



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



# SME Info Day

**18 October 2024**

Hybrid meeting – Broadcast/Meeting room 1C (EMA, Amsterdam)

The SME Info Day is a training event dedicated to small and medium-sized enterprises in the pharmaceutical sector. It highlights programmes and initiatives and provides updates on regulatory topics related to medicines for human use. This year's event covers various topics such as EMA scientific advice, clinical trials, medical devices, the new EU HTA regulation, the new EMA fee regulation and medicine shortages.

In addition to the training event, there will be an opportunity for SMEs to engage with EMA staff during the lunch break. This "Meet EMA" event is designed to increase awareness of the various support tools available at EMA for medicine development. EMA staff from relevant areas such as the Innovation Task Force, Scientific Advice, Orphan, and Paediatric Medicines will be present to answer questions and provide information.

The event is open to companies assigned SME status by EMA and representatives of stakeholder organisations. Furthermore, it will be broadcast and recorded for interested parties to follow the proceedings.

# SME Info Day

*Co-chairs: Leonor Enes and Constantinos Ziogas (EMA)*

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## **09:30 Welcome and opening remarks**

*Emmanuel Cormier (EMA)*

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## **09:45 Session 1: Scientific Advice**

### **How to use EMA scientific advice to support your development**

*Iordanis Gravanis (EMA)*

### **Questions and answers**

*Moderated by Thomas Ballotti (EMA)*

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## **10:45 Coffee break**

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## **11:00 Session 2: Clinical Trials**

### **Latest developments on the clinical trials landscape**

*Laura Pioppo and Francesca Scotti (EMA)*

### **Questions and answers**

*Moderated by H el ene Casaert (EMA)*

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## **12:00 Session 3: Health Technology Assessment (HTA)**

### **Implementation of the new HTA regulation**

*B ela Dajka (EC), Anne Willemsen (HTACG)*

### **Panellist**

*Michael Berntgen (EMA)*

### **Questions and answers**

*Moderated by Leonor Enes (EMA)*

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## **13:00 Lunch**

**'Meet EMA' event**

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**14:00**      **Session 4: Medical devices**

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**EMA activities on medical devices**

- *Medicinal products used in combination with medical devices*
- *Companion diagnostics*
- *Expert panels on high-risk medical devices*
- *Initiatives on development support*

*Christelle Bouygues, Antonella Baron, Hilde Bastaerts and Stiina Aarum (EMA)*

**Questions and answers**

*Moderated by Constantinos Ziogas (EMA)*

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**15:00**      **Coffee break**

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**15:15**      **Session 5: The New EMA Fee Regulation**

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**An overview of upcoming changes**

*Patrick López Fernández and Claudia Galeazzo (EMA)*

**Questions and answers**

*Moderated by Héléne Casaert (EMA)*

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**15:45**      **Session 6: Management of Shortages**

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**Improving the availability of medicines in the EU**

*Sandra Dang and João Ferreira (EMA)*

**Questions and answers**

*Moderated by Thomas Ballotti (EMA)*

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**16:15**      **Closing remarks**

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*Leonor Enes and Constantinos Ziogas (EMA)*

## List of speakers and panellists

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<b>Emmanuel Cormier</b>	EMA, Head of Regulatory Science and Innovation Task Force
<b>Constantinos Ziogas</b>	EMA, Head of SME Office
<b>Leonor Enes</b>	EMA, SME Office
<b>Hélène Casaert</b>	EMA, SME Office
<b>Thomas Ballotti</b>	EMA, SME Office
<b>Iordanis Gravanis</b>	EMA, Head of Scientific Advice Office
<b>Laura Pioppo</b>	EMA, Clinical Trial Transformation Workstream
<b>Francesca Scotti</b>	EMA, Clinical Trials Systems Workstream
<b>Béla Dajka</b>	HTA Secretariat of the European Commission
<b>Anne Willemsen</b>	Co-chair of the HTAR
<b>Michael Berntgen</b>	EMA, Head of Scientific Evidence Generation Department
<b>Christelle Bouygues</b>	EMA, Regulatory Affairs Office
<b>Antonella Baron</b>	EMA, Oncology and Radiopharmaceuticals Office
<b>Hilde Bastaerts</b>	EMA, Expert Panel and Groups Office
<b>Stiina Aarum</b>	EMA, Scientific Advice Office
<b>Patrick López Fernández</b>	EMA, Procedure, Revenue and Expenditure Service
<b>Claudia Galeazzo</b>	EMA, Finance Department
<b>Sandra Dang</b>	EMA, Supply and Availability of Medicines and Devices Workstream
<b>João Ferreira</b>	EMA, Supply and Availability of Medicines and Devices Workstream