

2nd HMA/EMA Multi-Stakeholder Forum on EudraVigilance and Signal Detection

1 December 2026 (09:00 – 17:30 CET)

The main objectives of Forum are to:

- mark the 25th anniversary of EudraVigilance and reflect on its critical role in safeguarding public health;
- inform stakeholders on ongoing and forthcoming relevant developments in international guidance, signal management updates and use of real-world evidence;
- further foster stakeholder engagement and collaboration.

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08:30 Joining and technical checks

09:00 Opening session

Welcome
Peter Arlett (NDSG co-chair, Head of Data Analytics and Methods Task Force, EMA) 5'

Opening remarks
Alexis Nolte (Head of Human Medicines Division, EMA) 5'
Ulla Wändel Liminga (PRAC chair, MPA, SE) 5'
Marco Greco (Co-chair of the Patients' and Consumers' Working Party) 5'
Piotr Szymański (Co-chair of the Healthcare Professionals' Working Party) 5'

Keynote presentation - The importance of patients' contributions to pharmacovigilance
David Haerry (European AIDS Treatment Group) 15'

09:40 Session 1: 25 years of EudraVigilance

Co-Chairs: Sabine Brosch (EMA) and Marco Greco (PCWP co-chair)

The journey of EU Pharmacovigilance
Nick Halsey (EMA), Wendy Huisman (former chair of Medicines for Europe pharmacovigilance group), Peter De Veene (EFPIA) 20'

Reflections on EudraVigilance – panel discussion with NCA and industry representatives 20'

NCA representatives: Edurne Lázaro Bengoa (AEMPS, ES), Sophia Venzke (CBG-MEB, NL), Ana Araujo (INFARMED, PT), Maria Luisa Casini (AIFA, IT)

Industry representatives: Attila Oláh (Medicines for Europe), Michelle Grimes (EuropaBio)

10:20 Coffee break

10:40 Session 2: EudraVigilance in practice

Co-Chairs: Georgy Genov (EMA) and Elvira Lázaro (AEMPS, ES)

Use of the ADR website and transparency
Rodrigo Postigo (EMA) *10'*

GVP IX Rev. 2 update
Eleni Savvaidou (EMA) *10'*

Signal management process and EMA perspective
Justina Januskiene (EMA) *20'*

NCA and PRAC perspective
Bianca Mulder (PRAC, CBG-MEB, NL) *30'*

Q&A *10'*

12:00 Lunch break

13:00 Session 3: EudraVigilance data quality and management

Co-Chairs: Edurne Lázaro Bengoa (AEMPS, ES) and Attila Oláh (Medicines for Europe)

ADR chapter of the Data Quality Framework
Tom Paternoster-Howe (EMA) *20'*

Expedited ICSR compliance reports
Richeal Nic An Rí (EMA) *15'*

ICSR QA and duplicate detection activities – Most common error findings
Tom Paternoster-Howe (EMA) *20'*

Improving MAH access to EudraVigilance data
Nick Halsey (EMA) *15'*

Industry perspective on MLM Service
Sebastian Horn (Medicines for Europe) *10'*

Q&A *10'*

14:30 Session 4: Developments in International Guidance

Chair: Dennis Lex (BfArM, DE) and Thomas Kuckuk (EFPIA)

Future updates to GVP VI
Gilles Touraille (EMA) *10'*

ICH guidelines - practical experience with implementation of ICH E2D (R1)
Joint industry presentation
Raphael Van Eemeren (EFPIA), Michelle Grimes (EuropaBio), Aniket Agarwal (Medicines for Europe) *15'*

Q&A *10'*

15:05 Coffee break

15:25 Session 5: Pharmacovigilance beyond EudraVigilance

Co-Chairs: Paolo Alcini (EMA) and Piotr Szymański (HPWP co-chair)

The European Health Data Space and EudraVigilance
Stefania Simou (EMA) *10'*

Real World Data in pharmacovigilance
Andrej Segec (EMA) *10'*

Q&A *10'*

15:55 Session 6: Updates on EudraVigilance, advancements in AI in pharmacovigilance and future perspectives

Chair: Paolo Alcini (EMA) and Jean-Michel Dogné (AFMPS, BE)

EudraVigilance updates
Joao Caetano (EMA) *10'*

Advancements in AI in pharmacovigilance
Julie Durand (EMA) *15'*
Luise Dürlich (MPA, SE) *15'*
Niklas Noren (Uppsala Monitoring Centre) *15'*
Lisa-Ann Chiriseri (EFPIA), Aniket Agarwal (Medicines for Europe) *25'*

Q&A *10'*

17:25	**Closing remarks**	
	Wrap up Peter Arlett (EMA, NDSG co-chair)	5’
17:30	**End of Forum**	

Data protection notice

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At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool Slido. Interaction via Slido is voluntary, and you may opt to remain anonymous.

Programme Committee



Paolo Alcini
Head of Healthcare Data, Data Analytics and Methods Task Force, European Medicines Agency (EMA)

Mr. Alcini joined the Agency in 2004 and since 2007 he is leading with his team the development of EudraVigilance and of the ICSR data management and analysis activities.



Georgy Genov
Head of Pharmacovigilance Office, Quality and Safety of Medicines Department, European Medicines Agency (EMA)

Dr. Genov is qualified as medical practitioner. He joined the pharmaceutical industry in 1998. Since then, he has gained experience in Drug Development, Medical Affairs and Pharmacovigilance. In 2010, he joined the Pharmacovigilance and Risk Management team of the European Medicines Agency.



Sabine Brosch
Data Protection Officer, European Medicines Agency (EMA)

Dr. Brosch oversees EMA's data processing activities, ensuring compliance with the European Data Protection Regulation (EUDPR) and guidance from the European Data Protection Supervisor and Board. Sabine has more than thirty years of experience in regulatory science and pharmacovigilance. As Business Lead for EudraVigilance and International Standardisation (2009–2013), Sabine helped develop global standards and held roles such as EU topic leader for ICH working groups and co-chair of expert panels.



Anja van Haren
Co-chair of EudraVigilance Expert Working Group (EWG) and Pharmacovigilance Business Team, EU representative in ICH E2B(R3) and E2D(R1) EWG

Anja has been working in the pharmacovigilance department of the Dutch Medicines Evaluation Board since 1998. First as pharmacovigilance assessor, and since 2001 involved in EudraVigilance related tasks, including ICSR exchange as well as signal management. She is co-chair of the EudraVigilance Expert Working Group, co-chair of the Pharmacovigilance Business Team and represents the EU in the ICH E2B(R3) and E2D(R1) Expert Working Groups.



Edurne Lázaro Bengoa

Head of the Division of Pharmacoepidemiology and Pharmacovigilance, AEMPS

Edurne is Head of the Division of Pharmacoepidemiology and Pharmacovigilance at the Spanish Agency of Medicines and Medical Devices (AEMPS). She leads activities in signal detection, risk assessment, and real-world evidence generation, and contributes to European initiatives on medicines safety, data science, and innovation in pharmacovigilance.



Attila Oláh

Head Global Patient Safety, Global Patient Safety Department, Gedeon Richter Plc.

Attila Oláh, MD, a medical doctor by profession, is Head of Global Patient Safety at Gedeon Richter Plc., leading global PV and end to end patient safety governance. A former EU-QPPV, he brings extensive international experience and contributes to EudraVigilance as an EV-EWG member.