SME info day:
Regulatory toolbox for medicines and combined devices developers

Friday, 26 October 2018

European Medicines Agency
London, United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

About this event

The SME info day provides an update on regulatory affairs topics for developers of human medicines and combined devices. It covers subjects such as data exclusivity and market protection, orphan and paediatric rewards, legal basis for submission of a marketing authorisation application, conditional marketing authorisations and approvals under exceptional circumstances, classification of advanced therapies and EMA activities in relation to the new medical device legislation. An update on Brexit-related activities will also be provided at the end of the event.

The "Meet EMA" event will provide an opportunity for SMEs to engage with EMA staff from different departments to increase awareness of the range of support available at EMA.

The event is open to companies that have been assigned SME status by EMA and to representatives of stakeholder organisations. It will be broadcast and recorded for interested parties to follow the proceedings.

Arrival at the Agency and registration

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to enter our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you there.

We strongly advise you to arrive up to 30 minutes before the start of the info day, to allow you time for registration. Please note that the Agency requires all visitors to provide a valid photo ID on arrival, such as passport, identity card or driving licence. Participants without a valid photo ID may be turned away.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union.

The Agency herewith informs attendees that this particular meeting will be recorded and broadcast. For more information about processing of personal data by EMA, please visit the EMA website or contact: dataprotection@ema.europa.eu

By attending this meeting you consent to any recording or broadcast.

Venue

European Medicines Agency
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Chaired by: Zaide Frias and Constantinos Ziogas

Friday, 26 October 2018, 09:00 - 16:00 - meeting room 3A

Registration and coffee / *8:30*

Welcome and introduction / *9:00*

- Welcome address and opening remarks by the chairpersons / *10'*

1. Regulatory considerations for human medicines development / *9:10*

- Data exclusivity, market protection, orphan and paediatric rewards / *35'*
  Sonia Ribeiro (EMA)
- Questions and answers / *15'*
- Legal basis for marketing authorisation applications and conditional marketing authorisations and authorisations under exceptional circumstances / 40'
  Stefanie Prilla (EMA)
- Questions & answers / 20'

Coffee break / *11:00 – 11:30*

'Meet EMA' event

IRIS awareness session / 15' (room 3L) / *11:10*

2. Orphan medicines / *11:30 – 11:50*

- Experience with the review of the orphan designation in the context of extension of indication / 10'
  Maria Sheean (EMA)
  Panellist: Laura Liebers (EMA)
- Questions & answers / 10'

3. Advanced therapies / *11:50 – 12:30*

- An update on latest developments and experience with advanced therapies classifications / 30'
  Patrick Celis (EMA)
- Questions & answers / 10'
  Moderated by Andrew Fox (Psioxus Therapeutics Limited)

Lunch break / *12:30 – 13:45*

'Meet EMA' event

IRIS awareness session / 15' (room 3L) / 13:00

4. Combined medicines and devices development / *13:45 – 14:45*

- Interface between medicinal product and medical devices development - Update on EMA implementation of the new medical devices legislation / 25'
  Armin Ritzhaupt and Ivana Hayes (EMA)
- An SME perspective on combined medicines and devices development / 15'
  Lars Hyveled-Nielsen (Zealand Pharma)
- Questions & answers / 20'

5. Update on Brexit-related activities for human medicines / *14:45 – 16:00*

Speakers: Anthony Humphreys and Leonor Enes (EMA)
Panellists: Monica Dias, Sandra Vanlievendael, Christelle Bouygues, Andrei Catalin Spinei, Marie-Helene Pinheiro, Sophia Mylona (EMA)

- Questions & answers / 45'

Closing remarks by the chairpersons / *16:00*

List of speakers and panellists

Zaide Frias	Head of Human Medicines Evaluation Division (EMA)
Constantinos Ziogas	Head of SME Office (EMA)
Sonia Ribeiro	Head of Regulatory Affairs Office (EMA)
Stephanie Prilla	Regulatory Affairs (EMA)
Maria Sheean	Orphan Medicines (EMA)
Laura Liebers	Regulatory Affairs (EMA)
Patrick Celis	Coordination of the CAT Committee (EMA)
Andrew Fox	Psioxus Therapeutics Limited
Armin Ritzhaupt	Regulatory Affairs (EMA)
Ivana Hayes	Regulatory Affairs (EMA)
Lars Hyveled-Nielsen	Zealand Pharma
Anthony Humphreys	Head of Scientific Committees Regulatory Science Strategy (EMA)
Leonor Enes	SME Office (EMA)
Monica Dias	Policy and Crisis Management (EMA)
Sandra Vanlievendael	Head of Long Term and Special Projects Office (EMA)
Andrei Catalin Spinei	Manufacturing and Quality Compliance (EMA)
Christelle Bouygues	Regulatory Affairs (EMA)
Marie-Helene Pinheiro	Corporate Stakeholders (EMA)
Sophia Mylona	Clinical and non-clinical compliance (EMA)

IRIS awareness session

Paolo Tomasi	Product Development Scientific Support (EMA)
Monica Gomar Mengod	Orphan Medicines (EMA)
Aina Staisiuniene	Telematics and Governance (EMA)