22 January 2026
EMA/384211/2025
Stakeholders and Communication Division

Draft Agenda – PCWP/HCPWP joint meeting

3 February 2026, 13:30 to 18:00 – meeting room: 1A

Co-Chairs: Juan Garcia-Burgos (EMA), Marco Greco (PCWP), Piotr Szymański (HCPWP)

Time	Topics	Speaker
13:15	Registration and reimbursement arrangements	
13:30	Welcome	Juan Garcia Burgos (EMA)
1. Revised pharmaceutical legislation		
13:40	1.1. Revised pharmaceutical legislation – outcome for EMA, patients and healthcare professionals	Lilia Luchianov (DG Sante) Anthony Rodiadis (DG Sante)
14:10	Q&A	
14:55	1.2. What are the next steps for EMA under the revised pharmaceutical legislation: focus on stakeholders	Alexis Nolte (EMA) Melanie Carr (EMA)
15:25	Q&A	
15:55	*Coffee break*	
2. Accessibility		
16:10	2.1. From regulatory decision to health technology assessment: the new developments in Europe	Michael Berntgen (EMA) Noemie Manent (EMA)
16:20	2.2. HTA Regulation – experience from the first year of implementation	Julie Spony (DG Sante)

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Time	Topics	Speaker
16:40	Q&A	
17:20	2.3. Patient and healthcare professional perspectives from HTA stakeholder network	Solene Jouan (EPF) Robin Doeswijk (EHA)
17:40	Q&A	
18:00	*End of meeting*	

Draft Agenda – PCWP/HCPWP joint meeting

4 February 2026, 9:00 to 16:00 – meeting room: 1A

Co-Chairs: Juan Garcia-Burgos (EMA), Marco Greco (PCWP), Piotr Szymański (HCPWP)

Time	Topics	Speaker
08:50	Joining and technical checks	
09:00	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
3. Availability and supply		
09:05	3.1. Next steps in the ECHA assessment of the PFAS universal restriction under REACH	Leonor Enes (EMA) Riccardo Mezzasalma (EMA)
09:20	Q&A	
09:35	3.2. How EMA manages shortage cases: step by step	Siofradh McMahon (EMA)
09:50	3.3. Update on Union list of Critical Medicines	Siofradh McMahon (EMA)
10:10	3.4. Union List of Critical Medicines from the perspective of rare diseases	François Houÿez (EURORDIS)
10:20	Q&A	
4. Sustainability of the network		
10:40	4.1. Candidate countries observing EMA activities	Katre Rugo (EMA) Michiel Hendrix (EMA)
10:45	Q&A	
10:50	*Coffee break*	
5. Leveraging data and patient experience in evidence generation		
11:05	5.1. ICH E22 guideline on general considerations for patient preference studies	Francesco Pignatti (EMA)
11:15	5.2. Patient perspective	François Houÿez (EURORDIS)
11:25	Q&A	
11:45	5.3. Enhancing transparency and discoverability: HMA-EMA catalogues of real-world data (RWD) sources and studies	Katerina-Christina Deli (EMA) Stefania Simou (EMA)
12:00	Q&A	
12:15	*Lunch break*	

Time	Topics	Speaker
13:15	5.4. Emerging topics from PED reflection paper consultation	Rosa Gonzalez-Quevedo (EMA)
13:20	5.5. Feedback from surveys in PED priority areas	Claire Espinasse (EMA) Friederike Wilke (Barmer – Statutory Health Insurance (Germany) Florence Borrelly-Konyakhin (EMA)
13:40	Q&A	
13:55	5.6. PED in non-interventional studies containing real world data	Diogo Manuel Monteiro De Almeida (University of Lisbon) Denise Umuhire (EMA)
14:15	Q&A	
6. Multistakeholder workshops		
14:30	6.1. Feedback from the HMA/EMA multistakeholder workshop on artificial intelligence	Luis Pinheiro (EMA)
14:40	Q&A	
14:50	6.2. Information on workshop for medicines and medical devices in the cardiovascular field	Ivana Silva (EMA)
15:00	Q&A	
15:10	6.3. Open discussion with working parties	Co-chairs (PCWP and HCPWP)
15:50	AOB • Establishment of an expert group on vaccine confidence – call for volunteers • 20 years of PCWP – June meeting • EUNTC training on Data Quality and Omics Data	 Rosa Gonzalez-Quevedo (EMA) Maria Mavris (EMA) Gianluca Gazzaniga (EMA)
16:00	*End of meeting*	