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20th Regulatory Affairs and Pharmacovigilance VIRTUAL CONFERENCE

19-21-22-27-29 January 2021 • 2 February 2021

Session 1 - Looking to the future – Horizon 2025

19 January 2021 from 14:30 to 16:00 CET

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

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

European Commission Pharmaceutical Strategy and European Medicines Agencies Network vision to 2025 - how is it going to affect the off-patent medicines sector? Where are resources to be put to achieve the best outcome for patients and for public health protection? What should be our priorities?

Speakers

- **Andrzej Rys**, Director of Health systems, medical products & innovation at DG SANTE, European Commission
- **Emer Cooke**, Executive Director, EMA
- **Karl Broich**, President, BfArM (DE), Chair of the EU Telematics Management Board
- **Hugo Hurts**, Executive Director, MEB (NL)
- **Kora Doorduyn-van der Stoep**, Chair of the CMDh/EU representative, MEB (NL)
- **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz

Session 2 - Digitalisation and operational excellence in the Pharmaceutical strategy

21 January 2021 from 14:00 to 15:30 CET

- How digitalisation can support the Regulatory business process - **Britt Vermeij**, Vice-Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, TEVA
- A coherent data strategy as foundation to respond to public health needs - **Remco Munnik**, Chair of the Telematics WG Medicines for Europe, Iperion

Open dialogue between industry and regulators: How digitalisation can support the regulatory objectives in the Pharmaceutical strategy and what are the concrete steps to move forward?

Panel Speakers

- **Hilmar Hamann**, Head of Information Management Division, EMA
- **Harald von Aschen**, IT, Research and Development, Strategy (BfArM), Chair of the IT Directors Executive Committee (EMA)
- **Joris Kampmeijer**, Chief Information Officer, MEB (NL)
- **Peter Bachmann**, Head International Liaison Office and Conferences, European Union and International Affairs, BfArM (DE)
- **Georg Neuwirther**, Head of IT, AGES (AT)

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Session 3 - Resilience of the supply chain: dependency of third countries?

22 January 2021 from 14:00 to 15:30 CET

Chair: **Tony Cordrey**, VP European Strategic Operations, Accord Healthcare
Co-Chair: **Koen Laenen**, Senior Quality and Regulatory Affairs Manager, Medicines for Europe

- What can be done from the regulatory perspective to improve supply chain resilience and help to mitigate shortages?
- "CEPs of the future" – changes in the EDQM approach
- Where do our active pharmaceutical ingredients come from? – a world map of API production
- Pharma Strategy: concrete actions towards manufacturing, supply chain resilience and shortages

Speakers and panellists

- **Maja León Grzymkowska**, Legal Officer, DG SANTE, European Commission
- **Andreas Meiser**, CEO, Mundicare
- **Hélène Bruguera**, Co-chair of the IPRP Quality Working Group of Generics, EDQM
- **Damien Holly**, Supply Chain Head, Sandoz

Q&A

Session 4 - Future quality systems

27 January 2021 from 14:00 to 16:00 CET

Chair: **Mechthild Sander**, Chair of the Q&C WG, Medicines for Europe, AET
Co-Chair: **Koen Laenen**, Senior Quality and Regulatory Affairs Manager, Medicines for Europe

- How to handle some regulatory operations and compliance in a new, virtual way?
  - GMP virtual inspections and audits
- A rating system would characterise quality management maturity (QMM) and incentivise investments in quality manufacturing
  - Quality Management Maturity Pilot Programmes by FDA

Speakers and panellists

- **Brendan Cuddy**, Lead Scientific Officer, Clinical Trails and Manufacturing Taskforce, EMA
- **Cristina Baccarelli**, GMP Inspector, EDQM
- **Stefan Gimmel**, Director Global Quality Compliance, STADA Arzneimittel AG
- **Lyle Canida**, FDA, US
- **David Gaugh**, Senior Vice President for Sciences and Regulatory Affairs, AAM, US
- **Francisco Muñoz**, Quality Manager, Qualifyze

Q&A

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Session 5 - Pharmacovigilance in 2021: what can we expect?

29 January 2021 from 11:00 to 13:00 CET

Chair: **Susana Almeida**, Clinical Development and Safety Director, Medicines for Europe

- Update from EMA/PRAC
- Reference safety information and other work-sharing initiatives
- Follow up questionnaires position paper
- Inspection Risk-Based Questionnaires
- Virtual inspections during Covid times

Speakers and panellists

- **Sabine Straus**, PRAC Chair, MEB (NL)
- **Kora Doorduyn-van der Stoep**, Chairperson CMDh/EU representative, MEB (NL)
- **Klaudija Marijanović Barać**, Sr Director, Global Patient Safety & PhV – TPC, Teva
- **Tea Babić**, Director, PhV audits and inspections, Global Pharmacovigilance Compliance, Teva
- **Attila Olah**, Head Global Pharmacovigilance and EU-QPPV, Gedeon Richter Plc.

Session 6 - Life must continue after Brexit - Operating in the post-Brexit regulatory environment

2 February 2021 from 14:00 to 16:00 CET

Chairs: **Britt Vermeij**, Director Regulatory Affairs, Projects and Policy Implementation, TEVA and **Paul Fleming**, Technical Director, BGMA

- Impact of Brexit on the European regulatory environment
- UK future regulatory framework - MHRA guidelines
- Northern Ireland (NI) protocol - impact on regulatory submissions in the EU/UK and on access to medicines in NI
- EU - UK future relationship

Q and A session with speakers

Marilena Silvia Lungu - EC, Rita Purcell - HPRA, Susanne Winterscheid - CMDh, Marie-Hélène Pinheiro – EMA, Jack Turner - MHRA and Jonathan Mogford - MHRA

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Satellite Workshop - Connecting Notified Bodies with the Generic and Biosimilar medicines Industries

4 February 2021 from 11:00 to 13:00 CET

Speakers

- **Paul Scannell**, Senior Manager, Device Technical Regulatory, Viatris
- **Anabela Godinho**, Senior Manager Regulatory Affairs, Business Unit Generics and Complex Formulations ELAMA & Asia Pacific, Fresenius Kabi
- **Theresa Jeary**, Technical Specialist & Scheme Manager, BSI
- **Christiana Hofmann**, Teamlead Non-Active Medical Devices / Article 117 DACH & Nordics, TÜV SÜD Product Service GmbH

The registration for this workshop is now closed.

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