

28 February 2024 EMA/567941/2023 Stakeholders and Communication Division

Agenda – Joint Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) working parties meeting

27 and 28 February 2024 - meeting room: 2A / Webex

Co-Chairs: Juan Garcia-Burgos (EMA), Marko Korenjak (PCWP), Rosa Giuliani (HCPWP)

Day 1: 27 February, 13:30-18:30 CET

Time	Topics	Speakers		
13:15	Joining and technical checks			
13:30 (10')	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)		
1. Working party operations				
13:40 (10')	1.1. Working party work plan – mid-mandate review	Ivana Silva (EMA)		
13:50 (10')	1.2. Stakeholder Engagement report - overview	Maria Filancia (EMA)		
14:00 (10')	1.3. HMH (human medicines highlights) newsletter – new format	Kaisa Immonen (EMA)		
14:10 (15')	Q&A	All		
2. Third party interventions				
14:25 (10′)	2.1. Third party contributions during ongoing assessments	Fabrizio Boccacci (EMA)		
14:35 (25')	Q&A	All		
15:00 (15')	Coffee break			
3. What is happening in cancer				
15:15 (15′)	3.1. Cancer Medicines as pathfinder	Francesco Pignatti (EMA)		
15:30 (15′)	3.2. Conversations on Cancer	Caroline Voltz (EMA)		
15:45 (35')	Q&A	All		

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Time	Topics	Speakers		
4. Update on progress with Patient Experience Data				
16:20 (15′)	4.1. Patient experience data reflection paper	Rosa Gonzalez-Quevedo (EMA)		
16:35 (10′)	 Action plan (therapeutic area priorities), consultation and next steps – survey 	Rosa Gonzalez-Quevedo (EMA),		
16:45 (30')	Q&A	All		
5. Update on training resources				
17:15 (15′)	5.1. Update on the Network Training Centre	Esther Martinez (EMA)		
17:30 (10')	Q&A	All		
6. Policy on competing interests				
17:40 (15′)	6.1. EMA's policy on competing interests	Zahra Hanaizi (EMA), Hilde Boone (EMA)		
17:55 (35′)	Q&A	All		
18:30	End of day 1			

Day 2: 28 February, 09:00-16:00 CET

Time	Topics	Speakers		
08:45	Joining and technical checks			
09:00 (5')	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)		
7. Pharmacovigilance				
09:05 (20')	7.1. Preparation of amendments to Commission Implementing Regulation 520/2012 on the performance of pharmacovigilance activities	Izabela Taborska (EC, DG Santé)		
09:25 (20')	Q&A	All		
09:45 (25′)	 Risk minimisation for patient safety – update on policies and practices 	Priya Bahri (EMA)		
10:10 (20')	Q&A	All		
10:30 (15′)	Coffee break			
8. Feedback from Patient and HCP representatives in EMA groups				
10:45 (20')	8.1. European Network of Paediatric Research at EMA (Enpr-EMA)	Gunter Egger (EMA), Jose Drabwell (IPOPI)		
11:05 (10′)	Q&A			

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11:15	8.2. Review of the package leaflet template			
(10')	Update on the QRD subgroup	Monica Buch (EMA)		
(10')	 Feedback from patient, consumer and HCP members of the subgroup 	Courtney Davis (HAI)		
11:35 (25')	Q&A	All		
12:00 (60')	Lunch break			
9. Ongoing EMA activities				
13:00 (20')	9.1. COVID-19: Outcome of Long COVID workshop – EMA and patient perspectives	Stephanie Buchholz (EMA), Chantal Britt (Long COVID Europe)		
13:20 (30')	Q&A	All		
13:50 (15′)	9.2. ACT EU: summary of recent workshops and establishment of the Multistakeholder Platform (MSP) Advisory Groups	Ana Zanoletty (EMA), Maria Filancia (EMA)		
14:05 (15')	Q&A	All		
14:20 (15')	9.3. Data discoverability: HMA-EMA Catalogues of Real- World Data sources and studies	Ana Cochino (EMA)		
14:35 (15')	Q&A	All		
14:50 (20')	Coffee break			
10. Shortages				
15:10 (10')	10.1. Next phase to complete and extend the Union list of critical medicines	Joao Francisco Ferreira (EMA)		
15:20 (10')	Q&A	All		
15:30 (10')	10.2. Update on shortage of glucagon-like peptide-1 receptor agonists (GLP-1 RAs)	Klaus Kruttwig (EMA), Romana Micovcakova (EMA)		
15:40 (5')	Q&A	All		
15:45 (15')	AOB	Juan Garcia Burgos (EMA)		
16:00	End of meeting			