nore
Network of Orthopaedic Registries of Europe

NIMAC symposium

Friday, April 6th 2018
Brussels

Engaging with the new EU regulatory landscape for medical devices

Challenges and Opportunities

NORE (Network of Orthopaedic Registries of Europe) an EFORT standing committee
NIMAC symposium
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NH COLLECTION BRUSSELS CENTRE | Boulevard Adolphe Max - Adolphe Maxlaan, 7
1000 Brussels – Belgium

PROGRAMME

Engaging with the new EU regulatory landscape for medical devices.
Challenges and opportunities

Please note:
Individual speakers will decide whether they either present data in a formal or informal way, institute a debate on their topic or have a Q&A or have a mix.
At the end of each presentation we would like the chair people to summarise the output in a series of bullet points.

10.00 - 10.30	**Coffee**	**Foyer 2nd floor**
		Boardroom Liège 2nd floor
10.30 – 10.35	**Welcome & Introductions**	***Rob Nelissen***
10.35 – 12.00	**SESSION 1:**	
	The political and patient safety picture – Involving Regulators, scientists, industry and Clinicians in the EU decision making process	***Chairpersons:*** ***Tom Melvin and Per Kjaersgaard-Andersen***
10.35	Where we stand in EFORT	Per Kjaersgaard-Andersen
10.45	The Life of a TJR; the stages of regulating and monitoring a total joint replacement now and the future	Keith Tucker and Amie Smirthwaite
11.05	Major Proposals from the new Medical Devices Regulations	Tom Melvin
11.20	Impact on Industry of new regulations for medical devices	Oliver Bisazza
11.35	Patient Safety: the Regulatory Perspective and the Impact of the new MDR	Mark Grumbridge
11.50	Expert engagement in policies for scientific research and innovation in the EU	Rob Nelissen
12.00 - 12.15	**Coffee break**	**Foyer 2nd floor**
12.15 – 13.15	**SESSION 2:**	
	The new EU Medical Device Regulations	***Chairspersons:*** ***Amie Smirthwaite and Rob Nelissen***
12.15	Shifting paradigms for high-risk devices – the objectives of the new regulations Orthopaedics – lessons learned from the past	Jörg Lützner and Per Kjaersgaard-Andersen
12.30	Rational minimum requirements for evidence of medical devices	Christine Quinton
12.45	Minimum requirements, clinical practice and lessons learned from the past	Tim Wilton
13.00	Discussion and Review of the morning's presentations	All
13.15- 14.00	**Lunchbreak**	**Restaurant with a view 9th floor**

14.00 – 14.15	**Questions and answers on morning session**	***Chair: Rob Nelissen***
14.15 – 15.15	**SESSION 3:** **What to do next, quality and safety for future patients**	***Chairpersons:*** ***Christine Quinton and Oliver Bisazza***
14.30	Monitoring by registries or do we still need clinical trials? The Pros and Cons	Sion Glyn Jones
14.45	Post-market clinical follow-up and registries, the example of the Dutch Arthroplasty, LROI	Rob Nelissen
15.00	The future from the eyes of a surgeon who is also connected to a manufacturer	Luca Orlandini
15.15 – 15.30	**Coffee break**	**Foyer 2nd floor**
15.30 – 16.15	**SESSION 4:** **Initiatives on quality and safety for future patients**	***Chairpersons:*** ***Luca Orlandini and Tim Wilton***
15.30	Pre-market approval guidelines and the new MD regulations	Amie Smirthwaite
15.45	NIMAC What could it say to Brussels?	Keith Tucker
16.00	**Review of presentations, Summary and Conclusions** An opportunity for each presenter to add a comment to what they originally said or change their mind! Your THM (Take home message)!! Train to London leaves at 17.56 hrs.	Rob Nelissen

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Faculty	**Presentation**
Prof.Rob Nelissen Orthopaedic Surgeon, Chair Dutch Arthroplasty Register (LROI) and Chair of NORE	- Value of real world data (registries) - Metrics to safeguard new implants introduction
Tom Melvin Medical Officer Medical devices HPRA, Co-Chair CIE group	
Mark Grumbridge Senior Clinical Advisor – Devices MHRA	This presentation will give an overview of patient safety from a competent authority perspective. Initiatives that impact patient safety will be examined along with patient safety aspects of the new MDR.
Oliver Bisazza MedTech Europe	
Amie Smirthwaite BSI, Member of NORE Advisory Committee	(see Keith)
Tim Wilton Orthopaedic Surgeon BOA, BC and ODEP	The presentation will show that detailed and timely examination of Registry data is essential for the initial tranche of cases with a new implant. Raw revision data is simply not enough and the capacity to go back and interrogate doubtful factors has proved absolutely essential during the recent UK monitoring programme. More than one outcome measure is also proving vital during the introduction of an implant.
Christine Quinton Regulatory Affairs G-MED Certification Division, Certification and Standards Department – LNE (or deputy)	
Luca Orlandini MedTech Europe, Orthopaedic Surgeon Medical Director Smith and Nephew Europe	My presentation will focus (with concrete examples) on operational aspects required to satisfy the actual and future level of evidence asked to a manufacturer and how much these translates or should translate into factual information and guidance to the practicing HCP. Additionally I will try to consider the sustainability of data generation both at clinical as well as manufacturer level, with a consideration on the growing role of wearable devices and new technologies for patient data collection.
Keith Tucker Retired orthopaedic Surgeon, Chair ODEP and Beyond Compliance advisory group. Member of NORE Advisory Committee	• Presentation 1 (Amie and Keith) We will endeavour to go through the present milestones which an implant has to pass before it is on the market and the conditions that allow it to stay there • Presentation 2 (at the end) We will endeavour to add to presentation 1, the new standards that have been outlined during the conference.
Per Kjaersgaard-Andersen 1st vice-President EFORT	
Prof. Dr. med. Jörg Lützner Orthopaedic surgeon, member of EPRD	Problems with orthopaedic implants, e.g. hip resurfacing
Siôn Glyn-Jones Professor of Orthopaedic surgery and Honorary consultant orthopaedic surgeon, Nuffield Orthopaedic Centre - Oxford University Hospitals	