



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2024
EMA/499299/2024

Agenda – 19th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

15 November 2024, 09:30-13:30, Virtual meeting

Co-Chairs: Ulla Wändel Liminga and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising <i>- Ulla Wändel Liminga and Evdokia Korakianiti</i>	09.30 – 09.40 10 min
2.	DARWIN EU and RWE studies in medicines regulation <i>Andrej Segec (EMA)</i> <i>Q&A (All)</i>	09.40 – 10.05 15 min 10 min
3.	PSUR updates <i>- EU network pilot (Maria Escudeiro Santos, Benjamin Pelle, EMA)</i> <i>- Frequency aspects (Marta Lopez Fauqued, EMA)</i> <i>Q&A (All)</i>	10.05 – 10.35 10 min 10 min 10 min
4.	Non-fixed Drug Combinations & Pharmacovigilance <i>Magnus Ysander (EFPIA)</i> <i>Q&A (All)</i>	10.35 – 11.00 15 min 10 min

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	Coffee break	11.00 – 11.10 10 min
5.	Guidance update - Pregnancy Labelling guideline update (Dinah Duarte, EMA) - Good Pharmacovigilance Practices (EU-GVP) – Update (Priya Bahri, EMA) Q&A (All)	11.10 – 11.40 10 min 10 min 10 min
6.	AI in PhV update Julie Durand, Luis Pinheiro (EMA) Q&A (All)	11.40 – 12.05 15 min 10 min
7.	EudraVigilance update - Retention of personal data (Rodrigo Postigo, EMA) - FU cases (Peter de Veene, EUCOPE) - Proposal to reduce replication of ICSR (Marcus Musilek, Medicines for Europe) Q&A (All)	12.05 – 12.45 10 min 10 min 10 min 10 min
8.	A.O.B Implementing Regulation (EU) No. 520/2012 update - Georgy Genov (EMA) Regulation (EU) 2024/568 – changes for PhV procedures - Mariana Rivera Vargas, Patrick Lopez Fernandez (EMA) Q&A (All)	12.45 – 13.20 5 min 15 min 15 min
9.	Summary and follow-up items Close of meeting - Ulla Wändel Liminga and Evdokia Korakianiti END	13.20 – 13.30 10 min

Participants List

EMA	
Patricia Almeida Priya Bahri Laurent Brassart Emil Cochino Dina Duarte Julie Durand Maria Escudeiro dos Santos Maria Filancia Georgy Genov Nick Halsey Benedicte Illien Evdokia Korakianiti Marta Lopez Fauqued Patrick Lopez Fernandez	Viola Sarinic Macolic Tom Paternoster-Howe Elas Pean Benjamin Pelle Loris Piccolo Marie-Helene Pinheiro Luis Pinheiro Rodrigo Postigo Mariana Rivera Vargas Andrej Segec Sabine Straus Agnieszka Szmigiel Gilles Touraille Daniel Zondag
EMA scientific committees and working parties	
Ulla Wändel Liminga Liana Gross-Martirosyan	Kora Doorduijn-van der Stoep Jitka Vokrouhlická
Industry	
AESGP Christelle Anquez-Traxler, AESGP Ghania Chamouni, Kenvue Pauliina Ehlers, Lääketeollisuus ry Christine Eising, Bayer Saloua Mekhfiwi, UPSA Paul-Etienne Schaeffer, AESGP EFPIA Vicki Edwards, Abbvie Wim Van der Spuij, BMS, Magnus Ysander, AstraZeneca Petra Lerner-Hiller, Merck Barbara De Bernardi, Pfizer, Katarina Nedog, EFPIA EuropaBio Marta Meszaros, CSL Behring	Medicines for Europe Indiana Castro Alonso, Medicines for Europe Sebastian Horn, Teva Klaudija Marijanovic Barac, Teva Pandhi, Shaloo, Sandoz Mohamed Ali Kotal, Sandoz Attila Oláh, Gedeon Richter Sanath Kumar, Viatrix Marcus Musilek, Ratiopharm EUCOPE Peter De Veene, MSD Suzanne Green, Regeneron Jukka Pesonen, Orion Achint Kumar, Incyte Andrea Rau, Moderna Seán Byrne, EUCOPE Europharm Graeme Ladds, Pharsafer