

# Third International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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**Track II: Interactive Case Studies in Navigating the Issues and Pitfalls of Sponsoring International Events, including Practical Considerations Relating to Local Country Approvals, Educational Grants, Involvement in Content, Sponsorship of Invitees, etc.**

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# Scenario

The Medical Affairs function in your Company's Global Headquarters wishes to sponsor a scientific educational program via a third party medical education provider. The event will be sole-sponsored by your Company and not be attached to any medical congress (i.e., a "stand-alone" event). The proposed venue is a European country. The speakers at the program are all clinical investigators and will be creating the content for their presentations, which will include investigational data related to your Company's marketed products. Your Medical Affairs function seeks your guidance to satisfy the following objectives: (1) ensure compliance with all applicable Company policies, country laws, and industry standards, (2) avoid unnecessary limitations of fair-balanced scientific dialogue, and (3) permit attendance from HCPs from as many countries as possible.

# Question 1

To meet the objectives for this event, would your Company sponsor the scientific event via an educational grant?

- A. Yes, this is the preferred method by my Company to ensure independence considering investigational data will be shared.
- B. No, unlike the US, European country standards do not generally distinguish "educational grants," and will apply the same standards to any Company-sponsored event (unless organized by an independent country university or medical institution).
- C. Not sure how my Company would handle this.

# Question 2

To meet the objectives for this event, would your Company require this event to be multi-sponsored?

- A. Yes, in order to ensure the least number of restrictions with various European countries, our Company chooses to conduct these scientific events with multiple sponsors
- B. No, my Company continues to conduct sole-sponsored scientific events and takes all necessary measures (including potentially limiting attendance from particular country HCPs) to comply with promotional standards of venue country and attendees' respective countries
- C. Not sure how my Company would handle this

# Question 3

Even though it is a scientific event in which the clinical investigator presenters create the content for their presentations, does your Company require local country promotional or medical review of the presentation materials?

- A. All Company scientific event presentation materials must be reviewed/approved by a global/regional promotional and / or medical review process, but not a local country promotional review process
- B. All Company scientific event presentation materials must be reviewed/approved by both a global/regional and local country promotional and / or medical review process
- C. Our Company does not review these presentations because it considers the content dictated independently by the clinical investigator presenters and the third party medical education provider
- D. Not sure how my Company would handle this

# Question 4

Does it matter whether your Company's product brand name or compound name is mentioned in the event agenda or materials?

- A. All Company scientific event agendas/materials do not include product brand names, but may include the product compound name
- B. Our Company avoids using Company product brand name and compound in any scientific event agenda/materials
- C. This will be determined by the local country standards of the venue where the scientific event is taking place
- D. Not sure how my Company would handle this

# Question 5

Does your Company permit sales and marketing associates to distribute invitations for scientific events such as this?

A. Yes

B. No

C. Not sure how my Company would handle this

# Question 6

Does your Company open attendance to this scientific event to anyone, or is it restricted to only those who are invited by your Company?

A. Open to anyone

B. Restricted to invitees only

C. Not sure how my Company would handle this



# Question 7

Does your Company permit country business units to sponsor (fund travel/lodging) for healthcare professionals to attend scientific events such as this?

- A. Yes, if in accordance with the local country laws and standards of the healthcare professional's country of origin
- B. Yes, if in accordance with the local country laws and standards of the **venue** country in which the event is taking place
- C. Yes, if in accordance with both the local country laws and standards of the healthcare professional's country of origin AND those of the venue country for the event
- D. No
- E. Not sure how my Company would handle this

# Question 8

Does your Company permit the presentation slides (i.e., enduring materials) to be provided to attendees of the scientific event?

- A. Yes, if in accordance with the local country laws and standards of the **venue** country in which the event is taking place
- B. Yes, but each country business unit must approve the distribution for healthcare professionals coming from their respective country to ensure compliance with local country laws and standards of the healthcare professional's country of origin
- C. Yes, if in accordance with both the venue country and home country laws and standards
- D. No
- E. Not sure how my Company would handle this

# Question 9

Does your Company permit sales and marketing associates to attend (observational) and/or conduct promotional activities at or adjacent to scientific events such as this?

- A. They can attend in an observational manner, but cannot conduct any promotional activities at or adjacent to the event
- B. They can attend to observe and conduct promotional activities at or adjacent to the event
- C. They cannot attend these scientific events
- D. Not sure how my Company would handle this

# Scenario General Discussion

- Are there any other considerations that your Company takes into account?
- What if this was a promotional meeting rather than a scientific discussion of clinical trial results?