



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Agenda – 21th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

20 October 2025, 13:00 – 17:30, Virtual meeting

(9B meeting room – for EMA speakers)

Co-Chairs: Petar Mas and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising <i>- Petar Mas and Evdokia Korakianiti</i>	13.00 – 13.10 10 min
2.	EudraVigilance updates <i>- 25th anniversary of EV (Rodrigo Postigo, EMA)</i> <i>- Compliance reports (Tom Paternoster-Howe, EMA)</i> Q&A (All)	13:10–13:40 10 min 10 min 10 min
3.	CMDh Work Plan 2026–2028, including transparency measures related to pharmacovigilance (Andrzej Czesławski, CMDh) Q&A (All)	13:40–14:00 10 min 10 min

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4.	AI initiatives in the field of PhV - EMA perspective (Julie Durand, Luis Pinheiro, EMA) - Orchestrating Generative AI in Pharmacovigilance (Rory Littlebury, EFPIA) Q&A (All)	14:00–14:40 10 min 20 min 10 min
5.	Real World Evidence update - Studies to support regulatory decision (Andrej Segec, EMA) Q&A (All)	14:40–14:55 10 min 5 min
	Coffee break	14.55 – 15.10 15 min
6.	PSUR updates - News items published in 2026 (Miguel del Rey Cristobal, EMA) - EU network: Proposed upcoming pilot on prefilling information by Industry in the PSUSA assessment report template (Benjamin Pelle, EMA) - Industry associations 2025 PSUR survey (Fabian Heisig, EFPIA) Q&A (All)	15:10–16:05 10 min 15 min 20 min 10 min
7.	Guidance update - Good Pharmacovigilance Practices overview (EU-GVP) (Priya Bahri, EMA), detailed updates for: - GVP IX rev.2 (Eleni Savvaidou, EMA) - GPV V rev. 3 (Emil Cochino, EMA) - Revision of "Guideline on Risk assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling" (Dinah Duarte, EMA) Q&A (All)	16:05–16:55 10 min 10 min 10 min 10 min 10 min
8.	A.O.B	16:55–17:05 10 min
9.	Summary and follow-up items Close of meeting - Petar Mas and Evdokia Korakianiti END	17:05–17:15 10 min

Participants List

EMA	EMA
Priya Bahri Emil Cochino Dinah Duarte Julie Durand Georgy Genov Evdokia Korakianiti Benjamin Pelle Miguel del Rey Cristobal	Tom Paternoster-Howe Luis Pinheiro Rodrigo Postigo Eleni Savvaidou Andrej Segec Agnieszka Szmigiel Gilles Touraille
EMA scientific committees and working parties	
Andrzej Czesławski Ulla Wändel Liminga Liana Martirosyan Bianca Mulder	María Martínez González Jitka Vokrouhlická Maria Luisa Casini
Industry	
Medicines for Europe Sebastian Horn Mohamed Ali Kotal Attila Olah Jelena Zanetic Indiana Castro European Federation of Pharmaceutical Industries and Associations (EFPIA) Vicki Edwards Wim Vanderspuij Peter De Veene Freia Zude Barbara De Bernardi Heike Schoepper Klaudija Marijanovic Barac Fabian Heisig Rory Littlebury European Pharmaceutical Association representing Small and Medium Sized pharmaceutical Companies (Europharm SMC) Graeme Ladds	Association of the European Self-Care Industry (AESGP) Charlotte Van Haverbeke Paul-Etienne Schaeffer Daria Rasa Stephan Köhler European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) Jukka Pesonen Suzanne Green Andrea Rau Mandeep Rai Achint Kumar Vaccines Europe Anna Czwarno Johanna Kintrup Irina Güell Casellas John Barnard Oksana Tkach-Motulyak Birgit Van de Vliet Antonella Fretta Arianna Lucini European Association for Bioindustries (EuropaBio) Shaun Jones