Thursday 27 February 2025

08.00 – 09.00 Networking welcome coffee and registration

09.00 – 11.00 Session 1: Looking to the future - What changes can we expect in the coming years in the pharmaceutical environment?

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. The session will provide an update on the European Parliament and the EU Council position on the revision of the EU Pharmaceutical legislation. The session will conclude with a presentation of the EMA&HMA Strategy 2028.

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

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

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

- **Priorities of the new European Commission related to pharmaceuticals**
- **Update on the Revision of the Pharmaceutical Legislation- what is the direction of journey?**
- **EMA& HMA Strategy 2028**

Speakers and panellists

Florian Schmidt, Deputy Head of Unit, DG SANTE, European Commission
Marcin Kołakowski - Vice President for Medicinal Products at the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products
Emer Cooke - Executive Director, European Medicines Agency (EMA)
Rui Santos Ivo - President, INFARMED (PT), a Vice-Chair of the EMA Management Board
María Jesús Lamas Díaz - Executive Director of the Spanish Agency for Medicines and Medical Devices (AEMPS), Chair of the Heads of Agencies Management Group
Caroline Kleinjan - Chair of the Regulatory and Scientific Affairs Committee, Medicines for Europe and Head Regulatory Europe, Sandoz

Panel discussion and Q&A

11.00 – 11.30 Networking coffee break

11.30
13.00

Session 2: Union list of critical medicines

The session will explore the union list of critical medicine. The union list is a major milestone to support the EU's efforts in ensuring supply security and preventing shortages of critical medicines. In this session, we will discuss what are the implications of products being on the list for the MAHs and how MAHs need to prepare for the implementation of respective requirements. Speakers will present the various proposed changes related to the introduction of the List and assess their impact on the daily regulatory practices of MAHs. We will also discuss best practices in industry preparedness for the legislation roll out.

Chairs: **Liana Petrosova** - Senior Regulatory Policy Manager, Medicines for Europe

Laure Geslin - Team Leader, European Commission's Directorate-General for Health and Food Safety (DG SANTE)
Joao Ferreira - Shortages Specialist, European Medicines Agency (EMA)
Ellen McGrath - Medicines Shortages and Borderline Classification Manager, HPRA (IE)
Jana Bošanská, Head of Regulatory Strategy and Policy - Europe, Viatris
David Jauch, Vice President Governmental Affairs & Public Policy, Fresenius

Panel discussion and Q&A

13.00
14.15

Networking buffet lunch

14.15
15.45

Session 3: Regulatory affairs fitting with the digital age – what is the journey and how to be prepared?

This session will explore the evolving role of digitalisation in the regulatory processes. As we move to a structured data driven ecosystem, a discussion with a horizontal focus will bring together experts with different backgrounds: PMS, ESMP, ePI project and the eCTD 4.0 pilot, in order to better understand the challenges faced by all the parties involved in the different stages of the process.

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

Speakers and Panellists
Runa Hauksdottir Hvannberg - Head of Agency, Icelandic Medicine Agency
Marcos Fernández Gómez - Master Data Manager, EMA
Veronica Lipucci Di Paola - PMS Product Owner, EMA
Fakhredin Sayed - Senior Assessor Pharmacovigilance, MEB
Nora Weitbrecht - Industry SME in PMS product team with EMA and the European Network and Team Lead 'System Process Support' (Information Management, RegOps), Sandoz
Javier Monvoisin - Vice President of Regulatory Operations, TEVA
Anjana Pindoria - Director of Product Strategy, Extedo
Christopher Fordham - Packaging Technology and Artwork Manager, Accord Healthcare

	Panel discussion and Q&A
15.45 **16.15**	**Networking coffee break**
16.15 **17.45**	**Session 4: Leveraging new technologies in regulatory science for the off-patent industry**

This session will explore the evolving role of Artificial Intelligence (AI) and Real-World Evidence (RWE) in shaping the future of regulatory science. As AI-driven tools enhance the analysis of large, diverse data sets, and RWE provides insights beyond clinical trials, regulatory decision-making is becoming more data-driven and efficient. Experts will discuss how these innovations can streamline approvals, improve post-market surveillance, and ensure safety and efficacy in the sector, paving the way for a smarter, faster regulatory framework.

Chair: Raluca Radu - Senior Manager, Pharmaceutical Policy, Medicines for Europe

Speakers and Panellists

Luis Pinheiro - Senior Epidemiology Lead at the Data Analytics and Methods Taskforce, EMA

Gabriel Westman - Representative of the Methodology WP, MPA (SE)

Volodymyr Stus - Head of Clinical Excellence Team, Zakłady Farmaceutyczne Polpharma S.A.

Mohamed Ali Kotal - Head Medical Safety, Sandoz

Panel discussion and Q&A

17.45	**Closure of the day** **Beata Stepniewska,** Deputy Director General and Head of Regulatory Affairs, Medicines for Europe
18.00 **20.00**	**Networking conference cocktail and finger food bites**

Friday 28 February 2025

08.30 **09.00**	**Networking coffee**
09.00 **11.00**	**Session 5: What's new in the revised Variations Regulation?**

The session will focus on highlighting the new aspects of the revised Variations Regulation, its impact on the regulatory operations. The session will also address future amendments to the Variations classification guideline and transition period.

Chair: **Phyllida Duncan** - Associate Director Regulatory Affairs Policy Europe, Sandoz

What's new in the revised Variations Regulation?
Susanne Winterscheid - Chair of the joint CMDh/CMDv Working Party on Variation Regulations

Implementation of the new provisions for CAPs and NAPs
Thomas Girard - Head of Regulatory Affairs Office, EMA and **Susanne Winterscheid** - Chair of the joint CMDh/CMDv Working Party on Variation Regulations

How the new provisions in the revised Variations Regulation are going to change companies' operational activities?
Lilia Bandeira - Senior Manager Regulatory Affairs, Fresenius Kabi, **Catherine Oleggini** - European Central Regulatory Affairs – Submissions Team, Viatris

Update of the Variations classification guideline – main changes to be expected; the status of process and transition phase
Alberto Ganan Jimenez - Head of Committees and Quality Assurance Department, EMA

Panel discussion and Q&A

11.00
11.30 **Networking coffee break**

11.30
12.45 **Session 6: The impact of the revision of the pharmaceutical legislation on product information**

This session will cover the latest proposals to amend the pharmaceutical legislation related to product information and their potential impact on companies' activities. The session will also explore the new QRD template and will identify further opportunities for refining it, addressing potential benefits and challenges. Finally, the ePI project and the steps forward will be discussed and addressed with a patient centric approach.

Chair: **Britt Vermeij** - Vice-Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe, Senior Director Regulatory Policy & Intelligence EU, Teva

Panel discussion composed of representatives from the authorities, the EC and the industry
Monica Buch - Senior Labelling Specialist, EMA
Dominique Westphal - Member of the QRD Group and the advisory SmPC Group at EMA, PEI (DE)
Juan García Burgos - Head of Public and Stakeholders Engagement Department, EMA
Evinn Drusys - AEMPS, ES - Member state representative participated in the ePI pilot and NCA network product owner, NCA network PL, E-labeling developer at the Spanish Agency for Medicines and Health Products (AEMPS)
Katja Pečjak Reven - Billev Pharma East, Industry SME for EMA ePI Pilot Project

Panel discussion and Q&A

12.45 – 14.00 **Networking buffet lunch**

14.00 – 15.30 **Session 7: Predictability of submissions - open discussion between the authorities and industry on possible way forward**

An opportunity to have an open discussion on possible actions from both sides, the industry and authorities, to improve the predictability of submissions and resource planning for non-centrally authorised products.

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

Speakers and panellists
Aimad Torqui - Division Head, MEB (NL)
Susanne Winterscheid - Chair of the joint CMDh/CMDv Working Party on Variation Regulations
Caroline Kleinjan - Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe and Head Regulatory Europe, Sandoz
Andrew Modley - Senior Director, European Generic Registrations and Maintenance, TEVA
Momir Radulovic - Executive Director, JAZMP (SI)
Kora Doorduyn-van der Stoep - Chair of the CMDh, MEB (NL)

Panel discussion and Q&A

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

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Environmental Risk Assessment (ERA)
Wednesday 9 April 2025 - 14.00-15.30 CEST

This webinar will look at the latest EMA guideline on Environmental Risks assessment, explore its implications and challenges for the off-patent industry, role of the CROs involved in ERA. The event will bring together thought leaders and stakeholders to examine the challenges, opportunities, and collaborative roles in implementing the new ERA framework. In addition, the session will address forward-looking provisions under the ongoing review of EU Pharmaceutical Legislation.

Chair: **Caroline Kleinjan**, Chair of the Regulatory and Scientific Affairs Committee Medicines for Europe and Head Regulatory Europe, Sandoz

David Brown, Associate Director, Cambridge Environmental Assessments
Vassiliki Thiakos, Supervisor of Regulatory Affairs, Pharos
Anabela Godinho, Senior Manager of Regulatory Affairs, Fresenius Kabi

ESMP: Shortages reporting
Wednesday 7 May 2025 - 11.00-12.30 CEST

Join us for an engaging webinar where we delve into the practical aspects of implementing the European Shortage Monitoring Platform (ESMP).

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

Sofia Zastavnik, European Shortages Monitoring platform (ESMP) Product Owner, EMA
Pedro Pina Ferreira, Monitoring Value Stream owner, EMA
Maria Rubio, Global Supply Chain Head at Sandoz and ESMP Subject Mater Expert, EMA
MS representatives

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Pharmacovigilance
Use of AI in pharmacovigilance processes: case studies and future prospects
Date TBC

This webinar will be focused on the real-world applications of AI in pharmacovigilance processes and considerations for the future. We will discuss what are the challenges and perceived benefits of AI use through case studies. We will also discuss what are the regulatory expectations regarding the use of AI as the industry faces the increasing large volumes of product safety information.

Chair: **Shaloo Pandhi**, Global Head Patient Safety, Sandoz

Christian Roes, Chair of Methodology Working Party (TBI)
Christine Prendergast, GCP/PV Inspection Manager (and inspector), HPRA
Julie Durand, Quality and Safety of Medicines, European Medicines Agency
TBN, Teva

Please note that the zoom links will be sent two days before each webinar to the participants of the Regulatory Affairs 2025

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