
# 19th REGULATORY AND SCIENTIFIC AFFAIRS CONFERENCE

## Thursday 30 January 2020

**08.00 – 09.00** Networking Welcome Coffee and Registration

**09.00 – 09.15** Opening address - Christoph Stoller, President of Medicines for Europe, Teva

**09.15 – 10.45** Session 1: Looking to the future - Strategy 2025 for pharmaceuticals

***This session will set the scene for a political discussion on the future direction of the pharmaceutical sector, focusing on the regulatory landscape for off patent medicines.***

**Chair:** Adrian van den Hoven, Director General, Medicines for Europe

**New EU political landscape - how will it impact pharmaceutical policy?**

**Priorities of the new European Commission related to pharmaceuticals**
Andrzej Rys, Health Systems and Products Director, DG SANTE, European Commission

**EMA and HMA Strategy 2025**
Guido Rasi, Executive Director, European Medicines Agency (EMA)
Lorraine Nolan, Chief Executive, Health Products Regulatory Authority (HPRA), (IE) a Member of the Heads of Medicines Agencies (HMA) Management Board
Rúna Hauksdóttir Hvannberg, Executive Director, Icelandic Medicines Agency - IMA (IS)

**Digital Agenda for pharmaceuticals - How can the EU Telematics Strategy deliver building blocks for future regulatory and operational efficiency?**
Karl Broich, President, BfArM (DE)

**Medicines for Europe Manifesto for 2025 - what could help to increase patient access to generic and biosimilar medicines from a regulatory perspective**
Beata Stepniewska, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe

Panel Discussion composed of session speakers and Caroline Kleinjan, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz

**10.45 – 11.15** Networking Coffee Break


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**11.15**
**12.45**

## Session 2: Availability of medicines

***The session will address the wider aspect of availability of medicines for patients and what all involved parties can do to avoid disruption in a patient's access to treatment. The perspective of various stakeholders, their challenges and their role in preventing shortages of medicines will be discussed.***

**Chair:** **Koen Laenen**, Quality and Regulatory Affairs Manager, Medicines for Europe

**What measures could be put in place to respond better to issues of availability of medicines?**

- Possible regulatory solutions to better mitigate and reduce the risk of shortages
- Handling supply chain challenges in view of preventing and mitigating shortages
- Regulatory and market incentives to authorise and maintain essential medicines for patients
- Detection and notification of shortages
  - How can communication be aligned between the authorities and MAHs to prevent and mitigate the supply issue?
  - Pilot project

**Panel Discussion** composed of representatives from the authorities, the EC and the industry: **Sandy Kweder**, FDA Liaison to EMA; **Giorgio Riccò**, TEVA Pharmaceuticals; **Esther Martinez**, EMA; **Laure Geslin**, FAMHP (Belgium); **Geraldine Moore**, Mylan; **Andrzej Rys**, DG SANTE, European Commission

**12.45**
**14.00**

## Networking Buffet Lunch sponsored by AMPLEXOR

**14.00**
**15.30**

## Session 3: Why is now the right time to modernise the variations system and the Variations Regulation in the EU?

***The current regulatory framework for the lifecycle management of medicinal products needs to evolve to better reflect scientific and technical progress and ensure operational efficiency in line with the objective of Better Regulation. The session will focus on experience gained since 2008 and an opportunity to move to a more adaptable, proportionate and optimised approach that better supports the innovation and life cycle of medicines.***

**Chair:** **Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe

**Issues to be discussed:**

- Which new factors have influenced the maintenance of medicinal products over the last 10 years?
- Where does the current EU regulatory system to report changes to the MA constitute a barrier rather than a support in bringing updated information and innovation to products on the market in a timely manner?



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- Where does the Variations system not achieve the principles of better regulation which aim to balance regulatory objectives with the need to reduce administrative burden for companies and authorities?
- How can the EU regulatory system of Variations to the MA be improved taking into account the technological and scientific evolution?
- Which changes have the potential to facilitate continual improvement, reduce manufacturing delays and mitigate supply issues?

**Panel Discussion** composed of representatives from authorities, the EC and the industry to discuss optimisation proposals: **Rúna Hauksdóttir Hvannberg**, Icelandic Medicines Agency - IMA (IS); **Susanne Winterscheid**, BfArM (DE); **Hélène Bruguera**, EDQM; **Florian Schmidt**, DG SANTE; Industry representatives: **Caroline Kleinjan**, Sandoz and **Astrid Krupp**, Fresenius Kabi

**15.30 16.00** — **Networking Coffee Break**

**16.00 17.15** — **Session 4: Watch this space in 2020 – Regulatory Focus**

**Chair:** **Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe

- Regulatory-Legal Interplay - **Sarah Faircliffe**, Bird & Bird and **Koosje van Lessen Kloeke**, Leijnse Artz
  - Any outcome of the recent court cases affecting regulatory strategy?
  - Regulatory evidence: data from public domain versus IP rights
- Medical devices
  - Update on the implementation of the Medical Devices Regulation - **Sonia Ribeiro**, EMA

**17.15 18.00** — **Closure of the Day and Networking Cocktail**
**Beata Stepniewska, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe**

**19.30 23.00** — **Networking Conference Dinner**

## Friday 31 January 2020

**08.30 09.00** — **Networking Welcome Coffee**


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| **09.00<br>10.45** | **Session 1: Is the current regulatory framework supportive of the development of more complex off-patent medicines?** | **09.00<br>10.45** | **Session 1: A Leader's perspective on Electronic Product Information: Is ePI a cross-enabler of collaboration of all Stakeholders?** |
| | ***The objective of the session is to address current challenges to the legal basis, study design, pre-submission dialogue, development of combination products, repurposing of known active substances, and multiplication of studies for global submission.***<br>**Chair:** Susana Almeida, Medicines for Europe<br>• Regulatory framework for complex off-patent medicines. A global product development perspective Nivedita Valentine, Accord Healthcare and Pavel Farkas, TEVA - Points to consider: the legal basis, study design, pre-submission dialogue, development of combination products, repurposing of known active substances, multiplication of studies for global submission<br>• Case studies on the challenges and opportunities in the development of Value Added Medicines Augusto Filipe, Tecnimede<br>• Clinical development pathways for fixed-dose combinations in Europe Jan Welink, MEB (NL)<br>• How to handle the digital compound? Sonia Ribeiro, EMA | | ***The objective of the session is to look at the ePI with an advanced perspective, by learning how a connected EU health network may help to empower EU patients, while gaining efficiencies in the EU Regulatory Network. The session will give opportunity for a dynamic and interactive between all participants. The following round-tables discussion are planned. Participants can choose to attend two of the following round tables.***<br>**Chairs:** Fakhredin Sayed Tabatabaei, MEB and Anjana Pindoria, Extedo<br>1. What are the drivers to move towards ePI?<br>2. The ePI process – upstream and downstream<br>3. ePI implementation – Telematics synergies and opportunities<br>4. ePI as a tool to empower patients<br>5. ePI as a tool to increase access to medicines and mitigate shortages<br>6. ePI in the Hospital setting<br>7. What is the value added of ePI?<br>**Speakers:** Juan Garcia Burgos, EMA; Laura Oliveira Santamaria, AEMPS; Georg Neuwirther, AGES; Peter Bachmann BfArM; Kevin Airey, Mylan; Britt Vermeij, Teva; Caroline Kleinjan, Sandoz; Stephanie Kohl, EAHP; Ellen Swanborn, Huidpatiënten Nederland (Dutch Skin Organisation). Patients and Healthcare professionals representatives will participate to the roundtable. |
| **10.45<br>11.15** | **Networking Coffee Break** | **10.45<br>11.15** | **Networking Coffee Break** |



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**11.15 – 12.45**

## Session 2: Streamlining global development of generic medicines: hope vs. hype

***The objective of the session is to discuss the progress in moving towards true global development for generic medicines and when a comparator product can be considered the same or different.***

**Chair:** Pavel Farkas, TEVA

- Harmonisation of scientific requirements in bioequivalence
- Comparator products: same or different?
- What's in it for all stakeholders?
- Way forward

**Panel Discussion** composed of session speakers: **Lei K. Zhang**, FDA; **Jan Welink**, MEB (NL); **Luther Gwaza**, WHO; **Susana Almeida**, Medicines for Europe

**11.15 – 12.45**

## Session 2: Telematics - Regulatory affairs fitting with the Digital age - From eCTD to data submission: is it still a dream?

***The objective of the session is to investigate what opportunities digital technology can bring to the Regulatory Network to address current operational challenges and improve the efficiency of the Regulatory processes. An update on the current Telematics projects will be part of the session.***

**Chair:** Remco Munnik, Iperion

- Digital Technology and automation- what opportunities are there for the Regulatory environment?
- Regulatory Network readiness to move from a document to a data driven process
- Telematics Agenda 2020-2023: what directions are we going to take?
- Multi-stakeholders' collaboration - Discussing the why, what and how to move quickly towards the Digital Regulatory era.

**Panel Discussion: Isabel Chicharo**, EMA; **Georg Neuwirther**, AGES; **Peter Bachmann**, BfArM; **Anjana Pindoria**, Extedo; **Stuart Izod**, Teva;

**12.45 – 14.00**

## Networking Buffet Lunch

**14.00 – 14.30**

## QA Session: Everything the Authorities always wanted to know about Industry but were afraid to ask

**14.30 – 15.30**

## Q & A Session: Put your questions to the Regulators

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 2 weeks in advance to beata@medicinesforeurope.com



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**Chairs:** **Laura Oliveira Santamaria**, Chair of the CMDh, AEMPS (ES) and **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz

**Q & A Session with representatives from the EU authorities**
**Susanne Winterscheid**, BfArM (DE) | **Kora Doorduyn-van der Stoep**, MEB (NL) | **Jitka Vokrouhlická**, SUKL (CZ) | **Ana López de la Rica Manjavacas**, AEMPS (ES) | **Sabina Uzeirbegović**, HALMED (HR) | **Hélène Bruguera**, EDQM

**15.30** **Closure of the Conference - Beata Stepniewska, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe**

**15.30 16.00** **End-of-conference Coffee**

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