



Innovation is where strength lies: New regulations and digital transformation on the European path

**November 27 – 29, 2025
Hotel Avala, Budva**



CONFERENCE PROGRAMME



Thursday, 27/11/2025

8:30 – 19:00 Registration and Reception

19:00 – 20:00 Conference Opening

Snežana Mugoša, Managing Director of ClnMED

Emer Cooke, Director of the European Medicines Agency

Rainer Becker, Director for Medical Products and Innovation at the European Commission’s DG for Health and Food Safety

Jo Etienne Abela, Minister of Health of the Republic of Malta

Vojislav Šimun, Minister of Health of the Montenegro

20:00 Cocktail

Friday, 28/11/2025

10:00 – 11:30 Session 1

The New Law on Medicines: The Path Toward Alignment with EU Legislation – Key Messages for Manufacturers, Distributors, and Marketing Authorization Holders

Jovana Novaković, Ministry of Health

Gordana Boljević Stanojević, ClnMED

Mira Kontić, ClnMED

Tatjana Babović, ClnMED

11:30 – 12:00 Coffee break

12:00 – 13:30 Session 2

The Montenegrin Medicines Market on the Road to the EU: Challenges, Opportunities, and Regulatory Perspectives

Pharmacovigilance in the EU: Preparing MAHs for the European Framework – John Joseph Borge, Malta Medicines Authority

Advancing the Pharmacovigilance System in Montenegro: From Reporting to Action – Veselinka Vukićević, ClnMED

New EU Regulation on Clinical Trials: Opportunities for Development and Positioning of Montenegro on the European Research Scene – Bojan Batinić, ClnMED

A New Era of Medical Device Regulation – Emergency Import and Vigilance – Uroš Labudović, ClnMED

13:30 – 15:00 Lunch break



CONFERENCE PROGRAMME



Friday, 28/11/2025

15:00 – 16:30 Session 3

Keeping Up With the Times: Digitalization, Artificial Intelligence, and Modern Management Approaches

Digitalization – Presentation of New ClnMED Services – Lilanda Ćorović, ClnMED

Revolution or Evolution? AI as a Driver of Change in Pharmaceutical Regulation – Svetlana Ibrić, Faculty of Pharmacy, University of Belgrade

Track and Trace System in Montenegro – Dragana Janinović, Ministry of Health

16:30 – 17:30 Session 4

Interactive Workshop With a Psychiatrist and a Pharmacist – Pavle Zelić, ALIMS and Dr. Vladimir Đurić

20:00 Cocktail

Saturday 29/11/2025

10:00 – 11:30 Session 1

Medicine Shortages and Emergency Imports: Experiences, Challenges, and Strategic Responses From Montenegro and the EU

Caroline Muscat, Malta Medicines Authority

Ivana Drljević, Montefarm

Tijana Mićović, ClnMED

11:30 – 12:00 Coffee break

12:00 – 13:30 Session 2

Medicine Prices and Consumption in Montenegro: New Regulation, Trends, and Challenges

Presentation of Medicine Consumption in 2024 – Lidija Čizmović, ClnMED

New Regulation in Focus: Regulating Medicine Prices in the Interest of Patients and the Healthcare System – Jovana Novaković, Ministry of Health

The Impact of Price Setting on the Structure of Current Medicine Consumption in Montenegro – Is It Possible to Provide More Within the Same Budget? – Jovan Mihajlović, Health Analytics

Interchangeability of Medicines – Iva Klarica Domjanović, HALMED

13:30 – 15:00 Lunch break

