EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2nd International Awareness Session

The EU medicines regulatory system and the European Medicines Agency

An introduction for international regulators, NGOs and academia

08-09 March 2018 - London

Chair: Dr Agnès Saint-Raymond

Programme

Day 01
08 March 2018
Room 2A / 08:45-17:30 GMT

Registration and welcome coffee / 08:00-08:45

Official welcome and opening remarks

Guido Rasi - EMA Executive Director / 08:45-09:00

01 - Setting the scene: introduction to the EU regulatory network

Moderator: Agnès Saint-Raymond / 09:00-10:00

- The EU and the EU regulatory network
- The EMA role

02 - Engagement with stakeholders

Moderator: Isabelle Moulon / 10:00-11:00

- Patients, healthcare professionals and academia
- Pharmaceutical industry

Coffee break / 11:00-11:30

03 - Early engagement on medicine development

Moderator: Enrica Alteri / 11:30-13:00

- Guidance to R&D programmes: scientific advice, qualification of novel technologies and biomarkers and the PRIME scheme
- Early engagement in R&D: The Innovation Task Force (ITF)
- The role of the academic experts: the experience of a Scientific Advice Working Party (SAWP) member

Lunch / 13:00-13:45

04 - ATMPs

Moderator: Ana Hidalgo / 13:45-15:00

- Advanced therapies: regulatory overview including classification
- Support for advanced-therapies - from developers to patients

Coffee break / 15:00-15:30

05 - Clinical trials in the EU

Moderator: Fergus Sweeney / 15:30-16:30

- Clinical trials authorisation in the EU: present and future
- Transparency on clinical trials information in the EU

06 - Hot topic: EMA support to innovation

Moderator: Anthony Humphreys / 16:30-17:30

- Operation of the EU Innovation Network
- The EMA regulatory science observatory and horizon scanning: a European and international perspective

Group photo
Networking event, EMA Promenade lounge
17:30-21:30

Day 02
09 March 2018
Room 2A / 08:30-17:00 GMT

Registration and welcome coffee / 07:45-08:30

07 - Benefit-risk assessment and good regulatory practice

Moderators: Evdokia Korakianiti/Jordi Llinares García / 08:30-10:30

- Benefit-risk assessment for initial marketing authorisations and standard of evidence
- Assuring scientific and regulatory quality through pre submission guidelines and use of experts
- Translating the benefit–risk discussion into regulatory outcomes (types of approvals and post-approval commitments)
- Benefit-risk assessment throughout the medicinal product lifecycle

Coffee break / 10:30-11:00

08 - Dealing with specific populations and types of products

Moderator: Enrica Alteri / 11:00-12:00

- Paediatric medicines, orphan medicines
- Generics, biosimilars and herbals

Lunch / 12:00-12:45

09 - Good practice and inspections

Moderator: Anabela Marçal / 12:45-14:00

- GMP supervision of manufacturers and inspections and dealing with quality defects
- GCP, GLP and GVP supervision and inspections

Coffee break / 14:00-14:30

10 - Patient safety and pharmacovigilance

Moderator: Peter Arlett / 14:30-15:45

- Overview of the EU pharmacovigilance systems
- Risk management plans
- Eudravigilance and signal detection
- Periodic safety update reports

11 - International cooperation

Moderator: Riccardo Luigetti / 15:45-16:45

- Globalisation challenges and new models for cooperation among regulators
- The EMA and international cooperation

Closing remarks

Moderator: Agnès Saint-Raymond, EMA
16:45-17:00

About this event

The European Medicines Agency (EMA) is pleased to hold its second two-day awareness session for non-EU international regulators, non-governmental organisations and academia, giving a unique insight into the EU regulatory system for medicines.

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

Participants will have the opportunity to meet EMA staff and explore the Agency's work in detail. Time will be set aside during the sessions to discuss specific issues of interest to participants.

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 makes the EU regulatory system unique.

The network is supported by a pool of some four 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.

Venue

European Medicines Agency
30 Churchill Place
Canary Wharf
London, E14 5EU
United Kingdom
EMAInternational@ema.europa.eu
www.ema.europa.eu
+44 (0)20 3660 6000

More information on the event

How to find us

Welcome to EMA!