



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29/09/2025
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Agenda – 20th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

13 November 2025, 13:30 – 17:40, Virtual meeting

Co-Chairs: Ulla Wändel Liminga and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising - Ulla Wändel Liminga and Evdokia Korakianiti	13.30 – 13.40 10 min
2.	Real World Evidence update - Studies to support regulatory decision (Andrej Segec, EMA) - RW metadata catalogue (Katerina-Christina Deli, Stefania Simou, EMA) Q&A (All)	13.40-14.20 15 min 15 min 10 min

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3.	Guidance update - Good Pharmacovigilance Practices (EU-GVP) (Priya Bahri, EMA) - Modernising GVP modules VI and IX (Marcus Musilek, Amit Kubavat MfE) - Off-patent sector perspective on aRRM, FU to 17th platform (Klaudija Marijanovic Barac, MfE) - Non-fixed Drug Combinations & Pharmacovigilance, FU to 19th platform – mapping of guidance (Andreia Dinis, EFPIA) Q&A (All)	14.20 – 15.25 20 min 10 min 10 min 15 min 10 min
	Coffee break	15.25 – 15.35 10 min
4.	EudraVigilance updates - Challenges in adverse event follow-up reporting (Peter De Veene, EFPIA jointly with EUCOPE, AESGP, MfE and EuropaBio) - Termination of the pilot of signal detection by Marketing Authorisation Holders (MAHs) (Eleni Savvaidou, EMA) - Compliance reports (Tom Paternoster-Howe, EMA) Q&A (All)	15.35 – 16.30 20 min 10 min 10 min 15 min
5.	Update on AI initiatives in the field of PhV - EMA perspective (Julie Durand, Luis Pinheiro, EMA) - Industry perspective (Andrew Semmes (EUCOPE), Martin Marshall (EFPIA)) Q&A (All)	16.30 – 17.15 15 min 20 min 10 min
6.	A.O.B Drug-device fixed combinations for reporting ADRs/incidents (Graeme Ladds, Europharm)	17.15 – 17.30 15 min
7.	Summary and follow-up items Close of meeting - Ulla Wändel Liminga and Evdokia Korakianiti END	17.30 - 17.40

Participants List

EMA	EMA
Patricia Almeida	Alexandra Pacurariu
Priya Bahri	Tom Paternoster-Howe
Calogero Cannavo	Luis Pinheiro
Katerina-Christina Deli	Rodrigo Postigo
Emil Cochino	Eleni Savvaidou
Julie Durand	Elisabeth Scanlan
Maria Filancia	Andrej Segec
Christopher Gadd	Stefania Simou
Georgy Genov	Agnieszka Szmigiel
Alberto Jimenez Ganan	Gilles Touraille
Margarida Guimaraes	Dunja Vukic
Evdokia Korakianiti	Daniel Zondag
EMA scientific committees and working parties	
Ulla Wändel Liminga	Anja van Haren
Liana Gross-Martirosyan	Katharina Weber
Kora Doorduyn-van der Stoep	Maris Kuningas
Industry	
Medicines for Europe Indiana Castro Alonso Sebastian Horn Klaudija Marijanovic Barac Amit Kubavat Mohamed Ali Kotal Attila Oláh Augusto Filipe Marcus Musilek European Federation of Pharmaceutical Industries and Associations (EFPIA) Vicki Edwards Wim Vanderspuij Andreia Dinis Peter De Veene Jürgen Zorn Raphael Van Eemeren Freia Zude Joanne Webbe Martin Marshall European Association for Bioindustries (EuropaBio) Jim Nickas Petra Lerner-Hiller European Pharmaceutical Association representing Small and Medium Sized pharmaceutical Companies (Europharm SMC) Graeme Ladds Parminder Kaurr	Association of the European Self-Care Industry (AESGP) Charlotte Van Haverbeke Dr Stephan Köhler Paul-Etienne Schaeffer Daria Giusi Rasà Cengiz Bereket European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) Achint Kumar Suzanne Green Jorg Plessl Mandeep Rai Sarah Derry Andrea Rau Marie Caby - Tosi Jukka Pesonen Andrew Semmes Vaccines Europe Irina Güell Casellas Marialodovica Chiesa Marta Meszaros Oksana Tkach-Motulyak Barbara De Bernardi Johanne-Sophie Depont-Seiller Lucia Serrano Marco Jonathan Fix

