
MAPS | eCademy
Webinar Series
Compliance Considerations in Medical/Commercial Collaborations

Disclaimer

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

Introductions

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Why Is This Important?

- Keeping scientific exchange free from sales/marketing **influence**
- Imperative: clear guidance compliance → MA
- How?
  - Separation of Med Affairs and Commercial
  - SOPs and other guidance
    - Off label communications (solicited? Unsolicited?);
    - sending MSL's to physician offices to discuss approved uses?
    - What can I say? What can't I say?
- Goal – collaborate in a compliant way; protects the patient

Collaboration: Situational Applications

- Advisory Boards
- Joint Medical/Commercial Meetings

Guidance – What resources?

- Laws/regulations
  - False Claims Act
  - Anti-kickback statute
  - FDA (Food Drug and Cosmetic Act)

  **Ex US*: laws and regulations country-by-country

Guidance – cont'd

- Industry Codes of Conduct
  - US
    - PhRMA Code (pharma)
    - Advamed (medical device)
    - State Codes
  - *Ex-US*: Other country codes (e.g., Japan, Australia)

- Company policy

Guidance – cont'd

- OIG (Office of Inspector General)
  - Compliance Guidance for Pharmaceutical Manufacturers
  - OIG Bulletins and Advisory Opinions
  - Corporate Integrity Agreements (CIA's)
    - Med Affairs is an important compliance tool and required control around medical information activities
    - CIA's from 2004 To present
    - Forecast - where enforcement is heading

Guidance, cont'd

Corporate Integrity Agreements:

Have addressed conduct such as:

- Promoting MSLs based on ability to sell
- Training MSL's to prompt off-label questions
- MSL's accompanying sales reps on in-office visits and providing presentations on off-label uses
- Developing KOL's to support and promote off-label uses
- Using advisory boards to promote off-label uses
- Funding CME on off-label uses and creating and controlling content
- Preparing and publishing a misleading journal article that misreported clinical trial results

Corporate Integrity Agreements

- Aegerion Pharmaceuticals, Inc.
- Cardiovascular Systems, Inc.
- Olympus
- Novartis
- Millenium Health LLC
- Health Diagnostic Laboratory
- Daiichi-Sankyo
- Shire
- Endo Pharmaceuticals
- Endogastric Solutions
- Johnson and Johnson
- Par Pharmaceutical
- Amgen

CIA's - Links

- https://oig.hhs.gov/fraud/cia/agreements/Aegerion_Pharmaceuticals_Inc_09222017.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Cardiovascular_Systems_Inc_06282016.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Olympus_Corporation_of_the_Americas_02292016.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Novartis_Pharmaceuticals_Corporation_Addendum_11192015.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Millennium_Health_LLC_10162015.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Health_Diagnostic_Laboratory_03312015.pdf

CIA's - Links

- https://oig.hhs.gov/fraud/cia/agreements/Daiichi_Sankyo_01072015.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Shire_09152014.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Endo_Pharmaceuticals_02212014.pdf
- https://oig.hhs.gov/fraud/cia/agreements/EndoGastric_Solutions_02112014.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Johnson_Johnson_10312013.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Par_Pharmaceutical_03042013.pdf
- https://oig.hhs.gov/fraud/cia/agreements/Amgen_12142012.pdf

Medical/Commercial Collaboration Scenarios

Scenario 1:
A Global Advisory Board

- The launch of a new global product is in preparation
- The Global Medical Affairs (GMA) team
  - is planning an advisory board with important global thought leaders
  - developed list of questions that the team is looking to get insights on to inform medical launch strategy
  - identified the thought leaders that they consider best suited to providing insights
- The commercial team
  - considers these insights also highly relevant to inform commercial strategies
  - would like to be involved in the preparation of the advisory board
  - commercial team members request to be invited to the meeting
  - suggest thought leaders that they consider important to be invited and to get engaged with

Scenario 1:
A Global Advisory Board

- Meeting to take place adjacent to an international congress that many of the thought leaders plan to attend
- Commercial team
  - would also like to hold a commercial advisory board
  - suggests to have the meeting take place in the same location as the medical advisory board
  - provide advisors the opportunity to meet both teams over lunch
  - suggests broadcasting the medical advisory board to an extra room

Points to consider:
Participation of commercial team members in medical Ad Board

- Has a Needs Assessment for the Advisory Board been put together?
  - Is there a legitimate business need for the Advisory Board?
  - Who are the individuals from the commercial team that would like to participate in the medical advisory board, especially
  - What are their job titles/levels?
  - What are their functional responsibilities?
  - What are their geographical responsibilities?
  - Responsibilities more tactical more strategic?
  - Alternative methods for information sharing?

PMCPA's recent Advice on Advisory Boards. http://www.pmcpa.org.uk/advice/meetings/Pages/Advice-on-advisory-boards.aspx Accessed 31 July 2018

"Rule of thumb": General Guidelines

- Refer to your company's policies on Advisory Boards and Interactions with HCPs
- Engage early with your compliance/legal partners
- Take into account your company's specific situation
- Ensure thoughtful preparation of Needs Assessment
- Medical activities may never be perceived as being promotional
- Develop predefined questions
- Plan for documentation of the discussion, preparation of a report/summary
- Plan for how information will be shared within the company

Points to Consider: Perspective of invited thought leaders

- How would they react to participation of commercial colleagues?
- Have any of them expressed sensitivity in this regard?
- Would they be comfortable with commercial colleagues participating or would that keep them from speaking freely?
- Do any of the thought leaders' institutions have policies that keep them from engaging in activities with commercial colleagues?

Points to Consider: Overflow Room

- Do you have to disclose in the contract
  - that there are more people than the people in the actual meeting room viewing/listening to the advisory board?
  - would you have to disclose that you are recording the meeting?
- How would the thought leaders' institutions view this? Could this keep some of them from being able to participate?
- How would they react to not knowing who the people are that are listening in?
- Would this negatively influence the discussion flow?
- What would be the risk of off-label discussions and how do you mitigate the risk?
- How would you control participation of the appropriate commercial colleagues?

Points to Consider: Joint Lunch for the Adjacent Commercial and Medical Advisory Boards

- Not all the thought leaders appropriate for the medical advisory board
  - may be needed/appropriate or
  - willing to also participate in the commercial advisory board
- Could you justify their participation in both based on their experience and expertise?
- Would it be appropriate to have some participate while others would not?
- Would that create an awkward situation and how would you manage it?
- If you would have both groups at a joint lunch, how would you manage the situation to ensure that commercial and medical engagements do not get mixed?

Scenario 2: Joint Commercial and Medical Meeting with a Thought Leader

- A member of the commercial strategy team requests a joint visit to an important thought leader with the medical director responsible for the lead compound currently in clinical development
- The commercial colleague
  - Has already made the arrangements
  - Requests that the medical director makes himself available
  - Requests a presentation on the compound, its status in development and recent unpublished data

Points to Consider:

- Refer to your company's policies on interactions with HCPs and medical and commercial interactions
  - Can medical and commercial attend joined meetings? What are title and areas of responsibility of the commercial and medical colleague?
  - What is the exact purpose of the meeting?
  - What exactly is supposed to be discussed?
  - Can medical respond to unsolicited off-label questions with commercial being present?
  - Is it appropriate for the commercial colleague to direct the medical director's activities?

Points to Consider:

- Why is the presentation needed?
- Why is it important to include the unpublished data? Is the data on label or off-label?
- Is it appropriate to share the unpublished data with the commercial colleague and in the context of a meeting with a commercial purpose?
- Could the sharing of unpublished data have negative consequences, e.g. regarding the planned publication of the data or could there be a risk that it is shared with competitors (e.g. is the thought leader an advisor for another company)?
- Are there safeguards in place regarding confidentiality, e.g. a confidentiality agreement or does that have to be put in place?

General Guidelines

- Refer to your company's policies on joint visits/meetings and Interactions with HCPs
- Take into account your company's specific situation
- The purpose of the meeting as well as roles & responsibilities of all participants in an HCP meeting must be transparent to the HCP
- In general, commercial colleagues should not participate in medical discussions while medical colleagues should not engage in commercial discussions
- If a medical presentation is needed to set the stage for the discussion, the medical colleague should leave the room when the commercial discussion is taking place
- The GMA team should ensure that medical activities may never be perceived as being promotional
- Commercial colleagues should not direct how GMA/R&D engages with HCPs
- The decision of how to interact with an HCP and which information is appropriate to share, rests with GMA/R&D