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22nd REGULATORY AFFAIRS AND PHARMACOVIGILANCE CONFERENCE

THE HOTEL, BRUSSELS
27-28 SEPTEMBER 2023

#PHVRAC23

Wednesday 27 September 2023

08.00 – 09.00 Networking welcome coffee and registration

09.00 – 10.45 Session 1: Access, affordability and availability: will the pharmaceutical legislation deliver on its objectives?

This session will set the scene for a discussion on the Commission's Legislative proposal to substantially amend the pharmaceutical legislation and how the revision will impact access to medicines. The perspective of stakeholders will be presented.

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

Welcome speech: Adrian van den Hoven, Director General, Medicines for Europe

Opening speech: How will the Pharmaceutical Legislation improve medicines access, affordability and availability?

Giorgos Rossides, Head of Cabinet for European Commissioner for Health and Food Safety, Stella Kyriakides, European Commission

Panel Discussion

Emer Cooke, Executive Director, European Medicines Agency (EMA)
Karl Broich, President, BfArM (DE), Chair of the Heads of Agencies Management Group
Csaba Kontor, Health Attaché, Permanent Representation of Hungary to the EU
Philip Hines, Engagement Manager, Thought Leadership, IQVIA
Caroline Kleinjan, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe and Head of the Regulatory Competence Centre, Sandoz

10.45 – 11.15 Networking coffee break

11.15 – 13.00 Session 2: Earlier generic and biosimilar medicines access: How will the pharmaceutical legislation facilitate generic and biosimilar medicines entry on day one of protection expiry?

The session will focus on changes to exclusivity and regulatory rules that should encourage earlier access to generic medicines.

Chair: Sergio Napolitano, General Counsel and External Relations Director, Medicines for Europe

Introduction of the new Incentives scheme and the revision of the Bolar Provision.
Florian Schmidt, Deputy Head of Unit, DG SANTE

Assessment of the impact of the new incentives scheme and revised Bolar provision on earlier access to off-patent medicines.
Sergio Napolitano, General Counsel and External Relations Director, Medicines for Europe

Panel Discussion composed of representatives from the authorities, the EC and the industry

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Sandra Kruger-Peters, MT-member, Department of Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, NL
Momir Radulović, Executive Director, Slovenian Medicines and Medical Devices Agency (JAZMP), SI
Sarah Faircliffe, Legal Director, Bird & Bird
Stella Koukaki, Scientific Affairs Director, Managing Partner, PharOS

13.00 14.15 **Networking buffet lunch**

14.15 15.45 **Session 3: New MAH obligations in the legislative proposal- what will be the impact on medicines access, medicines agencies and pharmaceutical companies?**

The session will address the various new obligations of the MAHs foreseen in the new legislative proposal and discuss their regulatory and commercial impacts on MAHs.

Chair: **Liana Petrosova**, Regulatory Policy Manager, Medicines for Europe

New obligations of the Marketing Authorisation holders- what will be the impact on pharmaceutical companies - Britt Vermeij, Senior Director Regulatory Policy and Intelligence Europe, TEVA and **Herta Palfi**, Chair of the Regulatory Affairs Committee, Hungarian Pharmaceutical Manufacturers Association

Issues to be discussed:
ERA
Shortage reporting and prevention
AMR-related obligations
Market access facilitations

Panel Discussion composed of representatives from authorities, the EC and the industry
Björn Eriksson, Director General, Swedish Medical Products Agency, MPA (SE)
Harald Mische, Deputy Head of Unit D2, DG SANTE, European Commission
Monica Dias, Head of Supply and Availability of Medicines and Medical Devices, European Medicines Agency (EMA)
Domenico di Giorgio, Head of Inspection and Certification Department and of the Pharmaceutical Crime Counteracting Office, AIFA

15.45 16.15 **Networking coffee break**

16.15 17.30 — **Session 4: Watch this space: EU Green Deal Objectives: how do these impact pharmaceuticals?**

This session will address the implications on pharmaceuticals of the Green Deal initiatives, including the Packaging and Packaging Waste Regulation, the F-gas Regulation and proposed ban on PFAS.

Chairs: **Sophie Dagens,** Regulatory Policy Officer, Medicines for Europe and **Katerina Patavou**, Head of European Public Affairs and Social Impact Strategist, Panhellenic Union of Pharmaceutical Industries

Different legal initiatives of the EU Green Deal, their complementarity and impact on pharmaceuticals.
Sophie Dagens, Regulatory Policy Officer, Medicines for Europe, **Katerina Patavou**, Head of European Public Affairs and Social Impact Strategist, Panhellenic Union of Pharmaceutical Industries and **Liana Petrosova,** Regulatory Policy Manager, Medicines for Europe

17.30 — **Closure of the day**
Beata Stepniewska, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe

17.30 20.30 — **Networking conference dinner sponsored by** acolad. LIFE SCIENCES

Thursday 28 September 2023

08.30 09.00 — **Networking coffee**

09.00 11.00 — **Session 5: Regulatory efficiency measures in the Pharmaceutical Legislative reform.**

This session will explore how the pharmaceutical legislation can deliver a modern, efficient regulatory framework, for example through simplification, reduction of duplication and delays, and digitalisation. Speakers will present the various proposed changes to regulatory procedures- (CP, DCP/RUP, ASMF Certification, Variations) and assess their impact on daily regulatory practices and their contribution to the overall agenda of simplification and cutting red tape while also allowing a faster reaction to patients' needs and supporting shortage mitigation.

Chairs: **Beata Stepniewska**, Deputy Director General and Head of Regulatory Affairs, Medicines for Europe and **Kora Doorduyn-van der Stoep**, Chair of the CMDh, MEB (NL)

Lilia Luchianov, Policy Officer, DG SANTÉ, European Commission
Caroline Kleinjan, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe and Head of the Regulatory Competence Centre, Sandoz
Andrew Modley, Senior Director European Generic Registrations, TEVA
Stella Koukaki, Scientific Affairs Director, Managing Partner, PharOS
Alexander Gehrke, Senior Manager Regulatory Affairs, Viatris

Panel Discussion composed of session speakers

11.00 – 11.30 — **Networking coffee break**

11.30 – 12.45 — **Session 6: Digital by default: how to drive efficiency and improved data use in the future medicines regulatory system?**

This session will explore how the revision of the pharmaceutical legislation can capture the benefits of digitalisation, including increased efficiency and improved data use in the medicine regulatory system. The session will also examine the proposal related to electronic product information (ePI) providing the possibility for Member States to choose paper and/or electronic version.

Chair: **Britt Vermeij**, Vice-Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Teva

Panel Discussion composed of representatives from the authorities, the EC and the industry
Anjana Pindoria-Rettenberger, Director Product Strategy, Extedo
Sara Rafael Almeida, Policy Officer, DG SANTÉ, European Commission
Jasper-Hugo Brouwers, Head of Corporate & Stakeholder Affairs, MEB (NL)
Peter Bachmann, Head International Liaison Office and Conferences, European Union and International Affairs, BfArM (DE)
Katja Pečjak, Billev Pharma East, Industry SME for EMA ePI Pilot Project
Zaïde Frias, Head of Digital Business Transformation Task Force, European Medicines Agency (EMA)

12.45 – 14.00 — **Networking buffet lunch**

14.00 – 15.30 — **Q&A with authorities**

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.

Chairs: **Kora Doorduyn-van der Stoep**, Chair of the CMDh, MEB (NL) and **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe and Head of the Regulatory Competence Centre, Sandoz

Q & A Session with representatives from the EU authorities and special guest, Julian Beach, Int. Executive Director, Healthcare Quality and Access, MHRA, UK

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

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Webinars

Monday 2 October 2023

14.00
16.00
CEST

Pharmacovigilance: enhancing patient safety through system efficiency

This webinar will focus on the latest developments in the pharmacovigilance space. We will discuss the opportunities that the new pharma legislation will bring and also learn how DARWIN and big data can contribute to enhancing patient safety.

Chair: **Klaudija Marijanović Barać**, Senior Director, Global Patient Safety & PV, Head TPC, Teva

Viola Macolic Sarinic, Scientific Adviser on Safety of Medicines, European Medicines Agency (EMA)
Kora Doorduyn-van der Stoep, Chair of the CMDh, MEB (NL)
Andrej Segec, Scientific Administrator, DARWIN EU® Project Manager, Data Analytics and Methods Task Force, European Medicines Agency (EMA)
Sophia Mylona, Senior Scientific Specialist, Inspections Office, European Medicines Agency (EMA)
Elena Rodionova, Pharmacovigilance Inspector, Austrian Medicines and Medical Devices Agency
Sebastian Horn, Global Head Patient Safety & Pharmacovigilance, Teva

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Monday 13 November 2023

14.00
16.00
CET

Impact of MDR on drug-device combination products: where are we?

In this webinar we will view the initial stages of the implementation of the new Medical Device Regulation and understand what the impact has been on our industry. We will also learn more about the EMA extended mandate and several initiatives to bring the worlds of pharma and medical devices closer.

Chair: **Rina Joshi**, Co-chair of the Medicines for Europe Medical Device Task Force, Teva

Christelle Bouygues, Regulatory Affairs Senior Officer, European Medicines Agency (EMA)
Theresa Jeary, Technical Specialist & Scheme Manager, BSI
Amanda Matthews, Senior Director, Pfizer
Paul Scannell, Co-chair of the Medicines for Europe Medical Device Task Force, Westpharma

Tuesday 5 December 2023

12.00
14.00
CET

Regulatory operational systems

This webinar will look at the latest developments in EU Regulatory Network IT projects, including PMS, ePI Pilot, eAF for human variations.

Chair: **Remco Munnik**, Chair of Telematics Working Group, Medicines for Europe

Kristiina Puusaari, EMA
Dr. Fakhredin Sayed Tabatabaei, MEB
Nora Weitbrecht, Sandoz
Katja Pečjak, Billev Pharma East, Industry SME for EMA ePI Pilot Project