

27 October 2022
EMA/855037/2022

Agenda – 17th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

07 November 2022, 09:00-12:30, Virtual meeting

Co-Chairs: Sabine Straus and Georgy Genov

Item	Agenda	Time
1.	Welcome and matters arising <i>- Sabine Straus and Georgy Genov</i>	09:00-09:10 <i>10 min</i>
2.	PSUR: Adherence to PRAC recommendations for NAPs <i>- Cristina Hentea, Jelena Rebernisak, Medicines for Europe jointly with EFPIA and AESGP</i> Q&A (All)	09:10-09:40 <i>20 min</i> <i>10 min</i>
3.	Good Pharmacovigilance Practices (EU-GVP) - Update <i>- incl. status of digital aRMM</i> <i>- Priya Bahri, EMA</i> Q&A (All)	09:40-10:05 <i>15 min</i> <i>10 min</i>
	Coffee break	10:05-10:15 <i>10 min</i>
4.	Update on PRAC Impact Strategy (Rev. 2) and impact research projects <i>- Thomas Goedecke, EMA</i> Q&A (All)	10:15-10:40 <i>15 min</i> <i>10 min</i>

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5.	Access of the off-patent sector to aRMMs & follow up questionnaires of the reference products - Klaudija Marijanovic Barac, Medicines for Europe Q&A (All)	10:40-11:10 20 min 10 min
6.	PSUR frequencies for active substances with DLP 2025 based on a risk-based approach - Marta Lopez Fauqued, EMA Q&A (All)	11:10-11:40 20 mins 10 min
7.	PASS update - Guy Demol, EFPIA jointly with Medicines for Europe Q&A (All)	11:40-12:10 20 min 10 min
8.	Summary and follow-up items Close of meeting - Sabine Straus and Georgy Genov END	12:10-12:30 20 min

Participants List

EMA	EMA scientific committees and working parties
Georgy Genov Viola Sarinic Macolic Marie-Helene Pinheiro Agnieszka Szmigiel Priya Bahri Thomas Goedecke Marta Lopez Fauqued Marta Satta Maria Giovanna Amaouche Nadia Emil Cochino	Sabine Straus Kora Doorduijn-van der Stoep Martin Huber Menno van der Elst Jitka Vokrouhlicka Maria Luisa Casini
Industry	
AESGP Christelle Anquez-Traxler Stephanie Pick Michael Albrecht Stephan Köhler Wendy Booth EFPIA Vicki Edwards Guy Demol Dave Lewis Barbara de Bernardi Fabian Heisig Achint Kumar Jean Kilgour Silvia Garcia EUCOPE Anne Gramkow Peter De Veene Marta Meszaros Sabrina Jahn EuropaBio Lorraine Ryan Chanbasha Shaik Lucy Palatin Fidelma Reid Sophie Jaillet Petra Lerner-Hiller	Europharm Graeme Ladds Parminder Kaur Paula Sanches Medicines for Europe Andreas Iwanowitsch Sebastian Horn Mohamed Ali Kotal Attila Olah Kabil Kalathingal Katja Pečjak Klaudija Marijanovic Barac Susana Almeida Cristina Hentea Jelena Rebernisak Vaccines Europe Andrew Moore Birgit Van de Vliet Vincent Bauchau Antonella Fretta Laurence Serradell Andreea Iordache Anna Czwarno