Breakout Session Scenarios

# IPCAA 2015 Seminar on Compliance, Zurich

## Scenario 1 Working Together

A major European medical conference is planned for May 2016. Your group is meeting to plan the arrangements for healthcare company participation. You must consider perspectives from medical societies, Pharma, Medical device companies and conference organising companies. You have the task to ensure that all necessary arrangements are made so that all parties work together to ensure a compliant and worthwhile conference. You should feedback your thoughts and recommendations to the panel when all groups reconvene. The facilitator will tell you for which item your group will have particular responsibility in leading the discussion, Feel free to raise your questions or concerns with the expert panel!

## Meeting Agenda 1

1. **Venue:** The venue for the congress is the Barcelona conference centre . <http://www.ccib.es/home> . A compliance officer at Company A has commented that Barcelona in May would not be an acceptable destination which the company could sponsor delegates. She is also concerned that the conference website front page includes pictures of tourist attractions in Barcelona. Are these concerns shared by other companies? What resolution can you suggest?
2. **Hotel accommodation:** A range of hotel accommodation is offered through the congress website. The main conference hotel where faculty will be accommodated is the Hesperia Tower. Special discounted rates are also offered through a block booking which is being offered to companies for their delegates. <http://www.nh-hotels.com/hotel/hesperia-tower?nhagentid=10160&nhsubagentid=101600000000&oodc=30_97232&source=ysm&dclid=CPLm3dXKxcMCFcFffAodWCwAuA> . Discuss the acceptability of companies using this 5\* hotel for their sponsored delegates, speakers and company staff.
3. **Sponsorship opportunities:** The medical society organising the conference is preparing the prospectus for sponsorship opportunities for healthcare companies. Take a look at the offerings at the last congress 2 years ago. [2014 sponsorship brochure](#sponsorship). Are they all still acceptable?
4. **Delegate sponsorship:** The organisers are concerned that they can expect fewer registered delegates this year because of new restrictions on delegate sponsorship from some companies (including all medical device companies) and from some countries. They propose to set up a central fund to cover registration fees and costs of delegates. Companies who contribute to the fund will receive details of how to claim support that they can pass on to potential HCP beneficiaries. What does the group think of this proposal?
5. **Catering Arrangements:** Recognising that networking with colleagues is one of the aspects of the congress most appreciated by delegates a suggestion has been made that a limited number of networking lounges be set up at the conference centre and the main conference hotel. These would provide an area conducive to discussions with colleagues and would be open during the breaks in the meeting and in the evening before and after dinner. Light refreshments, coffee and a bar (in the evening) would be available. Is this something that companies could sponsor?
6. **Accompanying persons programme**: The medical society has always included a tourist programme for accompanying persons. There has also been the possibility for delegates to extend their stay to take sightseeing excursions after the close of the meeting. These possibilities are mentioned on the meeting website but in a quite separate area. An advisor says that these activities must be dropped if a red/orange flag from the conference vetting schemes is to be avoided. (see: [Ethicalmedtech](http://www.ethicalmedtech.eu/) and [E4Ethics](http://www.efpia-e4ethics.eu/Farma_EFPIA/index.htm)) What advice can you offer?
7. **Advisory Board**: A company is proposing to hold an advisory board meeting immediately after the congress, taking advantage of the presence at the meeting of several international opinion leaders. They hope to incorporate topics presented at the congress into the advisory board programme and would like to work in co-operation with the conference organisers. What practical advice can you give (particularly from a compliance view)?

2014 prospectus brochure – sponsorship opportunities (extract)

1. **Core funding - Gold sponsorship € 40,000 (+VAT)**

* Support for all conference activities acknowledged on website, on front page of full programme, in all main conference rooms and on menus at gala banquet.
* Acknowledgement in meeting chair’s opening address.

1. **MINI / POCKET PROGRAMME - € 5,000 (+VAT)**  
   • Distributed to all participants.  
   • Advertisement on the back cover (corporate or product)  
   • Sponsor’s logo on Congress website, on Sponsors’ Board on-site and in full programme
2. **CONGRESS ELECTRONIC NEWSLETTER € 12,000 (+VAT\*)**

* Four pre-meeting newsletters will be sent to all society members. The purpose is to promote the scientific programme and update delegates on Congress news.
* The sponsor will be acknowledged and a banner included which can be hyperlinked to a URL of the sponsor’s choice.

1. **CONGRESS BAGS € 5,000 (+VAT\*)**  
   • The bag can bear the sponsor’s logo and / or a product logo  
   • Sponsor’s logo on Congress website, on Sponsors’ Board on-site and in full programme
2. **CONGRESS OFFICIAL NOTEPAD WITH PEN € 10,000.- (+VAT\*)**  
   Sponsor will provide the participants’ Notepads and Pens which includes  
   information on the scientific programme.  
   • The Notepads and Pens may include the sponsor’s company/product logo on the cover and each page  
   • Sponsor’s logo on Congress website, on Sponsors’ Board on-site and in full programme
3. **WIFI & LAPTOP LOUNGE € 25,000 (+VAT\*)**

* An area with wireless Internet service for delegates. The company logo will be displayed prominently.
* Access code materials with sponsors logos
* Sponsor’s logo on Congress website, on Sponsors’ Board on-site and in full programme

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# Scenario 2

Your group is meeting to plan the arrangements with respect to transparency and disclosure for healthcare company participation in major European medical conference to be held in May 2016 in Berlin. The organising medical society has a European scope and is based in Brussels. Delegates and speakers will come from France, UK, Germany and other European countries. There will be some US based speakers. You must consider perspectives from medical societies and their members, delegates, Pharma, Medical device companies and conference organising companies. You have the task to ensure that all necessary arrangements are made so that all parties work together to ensure compliance with the European and US disclosure requirements. You should feedback your thoughts, questions and recommendations to the panel when all groups reconvene. The facilitator will tell you for which item your group will have particular responsibility in leading the discussion, Feel free to raise any questions or concerns about other aspects of disclosure requirements with the expert panel!

## Meeting Agenda 2

1. There is some uncertainty about which elements and activities associated with the congress must be disclosed as ‘transfers of value’. Consult the [EFPIA disclosure code](http://transparency.efpia.eu/the-efpia-code-2) and list all ‘transfer of value’ items that could be associated with an international congress; covering delegates and speakers.
2. The question has arisen about who will be responsible for making disclosures. The organising medical society wishes to know how they should advise members and delegates about their responsibilities – and whether as organisers they have any responsibilities themselves. They wonder whether data privacy legislation means that delegates can refuse to be named as beneficiaries. Would it be helpful for congress material to encourage full disclosure? Consult the [EFPIA disclosure code](http://transparency.efpia.eu/the-efpia-code-2) and please prepare a short advisory note on these matters.
3. A pharmaceutical company has asked that the organisers prepare a report in the format of [the EFPIA template](http://transparency.efpia.eu/EFPIA%20DISCLOSURE%20CODE%20Schedule%202%20Template%20-%2013%20Template.pdf) so that the money they are providing as a gold sponsor can be accurately reported. They also ask that unique identifying data for each HCP be collected as part of the registration process. Take a look at the template and suggest a response.
4. The suggestion has been made that all contracts and arrangements are made through the conference organising company which is supporting the medical society since this might simplify disclosure responsibilities. Give your view on this proposal.
5. A US based company has asked for help in fulfilling their disclosure requirements under the US Sunshine legislation. They also mentioned France (see [main requirements review](http://www.scribd.com/doc/145762184/Client-Alert-French-Sunshine-Act#scribd)  ; [Details of the French requirements](http://www.chcuk.co.uk/wp-content/uploads/2014/01/French-Transparency-Law-incorporating-changes-of-09Jan.2013.pdf) )as a country that has different requirements and also covers medical device companies. What is your recommended response and advice?

# Scenario 3

Your group is meeting immediately before a major international congress to be held in Amsterdam (the [Dutch Code can be consulted here](http://www.cgr.nl/CGR.nl/media/CGR.nl/Gedragscode/Code-of-Conduct-Pharmaceutical-Advertising.pdf)) to make last minute arrangements to ensure the meeting proceeds smoothly and in a compliant and ethical manner. You must consider perspectives from medical societies and their members, delegates, Pharma, Medical device companies and conference organising companies. A number of concerns and queries have arisen in the weeks running up to the conference and these form the agenda for your meeting. You should feedback your thoughts, questions and recommendations to the panel when all groups reconvene. The facilitator will tell you for which item your group will have particular responsibility in leading the discussion, Feel free to raise any questions or concerns about other aspects of disclosure requirements with the expert panel!

## Meeting Agenda 3

1. A company representative reports that, in discussions with the local regulatory authority official, they were advised that the local interpretation of the prohibition on advertising prescription medicines to the public could mean that entry to the commercial booth area must be prevented to all non-prescribers. They also commented that journalists and patient group representatives should be barred from entry to the company’s satellite symposium where data on an unlicensed medicine will be presented. Discuss this advice and suggest a practical way forward.
2. A company reports that during the stand build period they noticed that a competitor company had material which promoted an unlicensed medicine. They were also planning to run a prize quiz on their stand which they believed was not allowed under the local code. They have submitted a request that the congress organisers immediately put a stop to these activities. What is your suggested response?
3. Materials (Programme, abstract booklet) for distribution at an official satellite symposium have been submitted to the organisers and the concern has been raised that they are branded with an abstract product logo and the background is in a distinctive product related colour. One of the abstracts mentions the trade name of the product. The product is expected to receive marketing authorisation soon. What is your suggested response?
4. A large booth from a major car manufacturer is included in the exhibition area. Attractive models are present on the booth and a competition to win a motor racing experience weekend is being offered with free mugs to all entrants. A medical device company has complained to the organisers. Is this a valid complaint? Could the concern have been avoided in some way?
5. A pharmaceutical company has complained to the medical society organising the Congress that their sponsorship material did not give clear guidance on the relevant parts of the local Codes of Practice and local legislation and this has led to very different interpretations between companies on what is permitted in the exhibition hall and elsewhere in the exhibition centre. Do you think the medical society has a responsibility in this area? Discuss.