More needs, Higher expectations, Smaller Budgets
Can the European MedTech Industry deliver?

15-17 October 2014, Dolce La Hulpe (Belgium)

DRAFT PROGRAMME

Last update 08 September 2014
(subject to change)

The European MedTech Forum is the largest health and medical technology industry conference in Europe. Organised by MedTech Europe's alliance members Eucomed and EDMA, the seventh edition of the MedTech Forum will take place on 15-17 October 2014 at the Dolce La Hulpe, Brussels.

Last year the conference brought together more than 500 participants active in the EU healthcare scene, including policymakers, scientific communities, patients' representatives, healthcare professionals, academics and representatives of the global medtech industry.

This year's edition will revolve around the theme "More needs. Higher expectations. Smaller budgets. Can the European MedTech Industry deliver?" Read more…

WEDNESDAY 15 OCTOBER

9.00 – 17.00 EDMA and Eucomed working group meetings

EDMA

- Regulatory Affairs Committee

Eucomed

- Regulatory Affairs Committee
- Market Access and Economic Policies Network
- Cardiovascular Sector Group
- Ophthalmology Group
- Surgical Care Sector Group

EDMA & Eucomed

- Communications Network

Other

- Global Medical Technology Alliance (GMTA)
- Patient MedTech Dialogue

17.30 – 21.30 Reception and Buffet dinner*

**Dress code: smart casual*

THURSDAY 16 OCTOBER (ALL SESSIONS BELOW ARE TENTATIVE AND SUBJECT TO CHANGE)

Day moderator: Cathy Smith, former BBC presenter and correspondent

9.30 – 10.00 Welcome coffee & Registration

10.00 - 10.30 Views from the MedTech Europe leadership

Jürgen Schulze, Rob ten Hoedt and Serge Bernasconi, together forming the leadership of MedTech Europe, will elaborate on how they view the environment in which the European MedTech industry operates. Focus will be given to key opportunities and challenges for the short and long term.

Speakers:

- Serge Bernasconi, CEO, MedTech Europe, EDMA & Eucomed
- Rob ten Hoedt, Chairman, Eucomed
- Jürgen Schulze, President, EDMA

10.30 - 11.30 The real value and practical implications of Big Data

Healthcare seems to have entered the 'big data' era. But has big data generated the knowledge necessary to bring personalized medicine to the clinic for example? For MedTech companies to thrive in the big data environment, technologies must find their place in a system where data is constantly being created, harvested, and used to make decisions. This session seeks to unravel and understand what 'big data' actually means for MedTech and how companies can survive and prosper in the new era.

Speaker:

- Sastry Chilukuri, Partner, McKinsey & Company
- John Parkinson, Director, Clinical Practice Research Datalink
- Klaus Stoeckemann, Co-founder & Managing Partner, Peppermint Venture Partners

11.30 – 12.00 Networking break

12.00 – 13.15 Parallel workshops

Parallel workshop I: Market Access: The benefits and challenges of 'Coverage with Evidence Development'

CED is increasingly being used to provide provisional coverage of medical devices while additional data is generated. EHTI has investigated the presence of CED policies worldwide and their application to medical devices in order to understand the key challenges for CED policies in general and for medical devices in particular and to identify the strategies to improve the current use of CED. In addition to outlining these challenges and strategies this workshop will present the views and experiences of national authority agencies implementing CED. Participants will also have an opportunity to share and discuss experiences of the schemes, resulting in a comprehensive overview of what to expect from coverage with evidence schemes.

Speakers:

- Mike Drummond, Professor of Health Economics, University of York
- Hedi Schelleman, Advisor, National Institute of Health Care, Netherlands

Parallel workshop II – Bringing value to your business through patient partnerships

During this workshop participants will learn about the benefits and value which a patient focus can bring to their companies. Through the Patient-MedTech Dialogue, an initiative of the European Patients Forum and MedTech Europe, leading pan-European patient organisations and medtech companies have partnered together to develop a 'checklist' that characterises a patient-centred company. These characteristics and their value to companies and patients alike will be discussed and debated. A number of case studies, showcasing patient-industry partnerships and the benefits which have been reaped by the companies involved, will also be presented and discussed.

Moderator:

- Cathy Smith, former BBC presenter and correspondent

Speaker:

- Audrey Craven, President, European Federation of Neurological Associations
- Michael Heuer, President Europe, Middle East, Africa & Latin America, Roche Diagnostics

Parallel Workshop III – Root cause analysis and managing Corrective and Preventive Actions (CAPAs) in a regulatory environment – sponsored by Maetrics

Recently FDA warning letters have identified CAPA programs as a source of significant quality system weakness. It is crucial that your organization is effectively implementing a CAPA system to ensure quality. This workshop provides strategies and best practices to implement, sustain, and ensure effectiveness of a CAPA program. Attendees will gain an understanding of the importance of CAPAs and root cause analysis, discover how to monitor the effectiveness of your CAPA program, identify effective root cause analysis tools and learn how to utilise them properly, explore common challenges and pitfalls with CAPAs and root cause analysis and understand how to avoid them, and learn best practices in deploying end to end CAPA program.

Parallel Workshop IV: From information to insight – how data is reshaping the future of healthcare and MedTech – sponsored by McKinsey & Company

The future of healthcare is changing in exciting and new ways. The advances in technology and data availability, together with an appetite to use them to increase outcomes in an era of decreasing budgets, is creating real discontinuities and giving rise to opportunities. Together we will discuss what data in healthcare means, how it is already affecting the environment, what opportunities it creates, and how these can be captured.

13.15 – 14.15 Networking lunch

14.15 – 15.15 The future of medical education

The need for medical education will remain but the way it is currently being delivered and funded may need to change. How would the perfect model for medical education look like and how can we make sure that healthcare professionals remain abreast of all the innovations in the MedTech arena? In this session you will hear different views from various stakeholders about the future of medical education

Speakers:

- Alexandre Connroy, President Americas, Europe Middle East, BD
- Thierry Herbreteau, Chief Executive Officer, Europa Organisation
- Prof. William Wijns, Co-Director, Cardiovascular Centre, Aalst

15.15 – 15.45 In discussion with payers: What do they really expect from the MedTech industry?

There is a growing perception that payers need to work with industry to solve problems. During this session speakers will address how this increased collaboration will look in the future, what format it will take, the potential benefits of collaboration and the problems that stand in its way.

Speaker:

- Silvia Ondategui-Parra, Global Market Access Leader, Ernst & Young

15.45 - 16.15 Networking break

16.15 – 17.30 Parallel workshops

Parallel workshop I - New EU funding opportunities: Should my company be involved?

In light of the increased financial constraints facing healthcare, this workshop will provide information on two key programmes financed by the European Commission - Horizon 2020, focused on research and innovation projects, and DG Sanco's Third Health Programme 2014-2020, focused on fostering good health and well-being. Speakers will present a broad overview of opportunities and discuss with participants how medical device and IVD companies can be involved.

Participants will receive advice on applying for grants, project management, and funding opportunities relevant for our Industry, practical tips on how to get involved, and concrete examples of companies from the health sector which have successfully participated in these programmes. A dynamic Q and A will follow, allowing company representatives to get the answers to those burning questions on how to feasibly participate and benefit from these programmes.

Moderator:

- Ludmilla Schlageter, Vice President Government Affairs Healthcare, Siemens

Speakers:

- Djilali Kohli, Manager Financial Subsidies Services, Kurt Salmon
- Arnd Hoeveler, Head of Unit Medical Developments, Directorate-General for Research and Innovation, European Commission

Parallel workshop II: How to win in the new payer ecosystem – sponsored by Ernst & Young

MedTech companies find themselves in increasingly unfamiliar terrain. Stricter regulatory regimes are partly the cause, but they pale in comparison with the complex relationships companies must forge with payers. How can the industry earn to embrace this complexity and cement new, better relationships with its most important customers? This workshop, incorporating new EY research, will generate discussion and debate among an audience of leading medtech practitioners.

Speakers:

- Patrick Flochel, Global Pharmaceutical Sector Leader, Ernst & Young
- Silvia Ondategui-Parra, Global Market Access Leader, Ernst & Young
- Iain Scott, Lead Analyst Global Life Sciences Center, Ernst & Young

Parallel workshop III – The EU Procurement Directive: Procuring value for money under the new rules

Considering the new Directive's deep focus on innovation, the MedTech industry and Trade Associations, can play a key role in supporting National Governments in their efforts to ensure a smooth and fast adoption of the new rules.
In this workshop attendees will gain a better understanding of the impact of the new rules. Participants will also gain insights into the MedTech industry's concerns and suggested solutions regarding key topics such as the use of the most economically advantageous tender (MEAT) criterion; E-procurement, and the 'Innovation partnership' tool and its potential for our industry. A panel composed of experts in Procurement related fields will discuss these issues and dive into the key features that Member States ought to consider and discuss during the transposition period.

Moderator:

- João Costa, Legal & Compliance Counsel, Medtronic

Speakers:

- Alyson Brett, Chief Executive Officer, NHS Solutions

- Caroline Hobson, Partner, CMS Cameron McKenna LLP
- Kjetil Marius Istad, Director of Purchasing and Logistics, Helse Sør--Øst RHF, Norway

Parallel workshop IV – Think evidence – How clinical evidence requirements will affect the IVD industry in Europe

An overview of the current thoughts and developments in the field of clinical evidence in the upcoming IVD Regulation. What clinical evidence entails and strategies for compliance will be explored as well as specific cases of IVDs, from the well-established to novel tests all of which will need to demonstrate clinical evidence. There will also be a review of thinking at the international level and the activities to harmonize clinical evidence requirements for IVDs around the world.

Speakers:

- Benny Ons, Director of Regulatory Affairs, Regulatory Compliance and Quality Management, BD Biosciences Europe
- Jesús Rueda Rodriguez, Director, Regulatory Affairs, EDMA

17.30 – 18.30 The European MedTech CEO Debate

Healthcare budgets are shrinking, but can the MedTech industry deliver and meet the needs and expectations of patients, payers and healthcare systems? During this session leaders from medical device and in vitro diagnostics companies will debate these challenges and share their experiences.

Speakers:

- John D. Coulter, Vice President, Diagnostics, Commercial Operations, Europe, Middle East & Africa, Abbott
- Cristiano Franzi, President, Covidien Europe
- Ciro Römer, Company Group Chairman, Global Orthopedics Group International, Johnson & Johnson

19.00 - 23.00 Reception and Gala Dinner*

**Dress code: Business attire*

Keynote address:

Prof Bongani M. Mayosi, Professor and Head of Department of Medicine Faculty of Health Science, University of Cape Town; Chief Specialist at Groote Schuur Hospital, Cape Town; President, South African Heart Association

FRIDAY 17 OCTOBER (ALL SESSIONS BELOW ARE TENTATIVE AND SUBJECT TO CHANGE)

Day moderator: Cathy Smith, former BBC presenter and correspondent

8.00 – 8.45 Welcome coffee & registration

8.45 – 09.15 Cutting to the chase – Is the MedTech industry delivering?

This session will determine if the MedTech industry is living up to expectations and how these expectations are likely to change in the coming years and address the key question of this year's conference theme.

Speaker:

- Kermit King, Senior Partner and Managing Director, BCG

09.15 – 10.15 Health consumerism and newcomers – a double blessing for MedTech?

The entrance of Apple, Samsung and other new players into the MedTech space has garnered widespread media attention and public interest. The entrance of these new players coincides with a wider trend of empowered and informed patients who know what they need and want from their technologies. What does industry need to know about these new entrants? How can the MedTech industry effectively interact with educated patients? How can traditional MedTech demonstrate its value and grow stronger against a backdrop of increased health consumerism? These questions and more will be addressed during a panel discussion.

Speakers:

- Brian S. Williams, Director Global Healthcare Strategy, PricewaterhouseCoopers
- Nikolaus Schumacher, CEO, Lifepatch
- Thierry Zylberberg, Head of Orange Healthcare

10.15 - 10.45 Networking break

10.45 – 12.00 Parallel Workshops

Parallel workshop I - How the 'new' MedTech business model is taking shape – sponsored by BCG

The MedTech industry continues to face pricing pressures that impact market access and reimbursement. Last year BCG presented MedTech's "New Business Model" at the MedTech Forum and this year they will discuss with participants how the new operating model is taking shape. Lessons learned and suggestions for future improvements will be the key focus of this interactive workshop session.

Parallel Workshop II – Innovation and opportunities for patient safety: Can Europe learn from the US example?

The US Department of Health and Human Services has set concrete targets for the reduction of specific healthcare-associated conditions as part of its plan to reduce the burden of adverse events, targets it is well on its way to meeting. Meanwhile in Europe, where healthcare-associated infections alone account for 37,000 deaths and impact 4.1 million patients annually, the situation is not improving. Tighter budgets are oft blamed for adding pressure to already strained systems and requiring more from a reduced number of healthcare employees, yet as the need for improvement has not disappeared, even as funds have, what can Europe do to step up its patient safety activities? What lessons can Europe learn from the US and are policymakers, industry and healthcare professionals ready for such changes? These questions and more will be debated by a panel of stakeholders from across the healthcare sector.

Speaker:

- Scott K. Fridkin, Deputy Surveillance Branch Chief, Division of Healthcare Quality Promotion, Centres for Disease Control and Prevention

Parallel Workshop III – MDD Revision Unplugged: How close are we?

As a follow-up to last year's popular session this workshop will look at the legislation 12 months further on as stakeholders assess where we are vs. where we thought we would be.

A high-level session, featuring both current and new players in the medical devices regulatory policy making process will provide an insight on what's envisaged in the coming months and how business leaders can prepare accordingly. This interactive discussion will allow decision makers and senior industry regulatory affairs leaders to have an open exchange on key issues of importance to them, while touching upon topics such as the approval system for certain categories of high-risk class medical devices and the revised clinical requirements.

Speakers:

- Roland Gerard, Chair, Eucomed Regulatory Affairs Committee; Vice President Regulatory Affairs and Quality Assurance, International Division, St, Jude Medical
- Despina Spanou, Director, Consumer Affairs, Directorate-General for Health and Consumers, European Commission

Parallel workshop IV - Innovative technology and community care: The answer to healthcare challenges?

In this workshop participants will learn why the community is a more appropriate site of healthcare delivery than hospital for those with chronic conditions, and how well-designed community care structures can help offset the challenges of an ageing population. Panellists will discuss the role that medical technology innovation can play in community care and decreasing the need for in hospital treatment. The benefits to society and healthcare systems of a shift towards prevention and care within the community will also be debated during the workshop.

Moderator:

- Ameer Ally, Chair Eucomed Community Care Sector Group ; Senior Director Healthcare Economics, Policy & Reimbursement, Covidien

Speakers:

- Marina Lupari, Professional Lead, Primary Care and Community Nursing, Royal College of Nursing, London
- Amanda Massey, Executive Director, Health First Europe

12.00 – 12.30 Networking break

12.30 – 14.45 EDMA and Eucomed General Assemblies
EDMA and Eucomed members only