EU Medicines Assessment - Opportunities for expert involvement

09 July 2025, 15:00 – 16:15 (CEST)

Virtual meeting

The European Medicines Agency (EMA) works closely with national competent authorities in the Member States of the European Economic Area on the scientific evaluation and supervision of medicines, including their safety monitoring. Together with the European Commission they form the European medicines regulatory network (EMRN). The EMRN work is supported by a network of scientific experts who contribute to various aspects of assessment and other related activities.

To raise awareness of the EMRN's work and encourage broader expert participation, EMA and Heads of Medicines Agencies (HMA) are organising a webinar. The webinar will explain how the EU regulatory system for medicines functions including the role of scientific experts in supporting the development, evaluation, and supervision of medicines for human use in the EU.

The webinar is open to non-commercial experts (i.e. not affiliated with the pharmaceutical industry), including healthcare and regulatory professionals with experience in clinical medicine, pharmacology, toxicology, inspections and other aspects of medicines research, development, manufacturing and surveillance, both within the EU and internationally. Expert participation in EMRN activities is based on relevant expertise, regardless of current professional status (retired experts are also welcome).

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Co-chaired by Karl Broich (HMA) and Emer Cooke (EMA)

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14:45 Joining and technical checks

15:00 Welcome and opening speech

Opening remarks **10 min**
Emer Cooke (EMA) and Karl Broich (HMA)

15:10 Introduction

Introduction to the assessment of medicines in the EU **15 min**
Bruno Sepodes (CHMP Chair)

The clinical assessment **15 min**
Anna Cunney (HPRA clinical assessor seconded to EMA)

The inspection process **15 min**
Tiina Holmberg (FIMEA GCP inspector seconded to EMA)

15:55 Opportunities

Opportunities for expert involvement in our core assessment and related activities **15 min**
Francesca Day (EMA)

16:10 Closing remarks

Wrap up and next steps **5 min**
Karl Broich (HMA) and Emer Cooke (EMA)

List of speakers

Karl Broich	President, Federal Institute for Drugs and Medical Devices, (BfArM), Member of the Heads of Medicines Agencies (HMA) Management Group
Emer Cooke	Executive Director, European Medicines Agency (EMA)
Bruno Sepodes	Chair, EMA's Committee for Human Medicinal Products (CHMP)
Anna Cunney	Health Products Regulatory Authority (HPRA) Ireland clinical assessor seconded to EMA
Tiina Holmberg	Finnish Medicines Agency (FIMEA) GCP inspector seconded to EMA
Francesca Day	Head of Therapeutics Area Department, EMA