Global MedTech Compliance Conference

AGENDA (draft)
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2019 Global MedTech Compliance Conference

"Compliance: What's the right message?"

14-16 May 2019

Cité des Sciences et de l'Industrie, Museum of Sciences and Industry,

30 avenue Corentin Cariou, 75019 Paris (France)

DAY	TIME	MEMBER-ONLY MEETINGS
		TUESDAY 14 MAY
	10.00 – 13.00	**MedTech Europe Ethics & Compliance Committee (ECC) Meeting (*Members ONLY*)**
		AdvaMed Global Compliance Steering Committee Meeting (*Members ONLY*)
	13.00– 14.00	**Networking lunch**
	14.00 – 15.30	**1st GMTA Global Compliance Network meeting**
	15.30 – 16.00	**Coffee break**
	16.00 – 17.30	**1st GMTA Global Compliance Network meeting (con't)**
	18.00 – 19.30	**MedTech Forum & GMTCC opening reception & PwC Compliance Achievement Award (tbc)**

DAY	TIME	GMTCC PROGRAMME
		WEDNESDAY 15 MAY
	9.00 – 9.30	**MedTech Forum opening**
	9.30 – 10.30	**MTF Plenary session – CEO Panel – #No filter** *Speakers:* - Michelle Brennan, Company Group Chair EMEA, Johnson & Johnson and chairwoman of the MTE Board *(confirmed)* - Serge Bernasconi, CEO, MedTech Forum *(confirmed)* *Moderator:* Ingmar de Gooijer *(confirmed)*

	10.40 – 11.00	**GMTCC Coffee break**
	11.00 – 11.15	**GMTCC plenary session: Keynote: view from the regulators** *(Auditorium)* *Speakers:* Patrick Moulette, Head of the OECD Anti-Corruption Division *(confirmed)* *Moderator:* Ingmar de Gooijer *(confirmed)* *Description:* This keynote will be discussing the regulators views on the following aspects: what is working and what doesn't with the current anti-bribery & corruption efforts; how can industry help and what are the key points for the industry to be aware of. In addition, considering that the industry is composed of more than 80% of SMEs, are there specific considerations for these companies?
	11.15 – 11.35	**GMTCC plenary session** *(Auditorium)* *Speakers:* - Dorothy Clark, vice president Healthcare Compliance, Johnson & Johnson and chairwoman of the AdvaMed DDCG *(invited)* - Anne Sophie Bricca, Deputy General Counsel, Terumo BCT and chairwoman of the MTE ECC *(confirmed)* *Moderator:* Ingmar de Gooijer *Description:* The two chairwomen will discuss the AdvaMed and MedTech Europe compliance priorities as well as how these relate to the topics tackled in the MedTech Forum.
	11.35 – 12.50	**GMTCC plenary session: Transparency: What next for industry?** *(Auditorium)* *Speakers:* - Julie Bonhomme, Legal affairs and Compliance Director, EFPIA *(confirmed)* - Kurt Seiler, Head of Compliance, Roche Diabetes Care *(confirmed)* - Loretta Van der Bie, Global Transparency Officer, Edwards Lifesciences (*confirmed*) - Marcin Rodzinka, Project Manager, Mental Health Europe (*invited*) *Moderator:* Ingmar de Gooijer

		Description: With the spreading transparency laws around the world, is there a need to start discussing global transparency? How can the debate move from Sunshine laws to publishing with a purpose? To help to debate this topic, it is also interesting to learn from the pharmaceutical industry what they would do better in insight; how the public reacted to their disclosure; what were the main questions, and whether there are discussions to also tackle transparency at international level. The practical and operational challenges of national and international rules should also be discussed in this debate.
	12.50 – 14.15	**GMTCC/MTF lunch**
	14.15 – 15.30	**Parallel Session 1: Distributors session** *Speakers:* - Scott Lane, Chief Executive Officer and Chairman, The Red Flag Group *(confirmed)* - Vasso Mangou Kriticos, Sales Manager, Mega Lab AR *(confirmed)* *Moderator:* *Description*: This session aims at addressing aspects such as: - How do companies manage distributors and agents with practical implementation of the new regional codes, as well as policing of these same codes? - Best practices in third party screening as well as engagement of new business partners - Sub-distributors/agents – what level of due diligence is being applied by companies
	14.15 – 15.30	**Parallel Session 2: The digital transformation & compliance: Roundtable discussion with Chief Privacy Officers** *Speakers:* - Jamie O'Donnell, EU VP and General Counsel, ResMed (*confirmed*) - Peggy Bodin, Senior Legal Counsel, Global Privacy Officer, Zimmer Biomet *(confirmed)* *Moderator:* Mary Devlin Capizzi, Drinker Biddle & Reath LLP (*confirmed*) *Description:* This session aims at discussing issues arising from the new digital age and changing business models, such as:

		- What are the new risks coming for the new digital age; - Should the compliance office become digital? - How to ensure data stewardship, in order to deliver new products? What type of governance set up should companies think about? - What are the privacy/data protection/GDPR considerations to keep in mind? - Is there a role for compliance when we talk about Artificial Intelligence? - How could open data and new technologies help to fight corruption and anti-bribery
	14.15 – 15.30	**Parallel Session 3: Workshop: Post-mortem analysis of the MedTech Europe Code** *Moderators:* - Anne Sophie Bricca, Deputy General Counsel, Terumo BCT and chairwoman of the MTE ECC *(confirmed)* - Roeland Van Aelst, VP Healthcare Compliance EMEA & Canada, Johnson & Johnson and chairman of the MTE Code Committee *(confirmed)* *Participating companies* ***(registration only)****:* • Zimmer Biomet *Description:* This workshop is open to up to 12 companies with two representatives each: one Europe/EMEA business leader and one Europe/EMEA compliance officer to discuss the practical challenges (e.g. speaker support) met by companies with regards to the MedTech Europe Code. Key outcomes will be worked into the issues that the MedTech Europe expert groups (i.e. ECC and Code Committee) will tackle. Therefore the presence of the two chair persons of these groups.
	15.30 – 16.00	**Networking Break**
	16.00 – 18.15	**GMTCC Ask the Experts session** *(Loft)* *Main moderator:* *Description:* This session will be set up in roundtable discussions. The time allocated will allow them to get to the heart of key issues. Attendance is limited to 12 persons per table. After 40 minutes, the participants are invited to switch tables. Each table lead will prepare in advance a one-pager with key topics/trends that they plan to address. After the

		discussions, key discussion points/outcome will be added to this one-pager and circulated to all participants. *Topics & Table Leads:* 1. **Brexit: Legal and practical challenges** 2. **Best practices in investigations** 3. **Data Protection & GDPR: one year on:** Peter Blenkinsop, Partner, Drinker Biddle & Reath LLP *(confirmed)* 4. **MTE Code**: Pablo Abad, Legal & Compliance Manager, MedTech Europe (MTE) *(confirmed)* 5. **Conference Vetting System:** Christine Sainvil, ethicalmedtech Compliance Officer *(confirmed)* 6. **Transparency in the Middle East** 7. **Applying the MTE Code in France:** 8. **AdvaMed new Code & key take aways for the future:** Nancy Travis, VP International Compliance & Governance, AdvaMed *(confirmed)* ***9.*** **Placement of equipment:** Adem Koyuncu, Partner, Covington & Burling LLP *(confirmed)* **10. Human rights & supply chain integrity** **11. Distributors** **12. Fair market value** **13. European class action/collective redress** **14. China** **15. India**
	18.30 – 19.30	**Welcome Networking reception**

	19.45 – 22.30	**GMTCC Networking Dinner** *(tbc)* *Sponsor: tbc*

DAY	TIME	GMTCC PROGRAM
THURSDAY 16 MAY		
	9.00 – 10.00	**MTF Plenary session – CEO Panel – #No filter** *Moderator:* Ingmar de Gooijer
	10.05 – 11.10	**GMTCC plenary session: MedTech as solution providers: Compliance challenges** *(Auditorium)* *Speakers*: - Anthony McQuillan, Vice President Legal & Compliance EMEA, Medtronic *(confirmed)* - Regina Puls, VP/Head of Rules and Procedures, Siemens Medical Solutions *(confirmed)* *Moderator:* Ingmar de Gooijer *Description:* The industry has been discussing the concept of value in healthcare systems as well as what it means in terms of new commercial models for a few years, but the legal and compliance challenges that these bring along a numerous and vary depending on which part of the world you are looking at. This session aims at discussing the significant organisations, legal and compliance challenges in the transition from a product-driven industry to one focused on services. To help that discussion, the panel will be looking at some hypotheticals.
	11.10 – 11.30	**GMTCC networking break**
	11.30 – 12.50	**Parallel Session 1: Role of industry in CME education** *Speakers:* - Prof. Vassilios Papalois, Secretary General of the European Union of Medical Specialists (UEMS) (*confirmed*) *Moderator:* *Description:* This session aims at discussing industry's role in supporting continuing medical education. What type of

		measures can be put in place to safeguard the provision of high quality, balanced medical education? What level of industry involvement is appropriate in order to allow essential interaction between the medical profession and medical industry?
	11.30 – 12.50	**Parallel Session 2: Compliance effectiveness & Risk management** *Speakers*: - Sapan Singh, Director Compliance, Global Indirect Channels and Data Analytics Programs, Stryker *(confirmed)* *Moderator:* George Fife, Associate FIDS, EY *(confirmed)* *Description:* This session aims at discussing: - How to harness data inside of the organisation in order to support the compliance function? - How to leverage the activities of other business parts within the same organisation? - Best practice exchange on how to measure effectiveness of key elements of compliance programs and initiatives with the data and analytics - Influence, integrity of data and new technologies
	11.30 – 12.50	**Parallel Session 3: Best practice exchange when providing Educational Grants: 1,5 years after the phase out of Direct Sponsorship** *Speakers:* *Moderator*: Thomas K. Hauser, Life Sciences Governance, Risk Management & Compliance, Navigant (*confirmed*) *Description:* This session is aimed at allowing companies to exchange of best practices in providing Educational Grants in Europe, following the ban of direct sponsorship at the beginning of 2018. How is this being managed within the different companies? How are companies monitoring compliance?
	12.50 – 14.00	**GMTCC & MTF Networking Lunch**
	14.00 – 14.40	**GMTCC Plenary session: Closing remarks & discussion** *Speakers:* - Anne Sophie Bricca, Deputy General Counsel, Terumo BCT and chairwoman of the MTE ECC *(confirmed)*

		- Dorothy Clark, vice president Healthcare Compliance, Johnson & Johnson and chairwoman of the AdvaMed DDCG *(invited)* *Moderator:* Ingmar de Gooijer
	14.40 – 14.50	*Change of rooms*
	14.50 – 15.40	**MedTech Forum plenary session: Disruptors** *Speakers:* - Josh Riff, CEO, Onduo *(confirmed)* *Moderator:* Ingmar de Gooijer *(confirmed)*
	15.40 – 16.00	**MedTech Forum closing**

GMTA Compliance Network

- Background:

  Similar trends in compliance are happening all over the world and in order to exchange best practices and trying to harmonise ethical business practices globally, companies members of MedTech associations around the world thought of creating a forum to do just that. This is supported and organized under the umbrella of GMTA.

  GMTA is the Global Medical Technology Alliance. Its members are national or regional medical technology associations, such as MedTech Europe and AdvaMed (for all members click here), which represent innovative companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics and equipment. It provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs.

- Composition:

  - Member companies' CCO as well as regional leads: EMEA, Asia Pacific, US, Latin America, Australia-NZ compliance officers
  - Associations Members of GMTA either CEO or Legal/Compliance director

- Mission:

Establish a network of MedTech compliance officers around the world, in order to seek collaboration with all industry players at global level to exchange best practices and trying to harmonise ethical business practices and promote the need and value of a culture of integrity and ethical business practices across the healthcare sector to continue to work for the patients' best interests.

- Topics/agenda

  - Welcome & introduction
  - Country updates – focus on key countries in each region
  - Panel discussion on Educational Grants systems around the world: Key take aways
  - What's next? (e.g. how to tackle new topics such as Code convergence; Transparency, Distributors?)
  - Closing remarks