EMA
EUROPEAN MEDICINES AGENCY

Funded by the European Union

Agenda - Instrument for Pre-accession Assistance (IPA)

Assessing medicinal products in the EU: a practical introduction

2-3 October 2025

Institute of Medicines and Medical Devices of Montenegro
Podgorica, Montenegro

Day 01
2 October 2025
09:30-17:00 CET

Welcome speeches and organisational remarks
09:30-09:45

Introduction – Decision-making at CHMP and benefit-risk balance
09:45-10:45

Coffee break / 10:45-11:15

Context, clinical and regulatory considerations in the assessment exercise
Harald Enzmann, BfArM
Daniela Philadelphy, AGES
Caroline Voltz, EMA
11:15-12:00

Lunch / 12:00-13:30

Assessment exercise - presentation of case examples
All participants
13:30-14:30

Coffee break / 14:30-15:00

Assessment exercise - questions and answers and tasks distributed; groups assembled
All participants
15:00-15:15

Group work on case studies
All participants
15:15-17:00

Social event / 18.00-22.00

Day 02
3 October 2025
09:00-13:00 CET

Group work on case studies
All participants
09:00-10:30

Coffee break / 10:30-11:00

Presentation of the case study and discussion
All participants
11:00-12:30

Conclusion and closing remarks
12:30-13:00

Trainers

Harald Enzmann, the German Federal Institute for Drugs and Medical Devices (BfArM).

Harald served as Chair of EMA's Committee for Medicinal Products for Human Use where he played a key role in the EU's regulatory response to major public health challenges. He began his career in oncology research at the German Cancer research Center and worked in the pharmaceutical industry before joining BfArM where he leads the department of European and International Affairs.

Daniela Philadelphy, the Austrian Medicines and Medical Devices Agency (AGES)

Daniela is the Austrian CHMP member and chair of EMA's Haematology Working Party. She has worked in AGES as a clinical assessor and now holds the position of Deputy Head in the Department of Clinical Assessment of Safety & Efficacy.

Caroline Voltz, the European Medicines Agency (EMA)

Caroline works as a scientific lead at EMA's Advanced therapies and haemato-oncology office. She has varied experience in regulatory aspects of advanced therapies, orphan medicines and international collaboration. Caroline is the scientific coordinator of the Cancer Medicine Forum dealing with treatment optimisation and is coordinating the European Specialised Expert Communities in Oncology and Haematology.

About this event

This event is part of the European Commission funded Instrument for Pre-Accession Assistance (IPA) programme.

The main objective of this training is to prepare the integration of current candidate countries and potential candidates into the European Union regulatory systems by bringing them in closer alignment with the Acquis Communautaire in the field of medicines regulation.

About the European medicines regulatory system and EMA

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network makes the EU regulatory system unique.

The network is supported by a pool of some four thousand experts drawn from across Europe, allowing it to source the best possible scientific expertise for the regulation of medicines in the EU and to provide scientific advice of the highest quality.

EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers.

Venue of the event

Institute for Medicines and Medical Devices of Montenegro
Boulevard Ivana Crnojevića 64a
81000 Podgorica
Montenegro

Contact

EMAInternational@ema.europa.eu
www.ema.europa.eu