European Federation of Pharmaceutical Industries and Associations

EFPIA Code of practice: ethical guidance in light of COVID-19

EFPIA and its members are fully committed to EFPIA Code requirements in the context of COVID-19. We continue to implement and apply the highest ethical standards and we comply with applicable laws and regulations such as competition, data protection, anti-bribery and anticorruption legislation.

When EFPIA and its members have to take urgent decisions (for example, in the context of a crisis and/or without any existing guidance), it is strongly recommended to assess these decisions with regards to the following EFPIA key ethical principles:

- **Patients first**
- **Integrity**
- **Respect**
- **Transparency**

The present document aims to remind the rules applicable to specific interactions occurring in the current environment.
This guidance could be amended to take into consideration concrete experiences occurring in the coming weeks/months.

1. Transposition of the new EFPIA Code provisions introduced during the consolidation

The EFPIA Code of Practice was agreed in 2019 with Member Associations asked to transpose the revised EFPIA Code provisions by 30 June 2020 and implement the EFPIA Code by no later than 31 December 2020. Member Associations started this work and although some have finished, others are still working on changes to their local codes.
In light of the COVID-19 Pandemic, Member Associations, which have not completed work on their national code, are asked to use their best efforts to implement the EFPIA Code and to inform the EFPIA secretariat of any delay in transposing or implementing the Code provisions.
Member Associations are expected to have transposed at the latest by 31 December 2020 and work to ensure that implementation is completed at the latest by 30 June 2021

2. Disclosure provisions (Articles 22-23-24 of the EFPIA Code of practice)

a. 2020 disclosure of 2019 ToV

Based on the current information and feedback received from some companies and associations, the disclosure period is not postponed and should happen between the 22nd and the 30th of June 2020.
Nevertheless, and due to the exceptional circumstances related to COVID-19 (including that it is inappropriate to contact the Healthcare Professionals and Healthcare Organisations to obtain consent), **Member Companies that cannot satisfy the requirements of the data protection regulations should disclose the data in aggregate and provide explanations for this aggregate disclosure in their methodological notes. EFPIA asks them to complete the disclosure with individual data when it will be possible.**

b. 2021 disclosure of 2020 data

Disclosure requirements remain unchanged, as a reminder each Transfer of Value made in 2020 with an identifiable recipient must be disclosed in June 2021 such as donations and grants, contributions to costs related to Events, fees for services.

c. Disclosure of ToVs related to Events cancelled

Even if an Event is cancelled, the Transfers of Value related to the Event must be disclosed if they can be attributed to a recipient. Planned Transfers of Value for educational support to Events should only be disclosed if a recipient received the benefit e.g. if Event was cancelled and no Transfer of Value occurred to an individual then no disclosure required, if an Event was converted from face to face to virtual and recipient will receive a Transfer of Value via a virtual registration that Transfer of Value must be disclosed.

d. Disclosure of registration fees for recorded Event (Section 23.05)

The registration fee for an Event, live and/or recorded, is a Transfer of Value that must be disclosed.

e. Methodological note

Member Companies must provide detailed explanations on the consequences of COVID-19 on the disclosure data in their methodological note.

3. Events and hospitality (Article 10 of the EFPIA Code of practice)

The rules applicable to the virtual Events[1] organized by a third-party are described in the Joint Guidance on Virtual International Medical Congresses impacted by COVID-19 in Annex.

Regarding the hospitality provided during virtual Events, Member Companies cannot provide hospitality for the Healthcare Professionals attending individually a virtual third-party organized Event.

Unless prohibited by local laws and regulations (including individual company's position), the hospitality provided to a group of Healthcare Professionals attending a virtual Event together could be assimilated to a face-to-face meeting.
Therefore, the rules applicable to Events and hospitality (Article 10) apply and the Member Companies must implement processes to ensure compliance with those rules.

[1] As defined in the EFPIA Code of practice – Definitions section

Annex:
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 pharmaceutic