IPCAA | Annual Seminar on Compliance

IPCAA ANNUAL SEMINAR ON COMPLIANCE 2019

Unanswered Questions

At the IPCAA Annual Seminar on Compliance held earlier this year, we had the opportunity to answer many questions posed by attendees or via the webcast. Due to time constraints, our presenters were not able to answer them all during the sessions – however, in the meantime, they have kindly taken the time to provide written answers.

Please find below the questions asked in each session, and the answer provided by the presenter. If you still have questions or would like more information, please let us know and we will endeavor to get you an answer personally as quickly as possible.

Day 1
Session – Codes and Regulations an Outlook to the Future

1. **Set up of scientific program for MedTech: 50% theoretical and 50% practical, and 2/3 hands on - can you give a good example?**

   Answer from Roeland van Aelst, MedTech: The question relates to third-party organized procedure training, which should be seen separately from a regular educational event. MedTech Europe created an exception for the ban on direct sponsorship regarding third-party organized procedure training. The main reasons being the typical smaller set-up of these trainings, and the narrower selection criteria for the participants as several courses require a certain level of existing skills specific to the course. So consequently, MTE drafted some criteria for an event to classify as "Third-party organized procedure training." In a nutshell these criteria are:
   - Self-standing and not part of a bigger regular event
   - Have a minimum of practice and a minimum of hands skills training on the procedure
   - Being organized in appropriate venues, etc.

   With respect to the practical part, in essence at least 50% of the total program needs to be practice-oriented. This can be case discussion, procedure demonstration though streaming, witnessing a procedure in another format, or performing the procedure "hands-on" on artificial body parts, organs or cadavers. At least 2/3 of the practical program needs to be of this hands-on nature.

2. **Medical societies: Have you looked into options to broaden your outreach to not only doctors but also other disease-specific experts (e.g. data scientists) to ensure a true cross-functional collaboration in order to advance and be innovative? Especially considering megatrends like digitalization where other stakeholders can provide truly advancing knowledge.**

   Answer from Aoife Delmas, ESC: The ESC has an inclusive approach and reaches out to all cardiology professionals including allied professionals in the areas of research, data science, among many other; we are constantly evolving to ensure that we are engaging with all specialty stakeholders in the field and have recently created a council on stroke as well as cardio-oncology. On the point of digitalization, we have a Working Group focusing on e-cardiology looking specifically

at this specialization but also a digital health committee driving the need for awareness & action in this field across all CV specialties.

3. With regard to the ESC presentation: what can we (everyone in this room) do to educate physicians on the need for compliance/codes/reporting? I find it quite disturbing that the industry codes are seen as barriers etc., when they are in place to protect the interests of all parties - industry, HCPs, and ultimately patients so they can be assured their physician has not been bribed to prescribe and so on.

   Answer from Aoife Delmas, ESC: There is an over-arching sense that the code was built out of a sense of mistrust and a lack of common understanding between the industry and physicians and this is creating a growing fracture in the relationship. I believe that if we are to change this, there would be a need for strong and meaningful collaborative discussions, taking on board different points of view and demonstrating how the discussion outcomes are reflected in future versions of the code.

4. What is ESC doing to train members on ethics and compliance issues?

   Answer from Aoife Delmas, ESC: We have invited key stakeholders in EFPIA & MedTech Europe to speak with our boards and leadership, we educate and inform committee members in meetings and newsletters throughout the year. We are a member of the Biomed Alliance who also seek to engage with industry regulators to understand ongoing concerns and upcoming code considerations.

5. What factors and elements is ESC considering to choose a location for congress?

   Answer from Aoife Delmas, ESC: We have a very comprehensive RFP process with a scoring card on components including congress service facilities, transport, accommodation, regulation environment, city support.

Session – Panel Discussion

6. What we see from industry side as a PCO is that budgets for sponsorships are decreased and there are lots of complex regulations, but where are the solutions for collaboration on congresses? I observe only negative lists, no positive lists. Why is it developing in this direction?

   Answer from Christian-Claus Roth, IPCAA: The industry is under increasing cost scrutiny, however still invests a significant amount of money into congresses. I think investments are made to high science, impactful medical congresses and educational activities – which should be the focus of the industry.

7. How is it ensured that the personal date of the HCP has a valid consent once ending up in any of the registration systems?

   Answer from Christian-Claus Roth, IPCAA: It is the shared responsibility of industry and their respective dedicated event agencies, as well as the PCO prompting the question.

8. Prescriber, non-prescriber – how do we know if this needs to be on the badge?

   Answer from Christian-Claus Roth, IPCAA: Please check with the local association and IPCAA in case of any doubts.

9. What are the main differences between the Pharma and MedTech code?

   Answer from Christian-Claus Roth, IPCAA: In the context of medical congresses: MedTech prohibits direct sponsorship of HCPs to attend medical congresses, but allows invitations to company-sponsored educational events, while the Pharma Code leaves this to the respective industry members to decide

10. What about the flyers in the congress bags, are they are still allowed? Is the bag then anyway a practical gift?

    Answer from Christian-Claus Roth, IPCAA: Flyers are allowed, congress bags, no.

11. What is IFPMA's general advice on providing pads and pens with a company logo (not a product specific logo) at industry sponsored satellite symposia during congress? Is this perceived as a promotional aid?

    Answer from Christian-Claus Roth, IPCAA: Pens and notepads may be provided at company-organized events for the purpose of taking notes during a meeting. These may only be company-branded, not product, must be of minimal value and in the necessary quantity for the purpose of the event.

Day 2

Session – GDPR and Compliance in a Digital Age

12. Can you please clarify the link with TOMs again? Is TOMs as in Tour Operator Margin levy?

    Answer from the EventLawyers: TOMs means "Technical and Organizational Measures". Controllers and processors are legally obliged to implement technical and organizational measures in accordance with the state of the art to protect the processed and used personal data from the GDPR.

    The GDPR requires
    - technical and organizational measures according to the state of the art
    - the data protection impact assessment as part of the risk-based approach
    - the obligation to introduce internal guidelines and procedures
    - specific measures for technical security, such as encryption and pseudonymization
    - specific consideration criteria

    Examples of TOMs include access control and transfer control concerning access and transfer of personal data.

13. "Release of liability in case of breach" = how?

    Answer from the EventLawyers: A controller will be able to release himself of the liability for a data protection breach caused by the processor if they can prove that they met all necessary technical and organizational measures, and that they ensured by an agreement that the processor will also meet all of these measures. In this case, the liability shifts to the processor where the data protection breach has taken place.

14. **In the case of an industry symposium, what attendee data can be shared with the industry partner? Is additional consent of participants necessary, or can general registration be considered as legitimate interest?**

    Answer from the EventLawyers: The term "personal data" is the gateway to the application of the basic data protection regulation and is defined in Art. 4 para. 1 No. 1. This is all information relating to an identified or identifiable natural person. For processing (here: sharing) to be lawful, personal data must be processed with the consent of the data subject or on another admissible legal basis. General registration can be a legitimate interest. However, this may depend on the exact details of the situation.

15. **When the controller sends data to the processor (i.e. personal data), is it obligatory for the controller to send this information on a secured / password protected platform? Or is standard email exchange sufficient?**

    Answer from the EventLawyers: There are no categorical rules, just a few guidelines. 'Processing' means any operation or set of operations which is performed on personal data or on sets of personal data. If you send personal data (regardless of the function as a controller), you do processing. Personal data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures. It is therefore possible for standard e-mail exchange to be an appropriate tool. Please understand that a final legal evaluation of this problem requires knowledge of the full facts.

16. **If I am a patient myself but working for a pharma company and treated with a product of my company, am I still allowed to speak about the product?**

    Answer from the EventLawyers: This depends on the function you are taking in the specific moment. If you are acting in your private life in which you are a private person on medication, you are in your "patient role." If, on the other hand, you are at work and communicate in your function as an employee of a pharma company, you are in your "professional role." As a patient you are allowed to speak about medication. As a professional you are allowed to do so only within the limits we have explained during our presentations – that is, you may never directly advertise prescription medication.

17. **Regarding patient engagement and laws: are there efforts from the patient side to support the law to be adapted to fulfill their thirst for information and exchange? Or to define the difference in between advertising and information (e.g. on request)?**

    Answer from the EventLawyers: Drafts for a new law can come from members of the Bundestag, from the Bundesrat or from the Federal Government (of Germany). A tool of participation from the instruments of direct democracy can be the citizen's decision. Like citizens' decisions, citizens' initiatives deal with concrete political problems, mostly at the local level.

    Furthermore, citizens have the right to address a petition to the competent authorities or even to the Bundestag. The German Parliament has set up a special Committee on Petitions to examine the petitions and, if necessary, request information from the authorities. Finally, it can ask the Bundestag to join the petition. Such a decision can help to eliminate the grievance expressed by the

petitioner. Advertising is a term from the economy, it serves the sales promotion. In contrast, information should be open and neutral.

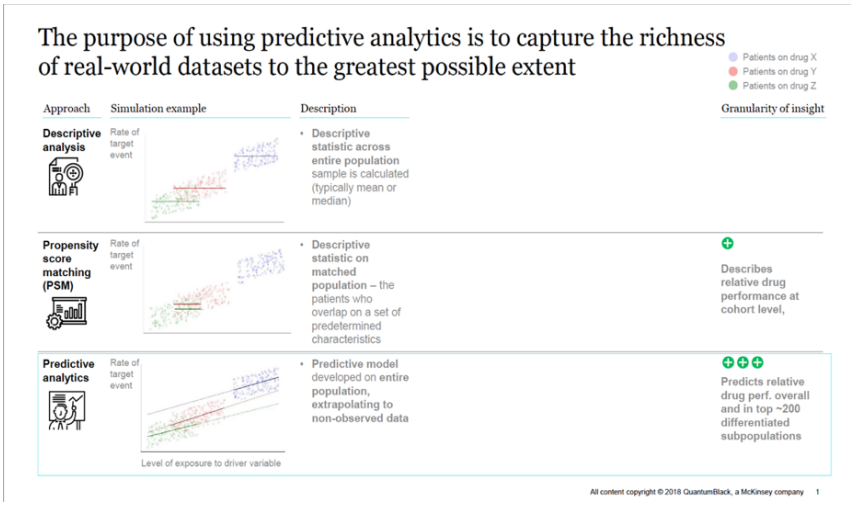
18. **What about a non-HCP, non-patient attendance? Would a badge identification be enough to comply so that Pharma can interact?**

    Answer from the EventLawyers: The pharmaceutical industry is obliged to always move within the limits of the given legislation. It may not directly advertise prescription medication to consumers. Therefore, it always needs to make sure who they're talking to. A general response to your question therefore cannot be given. Basically, the industry is only allowed to advertise prescription medication directly to doctors, pharmacists and so on. The badge itself doesn't alter that. In any case, basic communication is also be possible with people who do not belong to the healing professions, however the regulations outlined in our presentation have to be taken into account.

Session: AI – what's in there for the industry?

19. **Thinking of AI as a predictor of health risk and treatment effectiveness, how will we overcome or at least reduce the risk of human bias being coded into algorithms?**

    Answer from David Champagne, McKinsey: My go-to framework to explain how advanced analytics helps with bias correction is in the diagram below. In a nutshell, traditional RWE analytics methods correct for a handful of confounders based on a human hypothesis on what matters, versus advanced analytics on richer datasets, that can control for hundreds of confounder selected by "the machine" rather than humans. This helps remove human bias, have "machine-driven" hypothesis generation, and create more generalizable results.



20. **How are ethical questions answered by law and compliance? E.g. which frameworks exist for things which have never done before? How to evaluate? Who owns the algorithm? How to beat the black box approach of a learning system?**

    Answer from IPCAA: We've noted this down as potential content for the next seminar.