

21 July 2025 EMA/240573/2025 Stakeholders and Communication Division

Agenda - PCWP/HCPWP joint meeting

24 September 2025, 09:00 to 16:00 - meeting room: 2A

Co-Chairs: Juan Garcia-Burgos (EMA), tba (PCWP), tba (HCPWP)

Time	Topics	Speaker		
09:00	Welcome and introduction of new co-chairs	Juan Garcia Burgos (EMA)		
1. EMA activities – an overview and update				
09:10	1.2. Introduction to the assessment of medicines in the European Union	Bruno Sepodes (CHMP, Infarmed)		
09:25	Q&A			
09:35	1.3. Overview of EMA 30 th anniversary scientific conference	Steffen Thirstrup (EMA)		
09:45	1.4. EMA's first public Open Door Day	Maria Mavris (EMA)		
09:55	1.5. Ongoing public consultation on biosimilar reflection paper	Steffen Thirstrup (EMA)		
10:05	Q&A			
2. Engagement with other stakeholder groups – Academia and Industry				
10:30	2.1. Academia: outreach and engagement activities	Ralf Herold (EMA)		



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10:40	2.2. Small to medium-sized enterprises (SMEs): outreach and engagement activities	Helene Casaert (EMA)		
10:50	Q&A			
11:00	Coffee break			
11:15	2.3. Industry associations: outreach and engagement activities	Maria Filancia (EMA)		
11:30	Q&A			
3. Communication activities at EMA				
11:40	3.1. Communication materials on safety monitoring of medicines: engagement with stakeholders	Violeta Pashova and Stephanie Cohen (EMA)		
11:55	Q&A			
12:10	3.2. Risk minimisation measures webpage: what you can find	Priya Bahri (EMA)		
12:15	Q&A			
12:20	Lunch break			
4. EMA feedback surveys				
13:20	4.1. EMA surveys of organisation satisfaction	Ivana Silva (EMA)		
13:30	Q&A			
5. Update on activities related to pregnancy and lactation				
13:40	5.1. New GVP guidance on minimising embryo-fetal risks of medicines	Priya Bahri (EMA)		
13:50	Q&A			
6. Committee feedback				
14:00	6.1. Updates from Scientific Committees PRAC			

Time	Topics	Speaker		
		Ewa Bałkowiec-Iskra,		
	СНМР	Ingrid Wang		
	CMDh	Nina Malvik,		
		Jitka Vokrouhlická		
14:30	Q&A			
14:40	Coffee break			
7. Patient Experience Data				
15:00	7.1. Update on patient experience data reflection paper	Rosa Gonzalez-Quevedo (EMA)		
15:15	Q&A			
15:25	AOB			
16:00	End of meeting			