



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation – Agenda

17 October 2025, 09:30 – 14:30 (CEST)
Room 2C, EMA, Amsterdam

The European Medicines Agency (EMA) will be hosting a roundtable meeting with stakeholders to mark the 20th anniversary of EMA's SME regulation¹. The event will feature contributions from representatives of the European Commission and the European Medicines Regulatory Network, who will join EMA in highlighting the Regulation's achievements and discussing future opportunities for EU support for small and medium-sized enterprises (SMEs). Participants from public and private investors, life science incubators, patients' organisations and industry organisations will have the opportunity to exchange views on current challenges and future opportunities to foster innovation and support SMEs in the pharmaceutical and MedTech sectors.

The SME regulation was adopted in December 2005 to promote innovation and support the development of new medicines by SMEs. Its primary objective is to provide financial and administrative assistance through EMA's dedicated SME Office.

¹ Commission Regulation (EC) No 2049/2005

EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation

Chairs: Emmanuel Cormier and Constantinos Ziogas (EMA)

09:30 Welcome, introductory remarks and roundtable objectives

Emer Cooke, Emmanuel Cormier and Constantinos Ziogas (EMA)

10'

09:40 Session 1: EU support to SMEs and innovation

Moderator: Leonor Enes (EMA)

Policy perspectives

25'

Eszter Batta (EC, DG GROW)

Olga Solomon (EC, DG SANTE)

European funding perspectives

15'

Dana Burduja (EIB)

Orsolya Symmons (EISMEA)

Private funding perspectives

10'

Sander Sloodweg (Invest Europe)

Life science incubator perspectives

10'

Christel Bergström (Uppsala University)

Patients' organisation perspectives

5'

Virginie Hivert (Eurordis - Rare Disease Europe)

Questions and Answers

10'

10:55 Coffee break

11:05 Session 2: EU regulatory support to SMEs

Moderator: Helene Casaert (EMA)

Achievements of EMA's SME Regulation **15'**

Leonor Enes (EMA)

SME and innovation support in the European Medicines Regulatory Network **15'**

Laurence O'Dwyer (EU-Innovation Network)

EMA SME survey **10'**

Thomas Ballotti (EMA)

SME perspectives **10'**

Marte Cameron (Akigai)

Vissarion Gakopoulos (Vethellas SA)

Questions and Answers **10'**

12:05 Lunch

12:55 Session 3: Looking into the future

Tour de table of stakeholders' organisations followed by discussions moderated by Emmanuel Cormier and Constantinos Ziogas (EMA) **90'**

Veterinary medicines industry organisations

Elsa Vecino (Access VetMed)

on behalf of Access VetMed, AnimalHealthEurope, AVC

Human medicines industry organisations

Alexander Natz (EUCOPE)

on behalf of AESGP, ARM, EFPIA, EUCOPE, Europabio, EuroPharm SMC, Medicines for Europe, MedTech & Pharma Platform, Vaccines Europe

14:25 Closing remarks

Emmanuel Cormier and Constantinos Ziogas (EMA) **5'**

List of Speakers

Emer Cooke	European Medicines Agency
Emmanuel Cormier	European Medicines Agency
Constantinos Ziogas	European Medicines Agency
Leonor Enes	European Medicines Agency
Hélène Casaert	European Medicines Agency
Thomas Ballotti	European Medicines Agency
Eszter Batta	European Commission, DG GROW
Olga Solomon	European Commission, DG SANTE
Dana Burduja	European Investment Bank (EIB)
Orsolya Symmons	European Innovation Council and SMEs Executive Agency (EISMEA)
Sander Sloodweg	Invest Europe
Christel Bergström	Uppsala University
Virginie Hivert	Eurordis - Rare Disease Europe
Laurence O'Dwyer	EU Innovation Network (EU-IN)
Marte Cameron	AKIGAI
Vissarion Gakopoulos	Vethellas SA
Elsa Vecino	Access VetMed
Alexander Natz	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

List of Participants

Melanie Carr	European Medicines Agency
Jordi Torren Edo	European Medicines Agency
Eglantine Legros	European Medicines Agency
Alexandre Correia	European Medicines Agency
Maria Filancia	European Medicines Agency
Robert Klaus	Austrian Federal Office for Safety in Health Care (AGES)
Christian Taylor	Austrian Federal Office for Safety in Health Care (AGES)
Christophe Lahorte	Federal Agency for Medicines and Health Products (FAMHP)
Daniel Holy	State Institute for Drug Control (SUKL)
Lisbeth Lund Hemmingsen	Danish Medicines Agency (DKMA)
Evelin Saar	State Agency of Medicines (RAVIMIAMET)
Nina Hulin	National Agency for the Safety of Medicine and Health Products (ASNM)
Guillaume Vaquer	National Agency for the Safety of Medicine and Health Products (ASNM)
Nina-Abena Gross	Federal Institute for Drugs and Medical Devices (BfArM)
Bettina Ziegele	Paul-Ehrlich-Institut (PEI)
Angeliki Rompoti	National Organization for Medicines (EOF)
Teodora Bodea	National Centre for Public Health and Pharmacy (NNGYK)
Agnes Zotter	National Centre for Public Health and Pharmacy (NNGYK)
Eleonora Agricola	Italian Medicines Authority (AIFA)
Maria di Marzo	Italian Medicines Authority (AIFA)
Anne Westrheim	Norwegian Medical Products Agency (NOMA)

Katarzyna Zywiec	Office for Registration of Medicinal Products, Medical Device and biocidal Products (URPL)
Helena Baião	National Authority of Medicines and Health Products (INFARMED)
Luka Kosec	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)
Sonia Bermudez Gazquez	Spanish Agency of Medicines and Medical Devices (AEMPS)
Yona Nuevo Ordóñez	Spanish Agency of Medicines and Medical Devices (AEMPS)
Tomas Nilsson	Swedish Medical Products Agency (MPA)
Jurate Svarcaite	Association of the European Self-Medication Industry (AESGP)
Pieter-Jan Serreyn	Animal Health Europe
Silke Engl	Animal Health Europe
Paolo Morgese	Alliance for Regenerative Medicines (ARM)
Rimma Ishimbaeva	Association of Veterinary Consultants (AVC)
Heidi Schwer	Association of Veterinary Consultants (AVC)
Marta Provencio	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
Audrey Wolf	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Alain Verrijdt	European Pharmaceutical association representing Small to Medium sized Companies in Europe (Europharm SMC)
Telma Lapa Costa	European Pharmaceutical association representing Small to Medium sized Companies in Europe (Europharm SMC)
Nathalie Schober-Ladani	MedTech & Pharma Platform (MPP)
Karoline Hahn	MedTech & Pharma Platform (MPP)
Anke Arnold-Tugulu	Azafaros
Félicie Caire	Voisin Consulting Life Sciences
Alfonso Garcia Cañamaque	León Research
Sergio Miguel Zunino	NgenLab Germany GmbH
Jonas Zechner	NgenLab Germany GmbH
Valentina Guatri	Invest Europe
Marc van Voorst tot Voorst	Forbion