non-member companies who are signatories to the PhRMA, IFPMA, or EFPIA Codes (collectively, "Companies") should consider when determining which code and/or label to use as reference for the Company activities at such Virtual International Congresses. All other congresses, such as national congresses organized by medical associations/societies in one country with a focus on HCPs from that country, company-organized meetings, etc. are excluded from the scope of this guidance.

Purpose of the Guidance

The pharmaceutical industry supports a wide range of local, national, and international meetings, organized by third parties, providing funding to assist in the medical education of HCPs, sponsorships to medical societies organizing events, hiring of exhibition space, support of speakers, etc. These activities are covered by Article 7 (Events and Meetings) of the IFPMA Code, Article 10 of the EFPIA Code and Articles 4, 5 and 7 of the PhRMA Code. While these requirements were originally drafted for in-person meetings, they apply similarly to virtual meetings and require that support and attendance be based on the event's educational value, considering the educational program, overall cost, nature of the audience, and cybersecurity and privacy arrangements, with attention paid to the overall impression given by all the various arrangements. Companies might find it helpful to clearly document their reasons for supporting events, including Virtual International Congresses.

IFPMA, EFPIA and PhRMA code provisions also cover the appropriate communication of promotional information during International Congresses, deferring to host country regulations in instances where medicine is not approved in the host country or not approved in the country of a participating HCP. In the context of virtual meetings, the notion of host country is no longer applicable, and this guidance seeks to replicate the Codes' pragmatic approach in the virtual format. This guidance aims to inform other stakeholders such as medical associations/societies, third party organizers etc. about the arrangements Companies should fulfil in a virtual setting. Companies should also ensure they are aware of guidance issued by medical associations/societies etc. on organizing Virtual International Congresses.

Guidance

Short-term (until December 31, 2020)

Activities organized by a Company (e.g. exhibition stands, satellite symposia, poster sessions) associated with a Virtual International Medical Congress should comply with the following requirements:

- Given the global scope of the IFPMA Code, Companies are expected to use the IFPMA Code as the minimum standard. The EFPIA and PhRMA Codes reflect the principles and rules of the IFPMA Code and should be considered in conjunction with the IFPMA Code when the meeting is hosted by a European or American medical association.
- Companies should consider the code from the region from which the majority of delegates would be expected to come based on past experience. When there is no regional code, the IFPMA code applies. This particular code may be referred to for adjudication purposes, as may the code from where the individual attendees come from. When considering the distribution or display of promotional material at International Congresses and assuming the majority of delegates are expected to be from the US or Europe, Member Companies should consider the US and European label for the products being promoted.
- It is important for Companies to clearly state the label by which promotional materials were developed, to avoid any possible confusion. The promotional material must be accompanied by a statement indicating the countries in which the medicinal product is registered, and by an explanatory statement indicating that registration conditions differ internationally. Additionally, the statement should be prominently displayed (e.g. via a pop-up box or alternative display) informing delegates to refer to prescribing information from their home country as information may be different for each country (see Explanatory Statements/Disclaimer examples).
- Companies should ensure that a process is in place to confirm participants' status as HCPs/Non-HCPs (patient advocates, journalists, industry representatives, etc.). It is expected that they will work with the medical association to ensure that the congress' virtual platforms allow for participant categorization, and to work with the medical association/society (congress owner) to make reasonable efforts to restrict access to promotional material to HCPs only, where required by applicable rules and regulations. Where the medical association's platform does not have a categorization capability, Companies should consider alternative mechanisms to enable attendee classification for their promotional events.
- Congress attendees should sign a digital consent indicating awareness/acknowledging Virtual Congress terms and conditions, such as specific permission to access different virtual areas (lectures, commercial expositions, social engagement sites, the basis of promotional material development, etc.). Even if this is the responsibility of the medical association/society, Companies need to be aware of the content of these kinds of Explanatory Statements/ Disclaimers.

Mid- to long-term (post 2020)

Companies should explore putting in place systems to appropriately address the situation where HCPs view materials from countries other than their own. Of particular concern is potential promotion directed to people not qualified to receive such content and promotion of unlicensed medicines and/or indications. Companies should use the lessons learned from the July to December 2020 period to develop ways to address the concerns in a pragmatic manner together with medical associations/ societies. A Company sponsoring/collaborating with a booth at the virtual exhibition area should be able to identify those wishing to view its booth (HCP or Non-HCP) and therefore determine what information will be appropriate. Companies and medical associations/ societies (congress owners) are strongly encouraged to work together to share experiences and where possible jointly develop standards for all to follow.

Explanatory statements/Disclaimers

As stated above, Companies should include a statement explaining to delegates when entering their virtual booth/exhibition to help them understand the context by which the material was developed and to highlight that the content may not be applicable to their country.

Examples include:

- "You are viewing an International Virtual Congress run by [society name] and provided to international HCPs from around the world. Please note that prescribing information provided here may vary depending on local approval in each country. For purposes of [congress name], best efforts were undertaken by [society name] and congress sponsors to ensure compliance with [relevant code], however, you should review your local prescribing information and consult directly the local affiliate of the relevant Company to address any questions."
- "The materials for [PRODUCT(S)] contained in this virtual exhibition are approved for use only in [COUNTRY]. Prescribing information may vary depending on local approval in each country. Therefore, before prescribing any product, always refer to local materials such as the prescribing information and/or the Summary of Product Characteristics (SPC)."

Definitions

- For purposes of this guidance an **International (Medical) Congress** is a scientific meeting organized by a medical association/society etc. for their members with the opportunity for industry to participate in the form of exhibition (medical and commercial), satellite symposia etc. The medical association/society is the owner of the congress and responsible for attendee management, access, and other relevant criteria, e.g. the scientific agenda. The Congress gathers a multinational group of medical experts and professionals with the objective to increase the knowledge about and expertise in a disease state and treatment, to facilitate exchange and ultimately to advance patient care. The delegates usually comprise of HCPs, researchers and other individuals who work in the healthcare and/or research environment.
- A **Virtual International (Medical) Congress** is an International Congress where all activities are virtual/digital without an in-person event linked to it. Companies have the opportunity to participate in the form of virtual exhibition stands as well as virtual satellite symposia.
- **Exhibition Stands** are areas in the context of an International Congress where pharmaceutical companies (and other organizations) can display their product material to delegates in the commercial booth and their scientific material in the medical exhibition area.
- A **Satellite symposium** is a Company activity which occurs immediately prior, during or immediately after the main scientific program in the context of an International Congress.
- A **Healthcare Professional** (HCP) means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.