DIA SEE (Southeastern Europe) Region Conference

05 Jun 2024 - 06 Jun 2024 Zagreb, Croatia

The DIA Southeastern Europe Conference will once again connect regulatory experts working with or in the Southeastern Europe region with key regional, EU and international leaders.

Partners that often do not meet will have the opportunity to link and collaborate in an inclusive and uniting environment. The Conference will serve as a platform to discuss the impact new EU General Pharmaceuticals legislation on the regional regulatory systems, additionally highlighting the significance of reliance for quicker access and alignment with the EU regulatory framework.

During the Conference you will have a unique opportunity to learn from the best practice examples and to network with Regulators and key leaders from across Europe and beyond.

Audience

- Professionals involved in:
  - Regulatory Affairs
  - Regional Regulatory Development
  - Regulatory Submissions
  - Policy & Intelligence
  - Patient Engagement
  - Patient Advocates
  - Health Authorities
  - EU Integration office
  - PV
- Patient (patient journey/perspective)

Key Topics

- Regulatory Policy of the Future
- Regulatory Convergence, Reliance, and Collaboration
- Reliance in Action
- Increasing Stakeholders' dialogue across countries and regions
- Optimising Life-Cycle Management
- Digitalisation and new Technologies

Programme Committee

Ana Petrovic,
Managing Director, Association of Research-Based Medicine Producers in Bosnia and Herzegovina (UIPL), Bosnia and Herzegovina

Bojan Trkulja,
Managing Director, The Association of the Manufacturers of Innovative Drugs – INOVIA, Serbia

Ivana Ferber,
Regulatory Affairs Lead Croatia / Bosnia and Herzegovina, Merck Sharp and Dohme d.o.o., Croatia

Manuela Stojanovic-Pejovski,
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Regional Policy Lead, Pharma Technical Regulatory, F. Hoffmann-La Roche Ltd, Switzerland

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Principal Regulatory Affairs Advisor, HALMED, Croatia

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Head of Control Laboratory, ALMBiH, Bosnia & Herzegovina

Biljana Dimitrova,
Advisor for Licensing and QP Manager, Department of Licensing of Medicines and Medical Devices, MALMED, North Macedonia

DAY ONE: Wednesday, 05 June 2024

09:00 Registration and Welcome Coffee

10:00 Welcome Remarks and Introduction

10:20 Plenary Session: EU General Pharmaceuticals Legislation And Impact On SEE Region

Session Chairs:
Nick Sykes, EFPIA
Ivana Ferber, MSD

EU General Pharmaceutical Legislation and Impact on SEE Region: Legislation Milestones
Nick Sykes, EFPIA

The Proposed Revision of the EU Pharma Legislation - Perspectives from the Research-Based Pharma industry: Strengthening, Simplifying and Future Proofing the EU Regulatory System
Nick Sykes, EFPIA

An Update On The EU Variations Framework Revision: Reflections On The Adopted Delegated Act And Future Outlook
Alessandra Leone, EFPIA

The Process Of Harmonisation Of National Legislation With The EU Acquis
Erna Kasumović, Directorate for European Integration

Panellists:
Sabina Uzeirbegović, HALMED
Pavle Zelić, ALIMS

11:30 Coffee Break

12:00 Session 2: Regulatory Reliance

Session Chair:
Amira Younes, MSD

Advantage of Reliance
Marie Valentin, WHO

EMA Supportive Program to Facilitate Regulatory Convergence & Reliance
Victoria Palmi Reig, EMA

EMA Focus Group Summary
Andrew Deavin, EFPIA LCM chair

PAC Reliance Case Study with 48 NRAs Participation
Francesca Mangia, Roche

Reliance and Streamlining of Post-Approval Changes
Fotis Baxevanis, MSD

13:10 Lunch Break

14:10 Session 3: SEE Townhall Regulatory Panel

Session Chairs:
Sabina Uzeirbegovic, HALMED
Melly Lin, F. Hoffmann-La Roche Ltd

Feedback From Studies:
Regulatory Risk-Based Approaches – Are These Enabling Better Availability And Access To Medicines Globally?
Magda Bujar, CIRS

Regional Perspective On The Implementation Of Reliance
Srdjan Lucic,F. Hoffmann-La Roche

EMA And SEE Countries –Cooperating To Protect Public Health
Victoria Palmi Reig, EMA

Panellists:
Tanja Nedjic, ALIMS
Alija Uzunovic, ALMBiH
Elena Cvetanovska, MALMED
Andela Draskovic, CInMED
Victoria Palmi Reig, EMA

15:25 Coffee Break

15:50 Session 4: Pharmacovigilance

Session Chairs: Petar Mas, HALMED
Sabina Polimac, Roche BiH
Izabela Majic, IBS-Experts

Pharmacovigilance In Serbia: Opportunities And Challenges
Marko Eric, ALIMS

Regulatory Challenges In The Implementation Of Drug Traceability Monitoring In Bosnia And Herzegovina
Azira Čajić, ALMBiH

Risk-Minimization Measures
Barbara Kovačić Bytyqi, HALMED

Project Smart Pharmacist – The Importance Of Education In Pharmacovigilance
Svetlana Vujovic, CInMED

Panellist:
Marijana Danevska, MALMED

17:00 Wrap-up and Highlights of Day 1

17:20 Networking Reception

18:30 End of Day 1

DAY TWO: Thursday, 06 June 2024

08:30 Welcome Coffee and Registration

09:00 Session 5: Ensure Uninterrupted and Secure Supply to Patients

Session Chairs:
Amanda Tombs, Astra Zeneca
Pavle Zelic, ALIMS

Counterfeit Measures And Collaboration With EU
Pavle Zelic, ALIMS

Medicine Shortages:
1. Causes, Management and Prevention
Biljana Dimitrova, MALMED
2. Critical Medicines Act (EU)
Nick Sykes, EFPIA

Experience Of Shared Packs: Opportunities And Challenges
Ljiljana Lupsic, Merck

Generics interchangeability
Iva Klarica Domjanovic, HALMED

The implementation of regulatory frameworks for drug quality control in Bosnia and Herzegovina
Dženana Delić, ALMBiH

Panellist:
Alija Uzunovic, ALMBiH

10:10 Coffee Break

10:40 Session 6: Digitalisation

Session Chairs:
Andrej Gracner, Pliva Research Institute Ltd.
Marko Eric, ALIMS

Progress of E-submission in Serbia
Marko Eric, ALIMS

Electronic procedures for medicines and E-submission
Ajten Ademi Abduramanje MALMED

Best practice sharing on e-submission and eCTD
Dilaver Yesildag, Roche

Panellist:
Elena Cvetanovska, MALMED

11:50 Lunch Break

13:00 Closing Plenary

14:10 End of the Conference

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