Colleagues:

Thank you to all who participated in the "Ask the Experts" segment of the 2017 Global MedTech Compliance Congress. We are especially grateful for the contributions of those who served as table leads during the segment.

As we indicated during the session, what follows are summaries of the table discussions that took place during the segment. I've also included the contact information for the respective table leads submitting these summaries. We hope this will provide an additional benefit to your participation in the 2017 GMTCC and hope to see you next year at GMTCC 2018.

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Table Summaries

1. ***CSR and Human Rights***

- Many participants came with a genuine interest in the subject of Business and Human Rights (BHR) with no prior knowledge showing that there are discrepancies in the general awareness about this topic amongst MedTech companies and information is appreciated.

- There are specific examples of human rights impacts in the MedTech sector in public domain including poor labour practices and child work in the production of metal parts for surgical instruments in Pakistan and human rights impacts in the production of surgical gloves in Asia. NHS procurement in the UK is implementing requirements for raising labour standards in supply chains of its suppliers (LSAS) and certain companies operating in the U.K. have to report on steps taken to eradicate slavery and human trafficking in their business and supply chains under the Modern Slavery Act (please note the extra-territorial jurisdiction of the Act). There are requirements in other countries, too.

- CSR v BHR: CSR is still understood by many in the old traditional way of organising voluntary activities which link the businesses with, and do good for, the community. BHR is a substantive process oriented towards eradication of adverse human rights impacts on individuals potentially affected by the company both in its own operations and in its supply chains.

- The developing practice shows that mainstream guidance in the area of BHR is set out in the UN Guiding Principles on Business and Human Rights (UNGPs) and subsequent instruments and guidelines which incorporate them. The UNGPs comprise the obligation of companies to respect human rights and outline the process of Human Rights Due Diligence as the human rights risk management system.

- Operationalisation of Human Rights Due Diligence requires top management commitment and budgets, ownership of the agenda and cross-departmental involvement of compliance, legal, risk, Human Resources , CSR and potentially other departments

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2. ***China***

- Changes in China's regulatory environment:
  Since President Xi Jinping took office in 2013, China has been ramping up their regulatory enforcement. Starting with their anti-corruption drive, they have extended this to anti-trust, environmental, food safety and even taxes. Foreign companies can easily get caught in the cross-hairs of regulators who have "quotas" to fill and a remit to interpret the law broadly. Challenges facing foreign Medtech companies include:

    - Stakeholder maps have changed and now must include new regulators.

    - In addition to anti-bribery/corruption, there is an increasing focus on anti-monopoly regulation (abuse of market dominance, vertical price maintenance, etc.) and foreign Medtech companies have been targeted.

    - Companies need to "war-game" their strategies in insure that regulatory risks are identified and mitigated against.

- Concerns around "Made in China 2025":
  Late 2015, China issued a major industrial policy to guide it's manufacturing over the next ten years. "Made in China 2025" (MiC) encourages Chinese companies to become market leaders in high-tech

and high-value manufacturing. Chinese companies doing advanced medtech is one of the sectors that will receive major funding and support from the Chinese government and P.E. funds associated with the government. There are concerns around how the Chinese authorities use regulatory enforcement (anti-bribery, anti-monopoly, etc.) in combination with MiC to create a more difficult competitive environment for foreign medtech companies. Foreign medtech companies need to pay attention to several things:

  - Take a fresh look at Chinese competition and assess how these companies might take advantage of MiC in the coming years (e.g. what are their political connections, where are they getting investment, what are they investing in, etc.).

  - Assess their current market share and identify spaces where Chinese competition – if they receive investment and support – could start to gain share.

  - Get a deeper understanding of the implications of MiC for your own company and products and devise scenarios and mitigation plans for the near future.

- Doing effective risk assessments in China—"mapping the mechanics of malfeasance":

  - Given the very challenging markets in China, companies need to do a much better job of assessing risk, clearing identifying how threats will manifest themselves. Without knowing the "mechanics" of malfeasance, Compliance cannot adequately mitigate against market risks. Topics would include:

    - Examples of "mapping": i.e. if sales reps will be asked for a bribe, who will ask for it, how they will do it, how much will they ask for etc.

    - Training employees in "resistant strategies"

- Running effective investigations in China:
  The unique Chinese legal environment means that companies need to plan their investigations much more carefully and be prepared to take

action themselves following an investigation. This means taking a "recovery-led" approach:

- Adding critical steps to a traditional investigations plan
- Planning out scenarios for how to discipline/dismiss employees, focusing on business recovery
- Understanding how employees can react and mitigating risks

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3. ***Credentialing***

- No significant credentialing developments yet in mainland Europe (even though there are some developments in Belgium, where the trade association has been trying to develop a unique system);
- US has a longstanding practice to control presence of sales personnel. Third party vendors credentialers sell the concept to hospitals:
  - $1.7 billion in US spent on credentialing
  - Different standards between credentialers and hospitals
- Industry now looking for common standards and inter-operability;
- Are there privacy issues in setting up a national system to supplement credentials?
- Prevention is better than reacting but it needs buy in from senior industry people and ideally the Ministry of Health;
- Need to allow third party credentialers to use the national standards.

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4. ***Managing Risk: ABAC and Third Parties***

- Volume of third parties calls for a risk based approach
- Most companies using risk criteria to set initial flagging (geography, type, value, share of business)
- Following actions depending on risk factor(s)
- Approach not to be limited to distributors, as it needs to also address sub-distributors, as they act on behalf of the manufacturers as well
- Need structured actions not just for initial assessment, but also for follow up (some auditing the management action plans)
- To ensure follow up, some have included compliance in personal performance metrics, and are partly defining compensation
- To manage dependencies, some are ensuring all contracts are non-exclusive

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5. ***India***

- Advocate the importance and need of Company Organized Trainings in a country like India on the basis of different factors.
- Push the government to capture the same in the UCMDMP, try to check the viability and bring all MedTech associations in the country together with Advamed to have an Industry wide Code of Ethics.

Dhruv Goyal, Manager Ethics & Compliance Greater India, Edwards Lifesciences

6. ***MedTech Europe Code & Conference Vetting System (CVS)***

- *The Conference Vetting System*
    - The group discussed in details all aspects around the Conference Vetting System, which is an independently managed system, which reviews the compliance of third-party educational events with both MedTech Europe Code of Ethical Business Practice and Mecomed Code of Business Practice (the "Codes") to determine the appropriateness for companies which are members of MedTech Europe and Mecomed to sponsor Healthcare Professionals to participate in such conferences.
    - Questions concerned the CVS system functions and processes an the group also addressed the changes in procedures which will be introduced to allow for quicker response time to event organisers. In that regards, Christine also explained how the Ethical Charter will support this process.

- *MedTech Europe Code*
    - Educational Grants: Educational Grants to Healthcare Organisations will become the main way of supporting independent medical education, especially after January 2018. The group discussed the guidance around Educational Grants, as well as the practical aspects of the new model.
    - Transparency: Starting with the 2017 data of Educational Grants, all MedTech Europe members will need to disclose these payments in Transparent MedTech, the European transparency platform for the medical technology industry.

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7. ***France***

- The Transparency legislation
    - The Transparency legislation has been modified by the law of modernization of our healthcare system dated January 26, 2016 ("Touraine Law"), the Decree No. 2016-1939 of December 28, 2016 and the Ministerial Order dated March 22, 2017.
    - These modifications relate to new information which must be published. Also new timelines for the publication apply.
    - The new information to be published notably concerns, remunerations and indirect beneficiaries of "advantages" and/or remunerations. These two categories raise many issues. Hopefully the French Ministry of Health will publish guidelines, in the coming weeks.
    - In any event, the new information must be published at the next coming publication to be made not later than September 1st, 2017.
- The Anti-Gift legislation
    - The Anti-Gift legislation will be drastically modified in the coming months, in a sense stricter than what is in place currently.
    - The modifications of the Anti-Gift legislation are provided for under the Order No. 2017-49, dated January 19, 2017, which must be ratified by the French parliament. A draft ratification law has just been presented by the Minister to the Senate on April 26, 2017.
    - Three of the most important modifications are the following:
        - Extension of the Anti-Gift legislation which will apply to:
            - Companies manufacturing or commercializing health products, whether they are reimbursed or not (whereas today it applies only to companies manufacturing or commercializing reimbursed health products)
            - Companies providing health services which will be defined under the coming regulations

- All healthcare professionals, whereas it applies today only to 7 certain HCPs

- Switching from an opinion to an authorization process of all agreements entered into with HCPs, and all "advantages" (meals, travelling costs….) procured to them

- Grants to societies and HCPs' associations will have to be authorized

- The Sapin II Anti-Corruption law

  - The Law No. 2016-1691 dated December 9, 2016 on transparency, fight against corruption and modernization of the economy was published on December 10, 2016 and entered into force on December 11, 2016 but certain of its provisions require decrees which have not all been published yet.

  - Commercial businesses or industrial and commercial bodies, headquartered in France and having more than 500 employees or belonging to a group with more than 500 employees and whose parent company is headquartered in France and, which has a turnover, or consolidated group turnover, of more than € 100 million have an obligation to implement anti-corruption compliance programs by measures intended to prevent and detect corruption and influence peddling such as notably an internal code of conduct defining prohibited conduct likely to constitute corruption or influence peddling and training programs for managers and staff particularly exposed to corruption risks.

- Sponsorship / Code MedTech

  - As of 1 January 2018, companies, which are members of MedTech, will no longer provide direct financial support to HCPs to attend third party organized events.

  - Indirect sponsorship, which will be authorised, raises some practical issues as far as France is concerned, with regard to

the anti-gift legislation (especially in light for the coming modified rules – see below) and transparency.

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Olivier Sudre, Compliance & Transparency Officer, Johnson & Johnson Medical Devices France

8. ***Eastern Europe***

- Corruption risks in Eastern Europe
  - Per recent analyses (EY, TI, others) and based on experience, corruption in majority of Eastern European countries remains as a significant level
  - Health-care continues to be one of major sectors impacted
  - Enforcement varies (Romania and Poland vs. other countries) and in many times is politically driven
- Update on political developments in Eastern European countries driving regulatory changes and enforcement (and vice versa)
  - Russia – focus on promoting local products - data privacy laws, localization laws, etc.
  - Poland – current government about to make changes to the healthcare system , upcoming new reimbursement legislation, changes affecting the judiciary system and enforcement
  - Greece – recent scandal triggering massive investigation and parliamentary commission focused on scandals in the healthcare system
- Emerging regulatory and anti-corruption themes In Eastern Europe
  - Focus on corporate liability
  - Whistleblowers
  - Data privacy
  - Transparency
  - Conflicts (or perceived conflicts) between various laws

- Key risk areas affecting MedTech companies in Eastern Europe
  - Tenders
  - Use of third parties
  - Anti-trust risks

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9. ***Middle East***

- By May 18 Mecomed will be approvinf their new Code, which is very close to the MTE Code with only some minor differences, due to local practices. The draft Code proposes a full transposition by 1 January 2018, including the phase out of direct sponsorship. Transparency would be effective as of 1st January 2019.

- Distributors and TPI will be under the scope of the draft Code.

- Transparency and code of ethics for MedTech industries in KSA.

- Code of Ethics for all Healthcare Industries in UAE by the ministry of health.

- CVS Middle East has been started almost 3 years ago and cultural change can already be seen thanks to this project. Following the end of the funding scheme, Mecomed is now looking into how to ensure the sustainability of the system.

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10. ***Latin America***

- Anti-corruption legal environment in Brazil, Mexico, Chile and Colombia

- Enforcement – Brazil

- Third Party Compliance and market changes
- Direct Sponsorship & Educational Grants

Denis Jacob, Director Global Commercial Compliance, BD

11. Promotion and Advertising Practices

- In the United States, the advertising and promotion of medical devices is a highly regulated area that can implicate many legal issues and compliance challenges. It is therefore critical to stay abreast of the latest developments in the law and to exchange "best practices" for effective compliance programs. During this session, we will discuss:
- Developments Regarding "Off-Label" Communications.
    - Promoting an approved or cleared medical device for conditions of use that were not approved can give rise to enforcement by the U.S. Food and Drug Administration (FDA), the Department of Justice, and other enforcement agencies, as well as other legal liability.
    - But in several recent cases, courts have held that manufacturers have a right under the U.S. Constitution to engage in truthful, non-misleading speech, even if such speech involves unapproved uses of devices. In addition, FDA has issued guidance documents that permit manufacturer discussion of off-label topics under defined circumstances.
    - Therefore, companies are seeking to understand the state of the law and best practices for advertising and promoting medical devices. We will discuss these legal developments and compliance challenges they raise.
- Are Compliance teams getting pressure from Marketing?
- Enforcement Trends Relating to Advertising and Promotion of Medical Devices:

  - In light of changes in the law (including the First Amendment issues discussed above) and the incoming Trump administration, what is the current enforcement environment relating to advertising and promotion of devices, and what might we expect to see in enforcement in the coming years? What are the kinds of activities that are most likely to attract attention from enforcement agencies?

- How to Develop an Effective Compliance Program for Advertising and Promotion.

  - Establishing and maintaining an effective compliance program is critical to preventing and addressing any misconduct. Government authorities expect companies to have an effective compliance program.

  - We will discuss the elements of an effective compliance program related to advertising and promoting medical devices, including how compliance with industry codes can be part of an effective compliance program.

- Other challenges – how to deal with competitors that do not comply with codes or legal requirements?
  - Investigate - often complaints but in fact there is nothing there.
  - Reach out to companies via compliance officers or lawyers
  - If very serious, go to government officials
  - But careful, since can have boomerang effect (make sure you are complying perfectly)

- Social Media – lots of challenges
  - Off label issues
  - Allowing employees to tweet or post about company products – generally prohibited but very hard to monitor effectively
  - Some companies have clear policies on social media, others do not
  - Digital health introducing new challenges

- Training of HCPs
  - How to keep on label
  - Do they review decks before - yes
  - But can trainers answer questions about off-label (yes for most)

- In surgical suite – what policies?
  - Can only attend procedure if it is on label
  - If it goes off-label, can answer questions only, no coaching

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12. Transparency & disclosure

- Most attendees don't feel confident in their abilities to comply with MedTech Europe and effective national transparency requirements.
- Dream to have one set of Transparency requirements for the Life Sciences industry (Pharma, generics, medtech etc.) in all countries.
- Complexity to ensure completeness and accuracy of the transfers of value to disclose
- Transparency is perceived as a burden and a cost rather than provided added value to the manufacturers.
- Multiple requirements and deadlines on Transparency add high complexity to fully comply with the regulations

Diva Duong, Vice President Compliance EMEA-APAC, IMS Health

13. Anti-corruption

The group discussed the following key areas:

- Discussion around the common occurrence recently of new companies set up by HCA's to provide training and education services. These are often set up as 'NGO's and receive 'charitable' donations from large corporates. These new entities are hard to conduct due diligence and even harder to assess whether they are legitimate and providing real training services. These new challenges have been brought about by the push towards indirect sponsorship
- We discussed the challenge of sub-dealers and how to conduct due diligence across this tier of the channel of most companies. We talked

about different risk levels for these dealers and how to manage them as part of an overall third party program

- We briefly touched on the Chinese Government initiative to reduce layers in the distribution chain and how this might affect the strategy of many companies in the healthcare space.

- It was acknowledged that the classic GTE (gifts, travel and entertainment) risks in most companies had 'settled down' and that the focus is now on third parties and how to address this growing list of demands from regulators

- We discussed the next area of focus being suppliers and providers of services to companies and how their due diligence practices for SMI's needs to be expanded to cover suppliers (which have much broader risks than just DD)

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