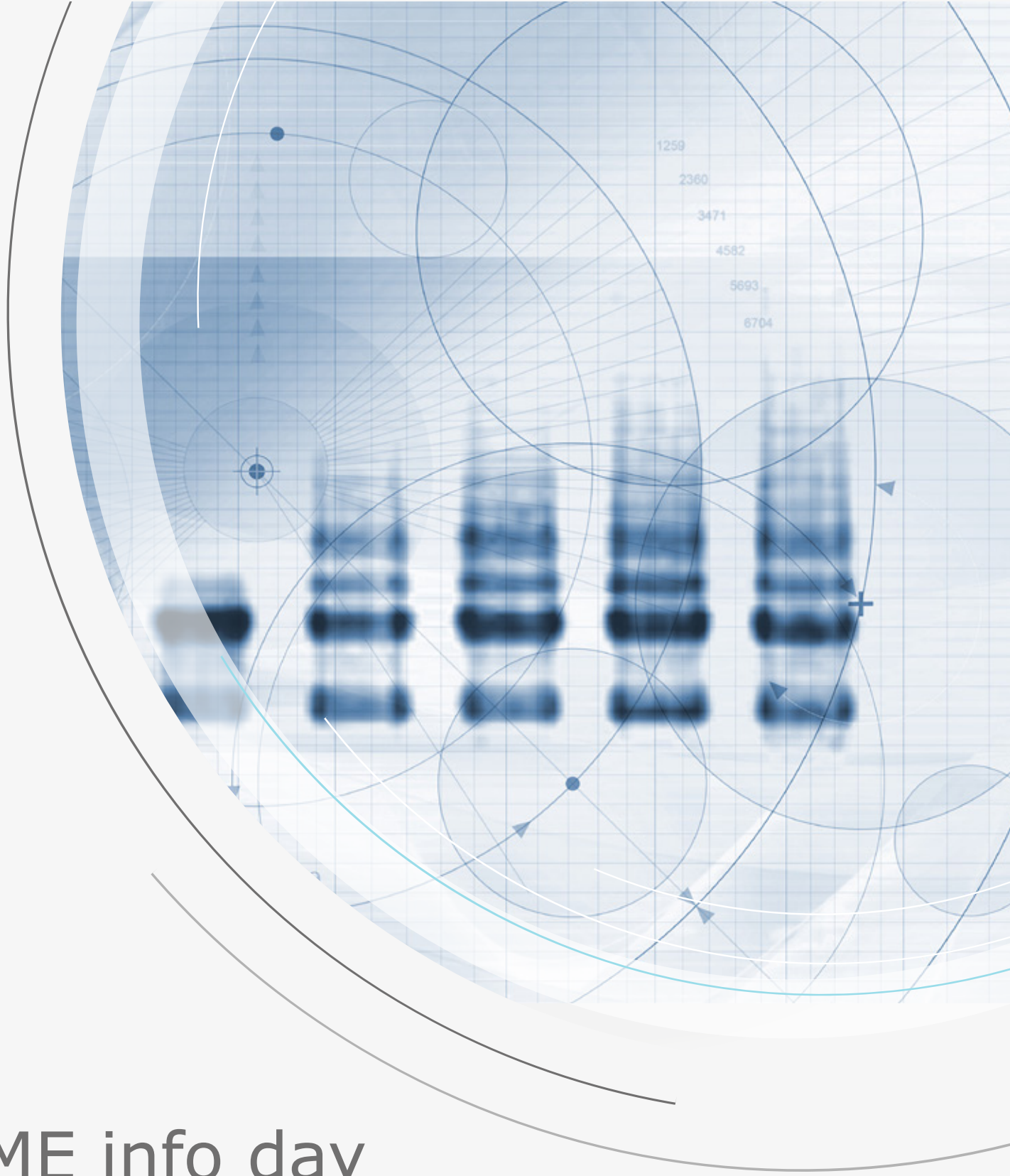


# SME info day

## Supporting innovative medicines' development and early access

Friday, 17 November 2017
European Medicines Agency,
London, United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

## About this event

The SME info day will provide an overview of EU initiatives supporting development stage small and medium-sized enterprises in the human medicines field. This info day will highlight future EU funding opportunities and platforms for early regulatory dialogue with the European Medicines Agency and the EU network. Topics covered will also include recent developments in scientific advice, the range of support that companies can access to optimise their development plans, and feedback on experience at stage of the marketing authorisation.

This event is organised in collaboration with the newly launched EU Innovation Network, a platform created to support pharmaceutical innovation both at national and EU level. The coffee break and lunch time event "Meet the EU Innovation Network Regulators" will provide opportunities for attendees to engage with its representatives.

An update on Brexit related activities will also be provided at the end of the event.

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
30 Churchill Place, Canary Wharf
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United Kingdom

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Chaired by:
Michael Berntgen, Head of Product Development Scientific Support Department (EMA)
& Constantinos Ziogas, Head of SME Office (EMA)

The event will take place in the meeting room 3A

Registration and coffee / *8:30*

Welcome and introduction / *9:00*

*Guido Rasi, Executive Director (EMA)*
*Michael Berntgen, Head of Product Development Scientific Support Department (EMA)*
*Constantinos Ziogas, Head of SME Office (EMA)*

**1.** SME programs supporting research and development / *9:10*

- An overview of EU/EC initiatives targeting SMEs / *20'*
  *Laszlo Helmle, DG Research & Innovation (EC)*
- An overview of EMA initiatives supporting SMEs / *15'*
  *Leonor Enes, SME Office (EMA)*
- Questions and discussion / *10'*

**2.** Early interactions to support innovative medicines and technologies / *9:55*

- Early interactions on innovation at EMA (ITF) / 15'
  *Falk Ehmann, Science & Innovation Support (EMA)*
- The new EU Innovation Network / 20'
  *Esa Heinonen, Chair of the EU Innovation Network (FIMEA)*
- The PRIME scheme: experience 1 year on / 20'
  *Robert Hemmings, Chair of the SAWP (MHRA)*
- Questions and discussion / 15'

Coffee break / *11:05*

Meet the EU Innovation Network Regulators / Info points in Room 3L

**3.** Maximising the outcome of scientific advice / *11:30*

- Scientific advice and its impact on marketing authorisation application reviews / 20'
  *Jan Regnstrom, Scientific Advice (EMA)*
- Multi-stakeholder parallel regulators/HTAs advice / 20'
  *Jane Moseley, Scientific Advice (EMA)*
- Questions and discussion / 25'
  *Additional panelist: Elisabeth Svanberg, Chief Development Officer, Ixaltis SA*

Lunch break / *12:35*

Meet the EU Innovation Network Regulators / Info points in Room 3L

**4.** Perspectives on specific populations / *14:00*

- Supporting orphan medicines development and addressing significant benefit requirements through protocol assistance / 25'
  *Matthias Hofer, Orphan Medicines (EMA)*
- Support to paediatric medicines development / 25'
  *Rocio Fernandez Fresquet, Paediatric Medicines (EMA)*
- Questions and discussion / 15'

**5.** Update on Brexit regulatory preparedness activities including Q&A / *15:05*

- Speakers: Anthony Humphreys and Monica Dias *(EMA)* / 20'
- Panellists: Marie-Helene Pinheiro, Sandra Vanlievendael, Christelle Bouygues, Anabela Marcal and Andrei Catalin Spinei *(EMA)* / 30'

Closing remarks / *15:55*

*Constantinos Ziogas, Head of SME Office (EMA)*

## List of speakers

| | |
|---|---|
| Guido Rasi | Executive Director (EMA) |
| Michael Berntgen | Head of Product Development Scientific Support Department (EMA) |
| Constantinos Ziogas | Head of SME Office (EMA) |
| Laszlo Helmle | DG Research & Innovation (EC) |
| Leonor Enes | SME Office (EMA) |
| Falk Ehmann | Science & Innovation Support (EMA) |
| Esa Heinonen | Chair of the EU Innovation Network (FIMEA) |
| Robert Hemmings | Chair of the SAWP (MHRA) |
| Jan Regnstrom | Scientific Advice (EMA) |
| Jane Moseley | Scientific Advice (EMA) |
| Elisabeth Svanberg | Chief Development Officer, Ixaltis SA |
| Matthias Hofer | Orphan Medicines (EMA) |
| Rocio Fernandez Fresquet | Paediatric Medicines (EMA) |
| Anthony Humphreys | Head of Scientific Committees Regulatory Science Strategy (EMA) |
| Monica Dias | Policy and Crisis Management (EMA) |
| Marie-Helene Pinheiro | Industry Stakeholder Liaison (EMA) |
| Sandra Vanlievendael | Head of Long Term and Special Projects Office (EMA) |
| Christelle Bouygues | Acting Head of Regulatory Affairs Office (EMA) |
| Anabela Marcal | Head of Committees and Inspections Department (EMA) |
| Andrei Catalin Spinei | Manufacturing and Quality Compliance (EMA) |

## List of representatives of EU Innovation Network

| | |
|---|---|
| Andrea Laslop | Bundesamt für Sicherheit im Gesundheitswesen (BASG), Austria |
| Christophe Lahorte | Federal Agency for Medicines and Health Products (FAMHP), Belgium |
| Alzbeta Kalasova | Státní ústav pro kontrolu léčiv (SÚKL), Czech Republic |
| Juha Kolehmainen | Finnish Medicines Agency (FIMEA), Finland |
| Caroline Auriche | Agence nationale de sécurité du médicament et des produits de santé (Ansm), France |
| Wiebke Loebker | Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany |
| Bettina Ziegele | Paul-Ehrlich-Institut (PEI), Germany |
| Krisztian Fodor | Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI), Hungary |
| Laurence O'Dwyer | Health Products Regulatory Authority / An tÚdarás Rialála Táirgí Sláinte (HPRA), Ireland |
| Valentina Mantua | Agenzia Italiana del Farmaco (AIFA), Italy |
| Luana Misfud Buhagiar | Medicines Authority, Malta |
| Jan Petter Akselsen | Statens legemiddelverk, Norway |
| Margarida Menezes-Ferreira | Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED), Portugal |
| Cesar Hernandez Garcia | Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Spain |
| Anna Mäkinen-Salmi | Läkemedelsverket, Sweden |
| Jens van Wijngaarden | College ter Beoordeling van Geneesmiddelen (CBG), The Netherlands |
| Julian Bonnerjea | Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom |
| Nathalie Gilmore | Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom |