



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2025
EMA/271255/2025
Stakeholders and Communication Division

Draft Agenda – PCWP/HCPWP and all eligible organisations meeting

18 November 2025, 09:00 to 17:30 - meeting room: 2A/WebEx

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

Time	Topics	Speakers
09:00	Registration and reimbursement arrangements	
1. Welcome and opening remarks		
09:15	1.1. Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
09:20	1.2. Highlights of 2025	Melanie Carr (EMA)
09:40	1.3. Overview of the evolution of patient and healthcare professional engagement in EMA activities	Maria Mavris (EMA)
09:50	Q&A	All
2. Update on New pharmaceutical legislation		
10:00	2.1. New pharmaceutical legislation: timeline and EMA stakeholder engagement activities	Hilde Boone (EMA) Kristina Larsson (EMA) Ralph Bax (EMA)
10:40	Q&A	All
10:55	Coffee break	
3. Leveraging data, digitalisation and artificial intelligence		
11:15	3.1. EU DARWIN studies: - Safety studies on GLP-1 receptor agonists (GLP-1 RAs). - Frailty and polypharmacy among adults with selected cancers at the time of diagnosis.	Daniel Morales (EMA)



Time	Topics	Speakers
11:45	Q&A	All
11:55	<i>Lunch break</i>	
4. Regulatory science, innovation and competitiveness		
13:00	4.1. Updates on Cancer Medicines Forum (CMF)	Caroline Voltz-Girolt (EMA)
13:15	Q&A	All
13:25	4.2. Update on ACT EU multistakeholder platform	Ana Zanoletty (EMA) Denis Lacombe (MSP AG co-chair, EORTC) François Houÿez (EURORDIS)
13:50	Q&A	All
14:00	4.3. General update on ACT EU	Laura Pioppo (EMA)
14:15	Q&A	All
14:25	4.4. A patient's quest to the magical land of clinical trials: is there a yellow brick road?	Ioanna Psalti (EU-EYE)
14:40	Q&A	All
14:50	<i>Coffee break</i>	
5. Work plans for working parties		
15:10	5.1. Update on work plans for working parties	Ivana Silva (EMA)
15:25	Q&A	All
6. Training activities		
15:35	6.1. Annual training 2026 - for patients, consumers and healthcare professionals involved in medicines-related activities at EMA	Kaisa Immonen (EMA)
15:45	Q&A	All
15:50	6.2. Training material on Scientific Advice	Liese Barbier (EMA)
16:00	Q&A	All
7. International EMA activities		
16:05	7.1. Overview on international EMA activities and update on African Medicines Agency	Martin Harvey-Allchurch (EMA)
16:20	Q&A	All

Time	Topics	Speakers
8. Members' voice		
16:30	8.1. Patient and consumer organisations EHN will present: - Cardiovascular Health (CVH) Plan and its relevance for the wider patients' and consumers' community. - The European Alliance for Cardiovascular Health (EACH) Summit, highlighting collaborative efforts to strengthen cardiovascular health across Europe.	Mehitabel Holler (EHN)
16:40	Q&A	All
16:50	8.2. Healthcare professional organisations Aligning policies with real-world medical needs: the bridging role of HCPOs in the EMA– The European Chemicals Agency (ECHA) regulatory overlap.	Mario Romano (EU-EYE)
	Presentation of EFPC and ongoing work for women's health and interprofessional collaboration.	Elena Petelos (EFPC) Victoria Vivilaki (EFPC)
17:10	Q&A	All
17:20	AOB	
17:30	<i>End of day 1</i>	

Draft Agenda – PCWP/HCPWP and all eligible organisations meeting

19 November 2025, 09:00 to 16:15 - meeting room: 2A/Webex

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

Time	Topics	Speakers
08:45	<i>Joining and technical checks</i>	
09:00	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
9. Availability and supply of medicines		
9:05	9.1. Critical Medicines Act	Vanessa Bennett (EMA)
9:35	Q&A	All
9:45	9.2. Introduction to shortages topic	Monica Dias (EMA)
9:55	9.3. Update on the Union list of critical medicines	Siofradh McMahon (EMA)
10:10	Q&A	All
10:20	9.4. Results of the Shortage Prevention and Mitigation Plans (SPP/SMP) pilot	Maria Jesus Alcaraz Tomas (EMA)
10:35	Q&A	All
10:45	9.5. Ongoing critical shortages	Klaus Kruttwig (EMA)
10:55	Q&A	All
11:05	9.6. EAHP Survey on the shortages of medicines and medical devices	Despoina Makridaki (EAHP)
11:10	Q&A	All
11:15	<i>Coffee break</i>	
11:30	9.7. EMA-HMA repurposing pilot report	Christelle Bouygues (EMA)
11:45	Q&A	All
10. Communication activities at EMA		
11:55	10.1. Update on EMA's communication campaigns	Giulia Gabrielli (EMA)
12:10	Q&A	All
12:20	10.2. Communication materials on safety monitoring of medicines: engagement with stakeholders	Violeta Pashova (EMA) Stephanie Cohen (EMA)
12:35	Q&A	All
12:45	<i>Lunch break</i>	

Time	Topics	Speakers
11. Update on activities related to pregnancy and lactation		
13:45	11.1. Gender equality in women's health – the forgotten priority	Corinne De Vries (EMA)
14:00	Q&A	All
12. Product information		
14:10	12.1. Update on the QRD template – revision of the package leaflet	Monica Buch (EMA) Alexios Skarlatos (EMA)
14:30	Q&A	All
14:40	12.2. Effect of a key information section in European patient leaflets on expectations about new medicines: results from an online, randomised controlled trial	Courtney Davis (HAI and King's College London) Avi Cherla (Harvard Medical School, London School of Economics and Political Science) Huseyin Naci (London School of Economics and Political Science)
15:00	Q&A	All
15:20	12.3. Medicine overviews: survey on target audience awareness and satisfaction	Catriona Ester (EMA)
15:30	Q&A	All
13. Update on Human Medicines Highlights (HMH)		
15:40	13.1. One year of revamped HMH newsletter	Kaisa Immonen (EMA)
15:55	Q&A	All
16:05	AOB	
16:15	<i>End of day 2</i>	