16th Regulatory and Scientific Affairs Conference
Meeting the Future Challenges and Opportunities
in the Regulatory Environments
25 - 26 - 27 January 2017
Radisson Blu Portman hotel, 22 Portman Square, London W1H 7BG, UK

Wednesday 25 January / Telematics Pre-conference Workshop (optional)
This optional interactive workshop will give you a detailed update on the latest developments of the Identification of Medicinal Product (IDMP) implementation and the impact on business processes. It will also cover the practical aspects how to be prepared for smooth implementation.

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<th>Time</th>
<th>Session</th>
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<tr>
<td>13:00 - 14:00</td>
<td>Registration and networking lunch</td>
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<tr>
<td>14:00</td>
<td>Opening address</td>
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<td>14:10 - 15:45</td>
<td>Session 1 - Identification of Medicinal Product - first reflections on implementation begin: what lies ahead?</td>
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<td>How far are with the implementation process? Plan for upcoming years and 2017 to-dos - Isabel Chicharo, EMA</td>
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<td>Are national competent authorities sufficiently prepared? Reflections from the NCA representative - Kevin Horan, HPRA, (IE)</td>
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<td>Industry’s perspective on challenges and opportunities - Remco Munnik</td>
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<td>Q&amp;A Session</td>
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<td>15:45 - 16:15</td>
<td>Networking coffee break</td>
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<td>16:15 - 18:30</td>
<td>Session 2 - Showcases: How can we best prepare for smooth implementation?</td>
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<td>This interactive session will cover the practical aspects of IDMP implementation and the impact on business processes and software tools. Three different examples will be given to address the topic in a holistic way.</td>
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<td>1.</td>
<td>ISO IDMP: where to start? Company’s readiness, service and product. How and where to find all relevant information to keep up the pace of implementation.</td>
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<td>Chair</td>
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<td>2.</td>
<td>Data migration – how to deal with the transition from XEVMPD to ISO IDMP. How to avoid traps, what you should be aware of and focus on. Practical examples.</td>
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<td>Each showcase will be followed by a Question &amp; Answer session for any queries not covered during the session. Workshop participants are kindly invited and encouraged to provide their questions in advance by email to <a href="mailto:lucia@medicinesforeurope.com">lucia@medicinesforeurope.com</a> as soon as possible.</td>
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<tr>
<td>18:15</td>
<td>Summary &amp; closing statements</td>
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<td>18:30</td>
<td>Cocktail reception</td>
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PRE-CONFERENCE TELEMATICS WORKSHOP SPONSORS

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Thursday 26 January 2017

DAY I - 16th Regulatory and Scientific Affairs Conference

08:00 - 09:00  Registration and networking welcome coffee

09:00  Opening and welcome address | Adrian van den Hoven, Director General, Medicines for Europe

09:00  Opening Session - Looking to future patient care - a new role for the pharmaceutical sector in 2025?
Chair | Beata Stepniewska, Deputy Director General & Head of Regulatory Affairs, Medicines for Europe

This session will set the scene for a political discussion on the future direction of the pharmaceutical sector and the role of regulators in responding to new developments.

Introductory presentation setting the scene, followed by a high level panel discussion | Pierre Meulien, Executive Director, Innovative Medicines Initiative (IMI)

- What will patients expect from their medical treatments?
- How will patient disease treatment pathways evolve? How to best integrate diagnostics and digital tools?
- What is the role of Medicines Agencies and Ministries of Health in shaping the future regulatory framework? How should pharmaceutical legislation evolve? In which direction?
- Big data in healthcare: utopia or the near future? Will future legislation balance data collection, data assessment and data privacy?
- Is the paradigm of assessment (QSE) still accurate or should criteria focusing on patient outcomes be included?
- What will be the future role of well-known medicines - generic, biosimilar and value added medicines?
- What will be the role of the pharmaceutical industry and the evolution within the industry? How should industry adapt to the future reality?
- Globalisation - a challenge or an opportunity?

Panel Discussion composed of session speakers Andrzej Rys, Health systems, medical products and innovation Director, DG Sante, European Commission; Hugo Hurts, Executive Director MEB (NL); Iris Grossman, VP, Head of Personalized & Predictive Medicine, Analytics and Big Data (PPM-ABD), Global R&D, Teva

10:30 - 11:00  Networking coffee break

11:00  Session 2 - Optimisation of regulatory operations- the way forward in 2017 and beyond
Chairs | Hugo Hurts, Executive Director MEB (NL) and Beata Stepniewska, Deputy Director General, Head of Regulatory Affairs, Medicines for Europe

- Driving the efficiency agenda | Peter Bachmann, Chair of the CMDh, BfArM (DE) from the Authorities and Caroline Kleinjan, Chair of the Medicines for Europe’s Regulatory and Scientific Affairs Committee, Sandoz
  - Business needs of the Competent Authorities and the industry
  - Mapping common interests

- Regulatory maintenance of medicinal products in a cost efficient way | Kevin Horan, HPRA, (IE)
  - The lean model to apply
  - Challenges of the variation process
  - Data quality

- How to move into a new fee model? | Christa Wirthumer-Hoche, AGES, (AT)
  - Different fee models
  - The Austrian way to flat fees – sharing an experience
  - The way forward recognising the pros and cons

Q&A Session with a panel composed of session speakers and Susanne Winterscheid, BfArM (DE)

12:30 - 13:45  Networking buffet lunch

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### Session 3 - How can we make technology our friend and get support in solving regulatory challenges?

**Chairs** | *Francisco Peñaranda Fernández*, EMA and *Remco Munnik*, Asphalion, Chair of the Medicines for Europe Telematics Working Group

*This session takes a broad look at some opportunities offered by the on-going implementation of processes and technologies which might address current regulatory challenges.*

- **Standardisation of data - ISO IDMP: are we aware of the potential?** | *Francisco Peñaranda Fernández*, EMA
- **Single assessment of the Active Substance and substance database - how to use the IDMP and gain efficiency in handling assessment?** | *Stan van Belkum*, MEB (NL)
- **Improving regulatory efficiency with the use of IT systems - planning the trip, buying the ticket or on the train already?** | *Stan van Belkum*, MEB (NL)
- **Single submission portal - will it bring everything together?** | *Georg Neuwirth*, AGES (AT)
- **Falsified Medicines Directive implementation: is there any possible benefit of using the system more broadly and connecting to other databases?** | *Kelly Hnat*, TEVA

**Q&A Session with a panel composed of session speakers**

### 15:30 - 16:00

**Networking coffee break**

### 16:00

**Session 4 - Data quality and integrity - How can Industry and regulators collaborate to mitigate data integrity issues?**

**Chairs** | *Anabela Luis De Lima Marçal*, EMA and *Koen Nauwelaerts*, Medicines for Europe

*This session will focus on the initiatives taken by regulators and industry to assure product supply chain and data integrity both from a European and International perspective and will offer the opportunity to discuss future strategies.*

- **Creating confidence in the quality and the integrity of data through good regulatory practices - An industry perspective** | *Ignacio Moreno*, Apotex
- **Expanding data integrity guidance to GxP - A GCP inspector perspective** | *Stephen Vinter*, MHRA (UK)
- **Assuring data quality and integrity in bioequivalence studies** | *Susana Almeida*, Inflamax Research

**Panel discussion** composed of session speakers

### 17:30

**Closure of the day**

### 19:30

**Conference dinner** | **Informal attire**
Friday 27 January 2017

**DAY II - 16th Regulatory and Scientific Affairs Conference**

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<th>Time</th>
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| 09:00 | Session 5 - Watch this space in 2017! | Chair | Beata Stepieniewska, Deputy Director General, Head of Regulatory Affairs, Medicines for Europe  
*This session covers several stand-alone topics to raise awareness in the industry of the upcoming implementation process and developments in the regulatory environment.*  
- New ICH guidelines under development: BSC Biowaiver and Bioanalytical Methods Validation | Susana Almeida, Inflamax Research  
- EU-US Trade Agreement - an opportunity for more regulatory convergence and mutual recognition? | David Gaugh, GPhA  
- Needs of the digital patient  
  - Apps to accompany your medicines - how will they be regarded by the regulators? | Valerie Field, Interim Group Manager Regulatory, Devices Division, MHRA (UK)  
  - Electronic product information - a future way of providing patients with information on medicinal products? | Kevin Airey, Mylan  
Q&A Session with a panel composed of session speakers |
| 11:00 - 11:30 | Networking coffee break |
| 11:30 | Session 6 - How to align on transparency of the global supply chain in the most efficient way and how to handle conflicts of interest | Chairs | Lynne Byers, Novartis and Mark Birse, MHRA, UK  
*This session will address the impact of current expectations from assessors and inspectors toward more supply chain information in the regulatory dossier and a more extended audit programme. Speakers will explore how the right balance can be found to allow compliance, transparency and operability.*  
- Conflict of interest - Legal analysis, findings and recommendations from Medicines for Europe | Lynne Byers, Novartis  
- How to maintain oversight of a globalised and fragmented supply chain - An inspector’s perspective | Mark Birse, MHRA, UK  
- The interplay between GMP and regulatory obligations - An industry perspective - Industry Speaker | Koen Nauwelaerts, Medicines for Europe  
- Assessors’ expectations - Why is transparency necessary and how can it be obtained in a pragmatic and effective way? | Thoughts of Jean-Louis Robert, Chair QWP will be presented by Mark Birse, MHRA, UK  
Q&A Session with a panel composed of session speakers and Marijke van Daalen, APIC |
| 13:00 - 14:30 | Networking buffet lunch |
| 14:30 | Session 7 - Put your questions to the Regulators | Chairs | Peter Bachmann, BfArM (DE) and Caroline Kleinjan, Sandoz  
*An opportunity to address questions to the European Regulators on various regulatory issues. Questions should be formulated generally, without reference to a given product/procedure and should be sent as soon as possible to beata@medicinesforeurope.com*  
Q&A Session with representatives from the EU authorities: Susanne Winterscheid, BfArM (DE) | Alberto Ganan Jimenez, EMA | Christin Olofsson, MPA (SE) | Rui Vilar, INFARMED (PT) | Kora Doorduyn-van der Stoep, MEB (NL) | Keith McDonald, MHRA (UK) | Maria Luisa Garcia-Vaquero Donaire, AEMPS (ES) | Sophie Colyn, FAGG (BE) | Joan Boye, DMA (DK) | Nienke Rodenhuis, MEB (NL) |
| 16:00 | End of conference and networking coffee |

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