



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The EU medicines regulatory system and the European Medicines Agency: an introduction for international regulators and non-governmental organisations

*18-19 September 2017
London*

Programme



About this event

For the first time, the European Medicines Agency (EMA) is organising a two-day awareness session for non-EU international regulators and non-governmental organisations, giving a unique insight into the EU regulatory system for medicines with all its complexities and intricacies.

This 2-day awareness session will give an overview of the EU medicines regulatory system, the role of EMA overall and scientific aspects of the Agency's work.

Participants will have the opportunity to meet EMA staff and discuss with them the Agency's work. There will also be time set aside during the sessions to discuss specific issues of interest to participants.

Participation in the awareness session is for free. Participants will have to cover the cost for travel and accommodation.

All modules will be broadcast and the recorded sessions will be published on the EMA website together with the presentations.

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 31 EEA countries (28 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network is what makes the EU regulatory system unique.

The network is supported by a pool of thousands of 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 medicine, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers. This works because EU legislation requires that each Member State operates to the same rules and requirements regarding the authorisation and monitoring of medicines.

How to register



Please send an email to EMA at emainternational@ema.europa.eu to register your interest in participating.

Deadline for registration is 8 September 2017.

Early registration is highly recommended as places are limited and obtaining visas to travel to the UK may take up to 3 months.

Venue



European Medicines Agency
30 Churchill Place, E14 5EU
London, United Kingdom
www.ema.europa.eu

We look forward to meeting you at EMA in September!

Welcome of participants / 8:00-9:00

Opening remarks

Guido Rasi - EMA Executive Director / 9:00-9:15

1. Introduction to the EU Regulatory Network: Transparency, Trust and Reliance

Moderator: Evdokia Korakianiti / 9:15-10:45

- The EU
- The EU regulatory network
- Marketing Authorisation routes
- The EMA role
- EMA committees
- HTAs
- Pricing

Coffee break..... 

2. Benefit/Risk Assessment and Good Regulatory Practices

Moderator: Jordi Llinares Garcia / 11:15-12:30

- Medicinal products lifecycle
- Scientific review
- Standards of evidence
- Guidelines
- Assessment teams
- Use of experts
- Peer review
- Types of approvals
- Commitments

Lunch..... 

3. Dealing with Specific Types of Medicines

Moderator: Michael Berntgen / 13:30-15:00

- Paediatric
- Orphan
- Advanced therapies
- Herbal
- Generic
- Biosimilar

4. Specificities of Products for Veterinary Use

Moderator: David Mackay / 15:00-16:00

- Innovation, development and evaluation of veterinary medicines
- Maximum Residue Limits (MRL)
- Availability and Minor Use Minor Species (MUMS)/limited market scheme
- Environmental risk assessment
- Veterinary pharmacovigilance

Coffee break..... 

5. Dealing with Unmet Medical Needs and Support to Innovation

Moderator: Michael Berntgen / 16:30-18:00

- Scientific advice
- SMEs initiative
- The Innovation Task Force
- Marketing authorisation under exceptional circumstances
- Conditional Marketing Authorisation
- Adaptive pathways
- PRIME

Networking event..... 

6. Clinical Trials in the EU

Moderator: Anabela Marcal / 09:00-09:45

- EU Clinical Trial legislation revision
- Clinical Trial Authorisation in the EU

7. Good Practice and Inspections

Moderator: Anabela Marcal / 09:45-11:00

- Good Manufacturing Practice (GMP), supervision of manufacturers and inspections
- Dealing with Quality Defects
- Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) supervision and inspections
- Good vigilance Practice (GVP) supervision and inspections

Coffee break..... 

**8. Patients Safety:
The EU System for Pharmacovigilance**

Moderator: Georgy Genov / 11:30-13:00

- Overview of the EU pharmacovigilance system
- Signal detection and management
- Eudravigilance
- PSURs
- Risk-management plans

Lunch..... 

9. Hot Topic: Publication of Clinical Data

Moderator: Anne-Sophie Henry-Eude / 14:00-15:00

10. Stakeholders Engagement

Moderator: Marie-Hélène Pinheiro / 15:00-16:00

- Patients and health-care professionals and academia
- Pharmaceutical industry

Coffee break..... 

11. EMA and International Cooperation

Moderator: Riccardo Luigetti / 16:15 - 17:30

- EU network international strategy
- Bilateral cooperation: confidentiality arrangements and clusters/mutual recognition agreements
- Multilateral cooperation (ICH/ICMRA/IPRF/etc.)
- Article 58 and promoting other reliance pathways

Closing remarks / 17:30 - 17:45

The chair of the two-day event will be Agnès Saint-Raymond, Head of International Affairs.