



1 October 2021
EMA/526063/2021

Agenda – 16th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

17 November 2021, 09:00-13:15, Virtual meeting

Co-Chairs: Sabine Straus and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome and matters arising <i>- Sabine Straus and Evdokia Korakianiti</i>	09:00-09:10 <i>10 min</i>
2.	Monitoring of COVID-19 products: toolkit <i>- Agnieszka Szmigiel / Emil Cochino, both EMA</i> Q&A (All)	09:10-09:50 <i>40 min</i>
3.	PSUR: Adherence to PRAC recommendations for NAPs <i>Viola Macolic-Sarinic, EMA</i>	09:50-10:05 <i>15 mins</i>
	Coffee break	10:05-10:15 <i>10 min</i>
4.	GVPs update <i>Industry comments on GVP M XVI</i> <i>- David Lewis, Novartis / Klaudija Marijanovic Barac, Pliva</i> <i>GVPs updates incl. GVP XVI and PPP addendum III</i> <i>- Priya Bahri, EMA</i> Q&A (All)	10:15-11:10 <i>25 min</i> <i>30 min</i>

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5.	<p>Guideline on Registry-based studies – update</p> <p>- Kelly Plueschke, EMA</p> <p>Q&A (All)</p>	<p>11:10-11:40</p> <p>30 min</p>
6.	<p>Industry Perspective on PASS Impact and Pharmacovigilance obligations</p> <p>- Guy Demol, MSD</p> <p>Q&A (All)</p>	<p>11:40-12:10</p> <p>30 min</p>
7.	<p>Access of the off-patent sector to aRMMs/follow up questionnaires of the reference products</p> <p>- Klaudija Marijanovic Barac, Pliva</p> <p>Q&A (All)</p>	<p>12:10-12:40</p> <p>30 min</p>
8.	<p>EMA Medical Literature Monitoring (MLM) service update</p> <p>- Tom Paternoster-Howe, EMA</p> <p>Q&A (All)</p>	<p>12:40-12:55</p> <p>15 min</p>
9.	<p>Summary and follow-up items</p> <p>Close of meeting</p> <p>- Sabine Straus and Evdokia Korakianiti</p> <p>END</p>	<p>12:55-13:15</p> <p>20 min</p>

Participants List

EMA	EMA scientific committees and working parties
<p>Evdokia Korakianiti Georgy Genov Viola Sarinic Macolic Marie-Helene Pinheiro Agnieszka Szmigiel Priya Bahri Thomas Goedecke Nuria Semis-Costa Emil Cochino Kelly Plueschke Xavier Kurz Tom Paternoster-Howe Catherine Cohet Benjamin Pelle Lina Albakri Zaccaria Cosimo</p>	<p>Sabine Straus Kora Doorduijn-van der Stoep Martin Huber Menno van der Elst</p> <p>European Commission</p> <p>Aleksandra Opalska</p>
Industry	
<p>AESGP Christelle Anquez-Traxler Lilit Khatchikian Leonie Zimmermann Stephan Köhler Wendy Booth</p> <p>EFPIA Vicki Edwards Guy Demol David Lewis Judith Weigel Achint Kumar Silvia Garcia</p> <p>EUCOPE Anne Gramkow Sara Derry Michelle Rocher Sigrid Lang</p> <p>EuropaBio Almath Spooner Barbara De Bernardi Lara Sutton Petra Lerner-Hiller</p>	<p>Europharm Graeme Ladds</p> <p>Medicines for Europe Klaudija Marijanovic Barac Gábor Erdei Ana Real Shaloo Pandhi Nádia Fernandes Jana Brajdih Cendak Andreas Iwanowitsch Augusto Filipe Sebastian Horn Susana Almeida</p> <p>Vaccines Europe Andrew Moore Antonella Fretta Vincent Bauchau Oksana Tkach-Motulyak Sibilia Quilici Anna Czarwno</p>