IFPMA/EFPIA/PhRMA Joint Guidance on Virtual and Hybrid International Medical Congresses: 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. 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 Q&A 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. **Should we extrapolate the guidance to virtual international webinars or e-learnings organized by pharmaceutical companies?**

   No. Companies should refer to their internal processes for organizing such virtual meetings.

2. **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.

3. **Can you elaborate on longer-term plans?**

   Companies need to start to consider ways by which access to materials can be restricted as appropriate based on the home country of the HCP. 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.

4. **Does this guidance relate to pharmaceutical company-personnel or agencies working on behalf of a pharmaceutical company attending the congress?**

No. Such attendees, whilst not HCPs, have a critical role within the pharmaceutical company and have a need to attend.

5. **Does this Guidance relate to a company generating its own virtual symposium at the back of an International Congress where it is not included in the Congress' agenda?**

No. If not part of the official program, the company must ensure it adheres to the normal rules associated with hosting an event in the same way as a company-initiated event.

6. **Can a company generate its own microsite associated with the Congress?**

A company can initiate its own microsite but the following important principles should be considered:

- The congress society should explicitly offer and support this set-up.
- The company should obtain consent from the congress society that there will be a direct link from their congress platform to the company congress site (and a direct link back to the official congress platform) and that the company's microsite is an extension (still part) of the official society's congress platform.
- The Company should clearly designate their site as part of the relevant virtual congress (with society's consent and ideally with congress logo) but in doing so, the company should indicate to participants that this is a company operated congress site (e.g. pop-up check-box before entering our own site).
- Only HCPs who have registered for the Society's congress linked to the microsite can access the company's microsite and only via the official virtual congress platform**.**
- The company's microsite should only be accessible via the official virtual congress platform and not be searchable on the WWW.
- The Company should apply dedicated terms of use for their microsite (including applicable label, disclaimers, data privacy etc.).

<u>Determination of the Code and/or Label to use</u>

7. **Some US congresses, such as ASCO, 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 engage with the medical society on the rationale for their stated 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.

11. **If the only live (face-to-face) part of a congress only involves the speakers or Congress faculty does the jurisdiction still apply to the location of the live meeting?**

No. In such circumstances, the meeting would be treated as a completely virtual meeting and therefore, the appropriate Code and label will depend upon the jurisdiction of the majority of the delegates who are all attending virtually.

12. **If the company is only participating in the live (face-to-face) part of a hybrid meeting can we select the jurisdiction based on the location of the majority of delegates attending virtually or live?**

No. In such circumstances, the jurisdiction would be where the live meeting is taking place.

13. **If the company is only participating in the virtual part of a hybrid congress, which jurisdiction applies?**

The jurisdiction would be where the live meeting is taking place.

14. If presentations are running across multiple live hubs, which jurisdiction should be used?

The jurisdiction is the country where the hub is occurring at the time zone most convenient for delegates (i.e. what would be considered a normal working day of 9am to 5pm).

Working with Medical Societies

15. 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 should 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, 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).

16. 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 should ensure that when registering HCPs themselves, they counsel HCPs of the terms and conditions. Companies also should 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.

17. 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

18. I thought that at an International Congress level, promotion could occur if the main target audience are HCPs 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).

19. 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.).

20. 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.

21. 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.

22. 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.

23. Is it ok to include photos of a city where the congress had planned to take place if the meeting is now fully virtual?

As the jurisdiction could be determined to be a country different to originally planned, to avoid confusion, it is best that no photos of cities should be included in the material. The focus of any event should be the education and not the city.

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.

24. 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. Possible options include and are not limited to taking screenshots of the congress site (ideally with the login details) and sharing them with the HCP upfront or verbal / written briefing of the details so that they are 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.

25. Is it expected that we, as a sponsor, control the access of HCPs to virtual congresses?

Sponsors should exercise due caution by including reminders of obligations and onus of HCP through contracting stage or when providing login details that this virtual congress is intended only for the specific HCP and not others.

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 their login details with other HCPs they do so independently from the sponsoring company and they are liable to a complaint from the medical society rather than the sponsoring company, in the same way as they are responsible themselves should they register independently of the pharmaceutical company. Companies should inform the HCP that the registration is personal and should not be forwarded to other people.

26. 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.

27. 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

28. 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. As an example, for HCPs practising in the UK the ABPI Code will apply regardless if the congress will take place virtually or live outside the UK.

29. How does this Note for guidance align with the local codes?

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 may 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 consistent with the requirements of their local association.

References & Further Information

IFPMA Code of Practice

IFPMA Note for Guidance on Sponsorship of Events and Meetings