



IFPMA/EFPIA/PhRMA Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19: Questions & Answers (Q&A)

Introduction

This Q&A document offers assistance in interpreting the IFPMA, EFPIA and PhRMA joint guidance on Virtual International Medical Congresses. The questions included are based on those received by the IFPMA during and following a Webinar Session that took place in July 2020. 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.

This Note for Guidance Questions and Answers covers:

- The Scope of the IFPMA/EFPIA/PhRMA Guidance
- Determination of the Code and/or Label to use
- Working with Medical Societies
- Promotion
- Sponsoring HCPs to participate in a Virtual International Congress (i.e. registration)
- Working with Regulatory Agencies

The Scope of the IFPMA/EFPIA/PhRMA Guidance

1. Does the guidance also relate to hybrid meetings?

This guidance is specifically released for purely virtual meetings. Hybrid meetings should follow the principles of face-to-face meetings. If there is a virtual element to the congress, the guidance principles should be adhered to. Please note that for hybrid meetings, the 'host-country' code (as per face-to-face congress) and label is applicable. Therefore, companies can apply them in the development of materials or communications.

2. Should we extrapolate the guidance to virtual international webinars or e-learning organized by pharmaceutical companies?

Company-organized virtual meetings are excluded from the scope of this guidance. Companies should refer to their internal processes for organizing such virtual meetings.

3. Should we extrapolate the guidance to national congresses where meetings are focused on HCPs from a single country?

National Congresses are outside the scope of this guidance.

4. Is there a different guidance for synchronized virtual congresses vs. on-demand virtual congresses (recorded)?

The guidance is covering live international virtual congresses and does not address recorded on demand virtual congresses. We will look into those congress profiles in the next revision of the guidance.

5. Can you elaborate on longer-term plans?

Companies need to start to consider ways by which an HCP can be restricted to materials specifically related to his/her home country. Whilst pharmaceutical companies generally do not have the ability to restrict access to their booth during face-to-face meetings, the advantage of digital platforms is that such technology may be able to facilitate a restriction to access of foreign materials. It is expected that such technology cannot be arranged in the short term but we hope that in 2021, with the help from medical societies, such systems can be established. IFPMA, EFPIA and PhRMA are eager to hear feedback from member companies on the progress of such a mechanism.

Determination of the Code and/or Label to use

6. If a European medical society holds a congress which is a truly international meeting with historically more than 40% of delegates being from outside of Europe, would it be acceptable to share information about a product indication which is not approved in Europe, but is approved in, for example, North America and Japan?

The historical context of the meeting is important in determining which regional code to follow and which label to use. If the meeting normally only takes place in Europe, the audience of the meeting is intended to be European and the EFPIA Code and EMA label applies. However, if the medical society often holds the meetings outside of Europe, the meeting can be considered truly international in nature. In such circumstances, the IFPMA Code applies and the EMA and/or US label may be more applicable.

It is critical that the company clearly indicates which label has been used for the development of promotional materials and has a disclaimer indicating that registration conditions differ internationally and that HCPs should be referred to prescribing information from their country of practice, as information may be different for each country.

7. Some US congresses, such as ASCO, do have many delegates coming from overseas and it may mean that there are more European delegates than US delegates. Should these congresses be considered international or European?

Current IFPMA and EFPIA guidelines on 'Sponsoring Events' state that the location of the event should be appropriate with respect to the geographical scope of the event. As such, a European congress should be targeting mostly European HCPs and therefore should not be housed outside of Europe. Given this information and considering US medical societies, like ASCO, are primarily targeting their constituents who are based in the US, the guidance for the virtual event is that the PhRMA Code applies even if more delegates are expected from outside the US.

8. Does the location of the server where any webinars or webcasts are hosted determine the Code or label to be used? (e.g. do we need to consider US Code/label if the server is based in the US but the majority of "viewers" are based in Europe?)

For purely international virtual congresses, the location of the server does not play a role in the selection of the Code that companies will refer to in the development and review of materials. Companies should refer to the Code from the region where the majority of delegates would be expected based on past experience (if no regional code, IFPMA Code applies).

9. The medical society states that they are following the laws of a particular country. Should we not also use the label from that country?

Often the medical society describes their jurisdiction in relation to the commercial handling of the congress from a legal perspective rather than in relation to the scientific & medical content contained or communicated through their site. It is recommended that you check with the medical society the context of the jurisdiction.

Whilst you can consider this as part of your justification in using a particular label or in developing promotional materials, the medical society cannot tell the company which laws or codes to adopt in developing materials. The responsibility and accountability for this must be with the pharmaceutical company. Companies need to consider the historical delegation demographics of the congress and the regulatory status of the products. Companies will need to be able to provide upon request a document justifying their approach to the congress.

10. Was the approach for referring to the EU or US label aligned with regulatory authorities in countries outside of the EU and US, where some of the major medical societies have their seat (e.g. Switzerland, UK)?

The IFPMA working group included representatives from both companies and associations including national associations. However, the guidance was not endorsed or necessarily supported by any regulatory authorities. The guidance was developed to offer companies a minimum standard to follow both from a short-term and long-term approach. Many national associations would prefer companies to restrict entry into company sections of the medical society's site. However, given the technical and complex nature of 'geofencing' this has been included in the guidance as a mid to long-term goal.

Working with Medical Societies

11. How does our company control whether the medical society issues disclaimer(s) or the wording of the disclaimer(s)?

Companies cannot control a medical society's disclaimer and at the time of formalizing the sponsorship, the exact wording of the disclaimer may not be available. However, companies have a duty to ensure that an appropriate disclaimer will be put in place prior to agreeing to sponsor the event or setting up a virtual booth. We suggest you contact the Industry Board of the congress, IPCAA or the medical society directly and offer some wording in line with guidance, explaining that most, if not all, pharmaceutical companies will be expecting wording towards that effect. If you cannot be assured that the relevant disclaimers will be in place by the medical society, you have consider whether it is appropriate to sponsor the meeting.

Please note: each company should be able to develop their own specific wording for a disclaimer upon entering their dedicated company page or company organized virtual symposia within the virtual congress (e.g. virtual booth).

12. What are obligations to ensure privacy within the medical society is maintained? A number of medical societies are selling their detailed delegate list to sponsors. What happens if companies sponsor HCPs and register the HCPs on their behalf?

The obligations around privacy do not differ between virtual meetings and face-to-face meetings. Companies need to ensure that when registering HCPs themselves, they counsel HCPs of the terms and conditions. Companies also have an obligation to check that information around privacy will be included on the congress website so that HCPs are aware of the privacy implications upon entering the site. It is the medical society's ultimate responsibility to adhere to the privacy obligations of the country they are operating in and that they are clear to the HCPs as to what they are doing with their personal information.

13. Is it sufficient to have delegate click a checkbox confirming he/she is an HCP, or must the delegate provide additional information (name, country, professional affiliation, etc.)?

When a delegate enters a company area where promotional information is provided, there should be a clear disclaimer of what is presented. To confirm a delegate is an HCP, it is sufficient to use a mechanism such as a checkbox or by clicking a confirmatory link to the company's content. Thereby he/she accepts the shared responsibility that he/she will only access what he/she is supposed to see. An additional statement through which the HCP is informed on the registration status of the product/indication is also advised.

Promotion

14. I thought that at an International Congress level, promotion could occur if the main target audience are Healthcare Professionals as it is generally accepted that some of the audience who are non-HCPs are still considered experts. Are we saying that that does not apply in a virtual setting?

The guidance offered follows the same principles as face-to-face meetings. There are principles provided on what a company can present to HCPs or non-HCPs. Where promotion to non-HCPs is prohibited, companies having a promotional symposium must make every effort to ensure that only HCPs can attend (e.g. having a disclaimer and a pop-up box where the attendee has to confirm his/her HCP status).

15. Is it acceptable to use a 'chat-function' to answer HCPs' questions and can pharmaceutical companies only answer logistical questions?

Yes. Such a chat-function should preferably be restricted to a 1:1 interaction between the HCP and the company representative. It is important, when responding to questions in a chat-function, that you determine the HCP's country of practice so that you can provide relevant information from the label of that country. You should also determine the context of the question (scientific, commercial, research etc.) so that you provide only a response to the specific request. Ideally, the company should refer the matter to the appropriate in-house expert.

Please note: responses to questions in a chat-function should follow the same principles as what takes place in face-to-face congresses (e.g. functions, transparency, label etc.).

16. Can products not approved in Europe (e.g. US approval only) be promoted in a European medical society meeting if access is only limited to HCPs from the country where the product is registered, such as through geofencing?

The guidance has not focused on this scenario given that the technology is not readily available or used by societies. However, the medium to long-term approach is to restrict access to materials or communications to HCPs where that product is approved through channels like geofencing. If the medical society or the company has the ability to restrict access to specific HCPs then this is consistent with the guidance.

17. How should the virtual platform separate investigational and disease inquiries from marketed product inquiries?

As a minimum, disclaimers should be applied. Where possible, you can ask the HCP to categorize the query (e.g. through selection of a dropdown menu) prior to responding to the question.

18. Can brands be mentioned before each session begins if there is no segregation for promo like a virtual booth area?

As in face-to-face meetings, it is important to clearly indicate to the delegate what information is promotional and what is non-promotional. A medical/scientific session should not be associated with promotion of any product. When discussing brand information, you must follow the relevant code provisions for promotion.

19. What about color-coding scientific/promotional/'social area'?

The use of color branding should follow the relevant country code's provision for promotional activities. For non-promotional sites/areas, branding colors should not be used to avoid the perceived promotion.

Sponsoring HCPs to participate in a Virtual International Congress (i.e. registration)

All questions around sponsoring HCPs to participate in a Virtual International Congress are subject to company policies and procedures. As basic standards for sponsoring HCPs to attend a congress are not changing, please refer to your company's policies and procedures. The following questions and answers serve as a guide only.

20. If we are sponsoring an HCP to virtually attend a congress (e.g. registration), how can we ensure the HCP is aware of the various congress disclaimers at registration?

The onus is on the company to ensure the HCP is aware of the conditions of entering the virtual congress. Specifically, that there are elements of the site that may contain promotional messages from sponsored companies and that some information may not be applicable for his/her home country.

If registering the HCP, you can include the various details of the congress in the documentation you provide at the time of formalizing the arrangement. One suggestion is to take screenshots of the congress site (ideally with the login details) and share them with the HCP upfront so that he/she is aware.

Please note: there will be other disclaimers for various subsections of the congress site, but HCPs will need to click and confirm their acceptance at their own discretion. You can also ensure that the medical society includes the relevant disclaimer(s) upon the HCP connecting to the congress virtually.

21. Is it expected that we, as a sponsor, control the access of HCPs to virtual congresses? This may be challenging, as HCPs tend to pass their login credentials to other HCPs.

If a company is sponsoring the HCP to attend a virtual meeting (e.g. through paying for registration) and is coordinating all the paperwork, there is a responsibility of the company to alert the HCP of the appropriate disclaimers, including privacy information, prior to registering the HCP. This should preferably occur at the contracting stage or when providing the HCP with the login details. However, ultimately, the responsibility of protecting the personal information data remains with the medical society. For this reason, it is vital that the medical society lists the appropriate disclaimers when the delegate is entering the virtual meeting site.

If the HCP shares his/her login details with other HCPs he/she does so independently from the sponsoring company and he/she is liable to a complaint from the medical society rather than the sponsoring company, in the same way as he/she is responsible himself/herself should he/she register independently of the pharmaceutical company. Companies should inform the HCP that the registration is personal and should not be forwarded to other people.

22. If a company is sponsoring an HCP to virtually attend a congress, how could the company properly evidence that the HCP attended the virtual congress? This may be important for transparency reporting.

The guidance suggested at this stage is offered only in regard to organizing communications/materials when sponsoring purely international virtual congresses. Registration fees paid for by the pharmaceutical company are possibly subject to transparency reporting depending on the country in which the HCP practices.

Each company will need to determine the level of documentation they require when sponsoring individual delegates to attend the virtual event. We note that the same question would relate to face-to-face meetings.

23. What is meant by the congress attendees signing a “digital consent indicating awareness of the Virtual Congress Terms and Conditions” given that companies may register the HCP themselves?

This is a mechanism by which the HCP confirms and acknowledges the functionality, structure and areas of the congress site. It ensures the HCP appreciates that there are elements of the site that may contain promotional messages from sponsored companies and that some information may not be applicable for his/her home country.

Working with Regulatory Agencies

24. Is the expectation that no specific local law/jurisdiction will also apply to fully virtual congress activities or promotions?

Adjudications may be country-specific based on the code from the country in which the individual delegate practices so a company must be able to withstand scrutiny upon questioning. Companies need to document their justification for determining which code and label they use. The IFPMA/EFPIA/PhRMA codes are the minimum ethical standards companies need to follow.

25. Will the UK's ABPI Code apply in addition to the regional code if an HCP from the UK attends a virtual meeting outside the UK?

The guidance issued is the minimum standard by which companies should comply when sponsoring purely international virtual congresses. Companies will still need to consider local codes, as complaints will most likely be heard by the local association. Each company will need to be able to provide, upon request, a document justifying their approach to the congress, much in the same way, as they would need to justify their position in a face-to-face meeting.

References & Further Information

[IFPMA Code of Practice](#)

[Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19](#)

[Virtual International Medical Congresses – Case Study](#)

[Virtual International Medical Congresses - Webinar Slide deck](#)

[Virtual International Medical Congresses – Webinar recording](#)

[IFPMA Note for Guidance on Sponsorship of Events and Meetings](#)