Webinar 1 - Access, availability and shortages are central to Pharma Strategy: How will regulatory reforms deliver?

24 January 2022, 14.30 - 16.00 CET

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

The opening session will focus on the European Commission's Pharmaceutical Strategy and how legislative and regulatory amendments can deliver better access and supply of medicines.

Speakers

- **Sylvain Giraud**, Head of Unit "Medical products: quality, safety and innovation" in the Directorate General for Health and Food Safety, European Commission (DG SANTE)
- **Momir Radulović**, Head of the Slovenian Medicines Agency (JAZMP)
- **Jakub Velík**, Head of a Unit Expert Activity Coordination Department, State Institute for Drugs Control (SUKL), CZ
- **Kaisa Immonen**, Director of Policy, European Patients' Forum (EPF)
- **Thyra de Jongh**, Principal Consultant, Technopolis Group
- **Rebecca Guntern**, President of Medicines for Europe, Sandoz
- **Erick Tyssier**, Head of Government Affairs Europe, TEVA

Questions and answers

Webinar 2 - The future of generic competition and how to leverage global convergence

26 January 2022, 14.30 - 16.30 CET

Chair: **Gerald Beuerle**, Chair of the Bioequivalence WG Medicines for Europe, Teva

In this session we will discuss global convergence efforts for generic medicines, looking at the current legal framework and the way forward. We will explore the opportunities provided by parallel EMA/FDA Scientific Advice and how new approaches to bioequivalence can open the door to a new era in generic development, access and availability.

- International initiatives on regulatory convergence in the field of generics
- How joint scientific advice could promote international alignment
- Current legal framework in Europe: gaps and opportunities
- New tools to approach bioequivalence
- Single global development: a key to unlock access

Speakers and panellists

More information and registration on https://www.medicinesforeurope.com/events/racphv2022/

- **Sarah Ibrahim**, Associate Director for Generic Drug Global Affairs in the Office of Generic Drugs (OGD)/ Center of Drug Evaluation and Research (CDER), FDA
- **Kevin Blake**, Scientific Officer, Clinical Pharmacology, Scientific Evidence Generation Department, EMA
- **Vincenzo Salvatore**, Bonelli Erede
- **Jim Polli**, University of Maryland
- **Susana Almeida**, Clinical Development and Safety Director, Medicines for Europe
- **Nilufer Tampal**, Associate Director for Scientific Quality in OB within OGD, FDA

Questions and Answers

Webinar 3 - Upgrading Marketing Authorisation procedures to increase availability and tackle shortages and supply chain resilience

31 January 2022, 14.30 - 16.30 CET

Chair: **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz
Co-chair: **Beata Stepniewska**, Deputy Director General, Head of Regulatory Affairs, Medicines for Europe

The session will focus on the necessary changes to MA procedures: modernise the DCP/ RUP; changes to CP, self-standing ASMF assessment, variations to support the Pharma Strategy objective to optimise the regulatory processes and deliver on faster patient access to medicines.

Speakers and panellists

- **Susanne Winterscheid,** German CMDh representative, BfArM, DE
- **Christelle Bouygues**, Regulatory Affairs Senior Officer, EMA
- **Laura Galatti**, Italian CMDh representative, AIFA, IT
- **Stella Koukaki**, Founder and Managing Partner, Pharos
- **Herta Pálfi Goóts**, Chair of the Regulatory Committee, Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ)
- **Birgit Ziegler**, Head of Regulatory CMC, Global Regulatory Affairs, STADA Arzneimittel AG
- **Jonathan Rousell**, Vice President, Regulatory Affairs Generics – Europe & International Markets Teva

Questions and answers

Webinar 4 - Delivering on global patient safety in pharmacovigilance

2 February 2022, 14.30 - 16.30 CET

Chair: **Sebastian Horn**, Teva

We will discuss the developments in pharmacovigilance and understand how a global view of patient safety can impact day to day practice and implementation:

- PRAC update
- Review of pharma legislation: opportunities for PV
- Generic pharmacovigilance: FDA perspective
- How global PV impacts day to day operations
- Views and priorities of the off-patent sector

Speakers and panellists

- **Viola Macolic Sarinic**, Scientific Adviser on Safety of Medicines, PRAC Scientific Committee Lead, Pharmacovigilance Office, Quality and Safety of Medicines Department, EMA
- **Howard Chazin**, Director of the Division of Clinical Safety and Surveillance, FDA
- **Pilar Bonilla**, Safety Risk Management Manager, Sandoz/Novartis Global Drug Development
- **Vicki Edwards**, Abbvie
- **Klaudija Marijanović Barać**, Sr Director, Global Patient Safety & PV (TPC), Teva

Questions and answers

Webinar 5 - Mobilising the digital opportunity to achieve interoperability in the EU medicines agency network

3 February 2022, 14.30 - 16.00 CET

Chair: **Remco Munnik**, Chair of the Telematics Working Group at Medicines for Europe, Iperion
Co-chair: **Sabrina Conti**, Policy and Regulatory Operations Manager, Medicines for Europe

This session will look at advancing digitalisation to achieve interoperability and successful digital transformation for a truly integrated regulatory system:

- Pharmaceutical strategy and future legislative reform
- New Lean Governance and long-term digital objectives
- Agile Pilot: objectives and stepping stones of DADI – PMS and ePI
- Implementation: EMA, NCAs and industry perspectives

Speakers and panellists

- **Hilmar Hamann**, Head of Information Management Division, EMA

- **Kristiina Puusaari**, Programme Coordinator/Project Manager, Digital Change Workstream Digital Business Transformation Task Force, EMA
- **Georg Neuwirther**, Head of IT Austrian Medicines and Medical Devices Agency (AGES MEA), Chair of the eAF Maintenance Group, Co-Chair SPOR Taskforce
- **Karin Gröndahl**, Business Development Manager, Swedish Medical Products Agency
- **Javier Monvoisin**, Global Head Regulatory Operations, Teva

Questions and answers

Webinar 6 - Prioritising regulatory reforms to increase access to medicines and to mitigate shortages

9 February 2022, 14.30 - 16.30 CET

Chairs: **Adrian van den Hoven**, Director General, Medicines for Europe and **Beata Stepniewska**, Deputy Director General, Head of Regulatory Affairs, Medicines for Europe

This session will recap the key solutions and benefits for access and supply discussed in the conference and look at how to prioritise the reform agenda in line with the ambitious vision of the Pharma Strategy. One objective will be to align regulatory and industry timelines to deliver as quickly and efficiently as possible

Round table discussion with speakers

- **Dolors Montserrat**, Member of the European Parliament, EPP
- **Olga Solomon**, Head of B5 Unit, DG Sante
- **Emer Cooke**, Executive Director, EMA
- **Christa Wirthumer - Hoche**, Head of the Austrian Medicines Agency (AGES), AT
- **Kora Doorduyn-van der Stoep**, Chair of the CMDh, MEB, NL
- **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Sandoz
- **Remco Munnik**, Chair of the Telematics Group Medicines for Europe, Iperion

Questions and answers