Ask the Experts Summary
GMTCC 2019
14-16 May 2019
Cité des Sciences et de l'Industrie, Paris

a MedTech Europe event
The MedTech Forum
bringing HealthTech stakeholders together

Global MedTech Compliance Conference

The largest health and medical technology industry conference in Europe.

The MedTech Forum

Dear colleagues,

Thank you to all who participated in the "Ask the Experts" segment of the 2019 Global MedTech Compliance Conference last month. We are especially grateful for the contributions of those who served as Table Leads during the event.

What follows are summaries of the table discussions that took place during the Ask the Experts session. We have also included the contact information for several Table Leads submitting these summaries. We hope this will provide an additional benefit to your participation in the 2019 GMTCC and hope to see you next year at GMTCC 2020 in Berlin.

Clarisse Aillet
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Table Summaries

GMTCC Speaker profiles *(available here)*

Data Protection & GDPR: one year on
Peter Blenkinsop, Drinker Biddle & Reath LLP
Peter.Blenkinsop@dbr.com
Blog on MedTech views: Data Protection: If It ain't broke, don't fix it?

Topic 1: *How has the GDPR impacted clinical investigations of new medical devices?*

- What is the appropriate legal basis under GDPR Article 6 for processing of personal data in the context of a clinical investigation?
- What is the appropriate derogation under GDPR Article 9 for processing of sensitive personal data?
- What is the appropriate characterization for data protection purposes of the parties involved in the clinical investigation (controller versus processor, etc.)?

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Topic 2: *How has the GDPR impacted further processing of personal data for research purposes?*

- What options can be relied upon as a legal basis under GDPR Article 6 and derogation under GDPR Article 9 for the processing of personal data originally collected in a clinical investigation for secondary research purposes?
- What does Article 5(1)(b) mean with respect to its presumption of compatibility of further processing of personal data for scientific research purposes (subject to the conditions of Article 89)?
- When does Article 89 apply (concerning safeguards and derogations relating to the processing for scientific research purposes)?
- What does the phrase "based on Union or Member State law" in Article 9(2)(j) mean (concerning the derogation for processing of sensitive personal data for scientific research purposes in accordance with Article 89)?
- What does / does not qualify as "scientific research" for purposes of Article 89? Does this include product and service improvement activities?

Topic 3: *What are some of the key GDPR issues that are creating contracting challenges and how are companies addressing these challenges?*

- Defining the roles of the parties for data protection purposes (controller versus processor, etc.)
- Permissibility of using data collected for product/service improvement and similar secondary purposes
- Use of subprocessors
- Breach notification requirements (scope, timing, etc.)
- Other areas?

Topic 4: *What are challenges that companies have faced in operationalizing the following GDPR requirements?*

- Right of deletion
- Right of access, correction, portability
- Data protection impact assessments
- Privacy by Design and Privacy by Default

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MedTech Europe Code: Session with hands-on Questions and Answers
Pablo Abad, Legal & Compliance Manager, MedTech Europe
p.rojas@medtecheurope.org

AdvaMed new Code & key take-aways for the future
Nancy Travis, VP International Compliance & Governance, AdvaMed

*Link to the AdvaMed Code handout is available **here**.*

Since AdvaMed last revised its Code of Ethics ten years ago, the medtech community has seen great progress in harmonization and uptake of Codes of Ethics worldwide. Regionally, we have seen stakeholders come together to agree on shared values, provisions and goals that ensure health care professionals act in the best interests of their patients - in Asia, Kuala Lumpur Principles (2011) and in the Americas, the Bogota Principles (2017).

And last year at this meeting, we heard the news that the Global MedTech Alliance had approved a Joint Statement on Global Harmonization, with its member industry associations pledging to work together to promote strong codes of ethics worldwide.

Against the backdrop of this exciting progress, AdvaMed conducted a review of its Code of Ethics and worked with its members to bring it up to date, resulting in the revised Code of Ethics on Interactions with U.S. Health Care Professionals, effective January 1, 2020.

Why AdvaMed revised its Code of Ethics
Codes of Ethics have become increasingly widespread and encompassing. For AdvaMed to better support harmonization, we needed a refreshed Code with greater scope and enhanced clarity to both incorporate advancements made over the last decade and allow broader collaboration between all stakeholders throughout the next. So, we formed working groups of over 55 attorneys and compliance officers, collected feedback from across the industry, and engaged in a robust internal AdvaMed governance process to vet, review and approve

revisions to our Code. We announced our new Code in December 2018 and have been working toward its launch ever since.

Key Code revisions
From our exhaustive revision processes we have been able to update our Code with many valuable enhancements. We added a cover page, table of contents and glossary with new terms defined and old definitions enhanced. Every section now begins with "Key Concepts" to highlight top-level takeaways. We have also incorporated more visuals, graphics, callout boxes, examples, explanations and FAQs throughout the Code to ensure total clarity. With several months left until its January 1, 2020 effective date, we continue to revise certain details and welcome all stakeholder input.

Future priorities for AdvaMed's Code work
For the rest of 2019, AdvaMed will work toward its 2020 Code refresh by finalizing last details and developing new training and certification programs. We will coordinate with all stakeholders to ensure Code harmony with the Kuala Lumpur Principles, Bogota Principles and the principles laid out in our GMTA Joint Statement. We hope our new harmonization-focused Code will help lay the groundwork for another decade of progressing code of ethics adoption and standardization alongside an enhanced industry-wide effort to bring MedTech stakeholders across the global supply-chain into the fold of ethical interactions.

Placement of equipment – An underestimated compliance risk
Dr. Adem Koyuncu, Partner – Lawyer and Medical Doctor, Covington & Burling LLP, Brussels/Frankfurt
akoyuncu@cov.com

This table has focused on the "placement of equipment" by medical device manufacturers. The term stands for a hot topic in the international healthcare compliance practice. Placement of equipment is a significant compliance risk and it also appears as an underestimated risk. However, prosecutors and regulators in different countries express that they see the placement of equipment as a critical compliance concern to look into.

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The roundtable has first discussed the legal and compliance framework and then discussed the different types of placement of equipment at healthcare organizations or with HCPs. The session aimed to identify the different levels of risk associated with the different types of equipment placement.

The session has also discussed potential risk management and risk mitigation measures, including contractual and practical means, that medical device companies could deploy.

The session has followed this agenda:

1. Legal and compliance framework
2. Types of "Equipment Placement"
3. Compliance risks and legal ramifications
4. Risk management and mitigation measures

Collective Redress: landscape and future trends
Ekkart Kaske, Director, European Justice Forum
e.kaske@europeanjusticeforum.org

This roundtable's discussions will provide a high-level overview of the key elements and developments of "Collective Redress" in Europe and raise awareness about the trends and EU regulatory updates to consider.

The session will be structured as followed:
a) The Procedural Landscape
- Approach of the European Justice Forum
- Overview of key parameters to consider in the Procedural Landscape
- The various schemes of out-of-court and in-court settlements

b) The Regulatory Landscape: the proposed EU Directive on Representative Actions
- Background elements on the proposed EU Directive on Representative Actions
- EJF views and position over the initial proposed Directive
- Institutional state of play at EU level and next steps

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The session will also allow to touch on further questions related to the impact on compliance and more broadly on the potential impact of digitalization. These questions may raise issues concerning regulatory or reputational risks.

More supporting documentation is available:
Summary
Procedural landscape of collective Redress
Timeline – EU policy udapte on Directive on Representative Actions.

The Medical Profession, Industry and Continuing Medical Education: Finding the Balance That's Right for Patients

Michel Ballieu, Executive Director BioMed Alliance
&
David B. Vodušek MD, Chair of the CME Experts Committee, BioMed Alliance
vodusek.david.b@gmail.com

BioMed Alliance CME Experts Permanent Committee
The Biomedical Alliance in Europe is a unique organization, bringing together 30 leading European scientific societies, and represents through its members societies more than 400.000 medical researchers and healthcare professionals with shared interest in medical professional issues, primarily research and medical education, also continuing medical education (CME). The BioMed Alliance has recently nominated the CME Experts Permanent Committee, whose task is to work on the quality of independent Continuing Medical Education. The committee is composed of representatives from BioMed member societies with a well-balanced mix of volunteering leaders and senior staff, all closely involved in medical education.

BioMed Alliance CME Experts Permanent Committee's position on CME and the role of industry
Provision and participation in formal CME is costly and employer or state support is the exception rather than the rule. The medical industry has so far supported both providers (typically academic institutions and scientific societies) and consumers of educational activities. This has led to concerns of bias, but codes of conduct produced by and adhered to by the industry and the profession have made their relationship transparent and more acceptable.

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Recent medical industry initiatives in Europe have, however, raised concerns of the BioMed Alliance on what we view to be a growing trend by some industry companies to adopt a role of CME provider. Apart from concerns about the inherent bias of such CME, this development directly and indirectly jeopardizes funding of annual congresses of medical societies.

Acknowledging that there are areas of co-operation in the field of education between the medical profession and the medical industry from which both can benefit, we argue that medical education requires an objective approach that the primary fiduciary duty of medical industry companies precludes.

An ethical and transparent relationship between professional medical societies and the medical industry in the field of medical education should be based on a clear definition of roles and opportunities for collaboration aimed at best outcomes for patients through unbiased, high quality CME.

The not-for-profit nature of professional medical societies, their constitutions, governance and experience make them particularly suited to designing and delivering unbiased medical education.
The medical devices industry's role should be to provide product training, notably on the safe and effective use of its products. However, product training differs greatly from medical education that should provide an unbiased broad overview on the particular content.

By developing an ethical and transparent relationship between professional medical societies and the medical industry we can work together to safeguard medical education and standards of healthcare.

Hot topics discussed with participants:

1. Medical societies are not-for-profit organisations. Where there is a surplus, it goes towards enabling exchange of professionals in training, education of professionals from less affluent countries, supporting initiatives in the developing world and lobbying health and research policymakers.

2. National and international CME accreditation authorities have drawn up criteria to ensure high quality CME. In an effort to avoid commercial bias in events and programmes that receive financial support from the industry, the European Accreditation Council for Continuing Medical Education (EACCME) requires that all funding from sponsors must be provided as an unrestricted educational grant, free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of faculty members.

3. Product-specific training is important but is not CME in the formal meaning of the term. It would be concerning if industry partners sought to position themselves as direct providers of CME to physicians rather than collaborating with independent education providers on unbiased, high-quality curriculum.

4. The MedTech Europe Code indicates that industry should refrain from direct support of physicians attending medical conferences. This resulted in a worrying reduction of participants in recent independent medical conferences. Accordingly, new modes of collaboration should be implemented.

5. Although the industry has an overriding commercial responsibility to its shareholders, it also has an ethical responsibility to see its products used safely, effectively and appropriately for the benefit of patients and society. We argue this is better achieved by support of medical professional societies in their role as educators, rather than itself taking on those activities.

Transparency and ethical practices in the Middle East region (Mecomed)
Arwa Asiri, Compliance Officer, Mecomed
arwa.asiri@mecomed.com
&
Ghadeer Al Yacoub, Regional Healthcare Compliance Officer, Turkey, Middle East & Africa, Johnson & Johnson

Topics
* KSA Transparancy
* Mecomed Code Updates
* Certification Program
* CVS - MEA Updates

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Best practices in investigations
Rosanna Kay, Partner, Reedsmith

Topics
1. *How internal investigations can be conducted sensitively and efficiently*
2. *Key issues:*
    a. To investigate or not to investigate?
    b. The investigation Team
    c. Scoping the investigation
    d. Maintaining privilege
    e. Confidentiality
    f. Documentary evidence
    i. Employee communications
    ii. Data protection
    g. Interviews
    h. Internal communications
    i. Cross-border issues in internal investigations
    j. Concluding the investigation

Qualies: A Compliance System Maturity Evaluation Program developed in Brazil
Carlos Gouvea, Executive Director of IES (Instituto Ética Saúde)

QualIES is an Integrity System maturity evaluation program developed by IES - Instituto Etica Saude to support its members along the way of compliance implementation and corporate development towards ethics and sustainability

The program is voluntary to IES Members and is fully aligned with IES normative that are issued by its Ethics Council that has normative and judging functions acting as a beacon to IES members regarding the structure and content of their integrity policies and compliance procedures.

The program will grade members IS maturity from 1 to 5 according to standards and tests developed by IES in cooperation with EY, KPMG, PwC,

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Deloitte, Grand Thornton, that acted as voluntary participants of the program design and steering committee.

Those companies as well as others to join in the future will participate in the program in 3 roles.

1. Continuous development of the program as committee members
2. Implementation and Maturity Consultants to Members
3. Maturity Evaluators according to the program standards (provided not to evaluate former QualIES program consultancy clients)

Grades achieved will be publicized at a certificate provided by request of the participating member as a way to value its commitment to higher IS Maturity Standards.

Distributors/Third Party On-Boarding and Due Diligence
Scott Lane, Chief Executive Officer and Chairman, The Red Flag Group
scott.lane@redflaggroup.com

These are the key messages and trends being discussed across distributor management and on-boarding:

1. On-boarding and due diligence is not just a compliance initiative – it is becoming far more integrated into the business
2. On-boarding and due diligence is considering issues far beyond compliance and anti-corruption
3. On-boarding risks and due diligence also extend to suppliers, subscribers, donations, sponsors, recipients of benefits, customers
4. Monitoring is key and far more important to capture as a challenge for teams
5. Distributor management is increasing as a profession working well in with compliance

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COCIR Code of Conduct
Magali Leroux, Senior Legal Counsel, COCIR
leroux@cocir.org

More supporting documentation available **here**.

1. *Presentation of COCIR*
2. *COCIR Code of Conduct Committee role*
3. *COCIR Code of Conduct*
4. *Communication tools on COCIR change of Code of Conduct*
   - *Leaflet*
   - *Training materials*
5. *Current discussion of the Code of Conduct Committee: complexity of the new French anti-gift regime (not yet adopted) in view of ban of direct sponsorship*

Applying the MedTech Europe Code in France
Bénédicte Garbil, General Manager France, Edwards Life Sciences

Key topics of the session

- *How to deal with the MTE Code and current DMOS regulation in France*
- *Working with HCO and PCO under the MTE Code*
- *What will the future DMOS look like and how companies will have to anticipate in order to apply the MTE Code without business disruption?*

France is often seen as a "difficult" country when it comes to implement new initiatives such as MTE Code. Fact is France should not be seen as "difficult", but rather as "different". Indeed, local regulations are highly present and can be challenging sometimes. This is a common perception when it comes to implementing the MTE Code in France.

However, this perception is a rather false perception. Implementing the MTE Code in France may seem challenging given the existing DMOS regulation; however, combining successfully these two aspects is possible. It requires organization and anticipation. Support of all teams is critical to succeed in implementing the MTE Code in France: legal to adapt contracts, sales to

educates customers about this change, departments in charge of declaration to the national medical/pharmaceutical boards (Conseil National de l'Ordre des Médecins) etc.

Training is a key success factor to engage employees and should not be overlooked. It must be a constant effort and a shared preoccupation within companies. Compliance teams are the catalyst of these efforts.

The MTE Code is also an important change for PCOs and HCOs with whom we collaborate for congresses organization. Their engagement is critical in order to have a smooth transition, especially towards healthcare professionals. The most common challenge is timing to ensure declarations to national medical/pharmaceutical boards are performed in time.

This partnership will even be more important when the new DMOS is implemented in France. First drafts have highlighted the need of anticipation for every stakeholder: companies, PCO, HCO and even HCP. This will require an important effort of education that will need to be relayed by every stakeholder. It is important to raise awareness on the changes to come even if they are not official yet. Drafts shared by the authorities gave some clear indications on the upcoming changes and can already be considered as starting material for internal trainings.

Challenges to medtech companies in 'New Era' China"
Kent Kedl, Senior Partner, Greater China and North Asia, Control Risks
Kent.Kedl@controlrisks.com

1. How politics is – once again – influencing foreign business in China
2. China healthcare reform update (hint: don't believe the hype)
3. How "Made in China 2025" is hitting foreign medtech companies
4. Innovative approaches to managing intellectual property risk
5. Cyber- and data-security challenges for medtech companies

Let's continue the discussions & send us your preferred topics for 2020!

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More GMTCC Blogs publications *are available online!*

- *Building synergies between the business and compliance communities*
- *Transparency: What's next for the healthcare industry?*
- *Enhanced transparency in healthcare, a pure win-win situation*
- *MedTech compliance goes mainstream*

We hope this will provide an additional benefit to your participation in the 2019 GMTCC and hope to see you next year in Berlin, **on 25-27 May 2020**.

Share your topics of interest for next year's edition!

For any question, write to Clarisse Aillet: c.aillet@medtecheurope.org