

19 May 2020 EMA/275209/2020 Stakeholders and Communication Division

Agenda - PCWP/HCPWP joint meeting

24 June 2020, 14:00hrs to 17:30hrs - Virtual meeting

Co-chairs: Melanie Carr (EMA), Kaisa Immonen (EPF); Ulrich Jaeger (EHA)

Time	Topics	Speaker	
14:00	Welcome and introduction	Melanie Carr (EMA)	
1. Risk minimisation measures			
14:10	1.1 Objectives of the discussion session	Ulrich Jaeger (EHA)	
14:15	1.2 Introduction to the Good Vigilance Practices (GVP)	Priya Bahri (EMA)	
14:20	1.3 Purpose of revision of GVP module XVI	Nuria Semis (EMA)	
14:25	1.4 Remarks from the perspectives of patients and healthcare professionals	François Houyez (PCWP)	
		Jan de Belie (HCPWP)	
14:40	1.5 Questions for targeted discussion	Nuria Semis (EMA)	
14:50	Discussion	Participants	
15:50	Break		
2. Registry-based studies			
16:05	2.1 Public consultation on draft guideline	Xavier Kurz (EMA)	
16:20	Q&A	Participants	
3. Vaccine confidence			
16:30	3.1 International Coalition of Medicines Regulatory Authorities (ICMRA) statements	Marie-Agnes Heine (EMA)	



Time	Topics	Speaker	
16:40	3.2 Update on the European vaccination information portal (EVIP)	Christopher Gadd (EMA)	
16:50	Q&A	Participants	
4. EMA annual report			
17:00	4.1 Annual Report 2019: interactive online version	Monika Benstetter (EMA)	
5. AOB			
17:15	5.1 Feedback on EMA Virtual meetings	Nora Lazaro (EMA)	
17:30	End of meeting		