

05 February 2025
EMA/31466/2025
Stakeholders and Communication Division

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

1 and 2 April 2025 – meeting room: 2A / Webex

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

Day 1: 1 April, 09:00–17:45 CET

Time	Topics	Speakers
08:45	<i>Joining and technical checks</i>	
1. Welcome and opening remarks		
09:00	1.1. Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
09:05	1.2. EMA's 30th anniversary	Emer Cooke (EMA)
2. Regulatory science, innovation and competitiveness		
09:20	2.1. Clinical trials update	Peter Arlett (EMA)
09:30	2.2. ACT EU workplan 2025-2026	Laura Pioppo (EMA)
09:40	2.3. Feedback from ACT EU workshop on ICH E6 R3	Dong Ho Kim Pietsch (EMA) François Houÿez (EURORDIS)
09:55	Q&A	All
10:10	2.4. Update on Multistakeholder platform	Ana Zanoletty (EMA)
10:20	Q&A	All
10:30	<i>Coffee break</i>	

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3. Pharmacovigilance		
11:00	3.1. Risk minimisation in healthcare – Updates on policy, practice, research and engagement.	Priya Bahri (EMA)
11:15	Q&A	All
4. EMA policy on competing interests		
11:25	4.1. Update on EMA policy on competing interests (policy 0044)	Zahra Hanaizi (EMA) Luc Van Santvliet (EMA)
11:45	Q&A	All
12:00	<i>Lunch break</i>	
5. European Medicines Agency Network (EMAN) Strategy		
13:00	5.1. EMANS to 2028.	Melanie Carr (EMA) Rui Santos (INFARMED)
13:20	Q&A	All
6. Product information		
13:30	6.1. Update of the QRD template revision of the package leaflet	Monica Buch (EMA)
13:40	Q&A	All
13:55	6.2. Electronic product information (ePI) pilot and next steps	Elizabeth Scanlan (EMA)
14:10	Q&A	All
14:20	6.3. EPF's statement information to patients	Solène Jouan (EPF)
14:30	6.4. Joint statement on ePI	Diogo Teixeira Pereira (CPME)
14:40	Q&A	
15:00	<i>Coffee break</i>	
7. Availability of medicines. Shortages		
15:10	7.1. Introduction to shortages topic	Monica Dias (EMA)
15:20	7.2. Discontinuation of the HMA/EMA task Force on Availability of authorised medicines (TF AAM) and transition to Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and Medicine Shortages Single Point of Contact (SPOC) Working Party	Vanessa Bennett (EMA)

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15:35	Q&A	
15:45	7.3. Ongoing critical shortages	Maria Jesus Alcaraz Tomas (EMA)
16:00	Q&A	
16:10	7.4. European Shortages Monitoring Platform (ESMP) Update	Sofia Zastavnik (EMA)
16:25	Q&A	All
16:35	7.5. Webinar on shortages - patients and healthcare professionals	Inga Abed (EMA)
8. Committee feedback		
16:40	8.1. Updates from Scientific Committees COMP CAT PDCO HMPC	Committee members
17:20	Q&A	All
17:35	AOB	
17:45	<i>End of day 1</i>	

Day 2: 2 April, 09:00–15:50 CET

Time	Topics	Speakers
08:45	<i>Joining and technical checks</i>	
09:00	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
9. Leveraging data, digitalisation and artificial intelligence		
9:05	9.1. Data Analysis and Real World Interrogation Network (DARWIN EU)-three years of a journey	Andrej Segec (EMA)
9:20	Q&A	All
9:30	9.2. Update Patients experience data – reflection paper	Kaisa Immonen (EMA)
9:45	Q&A	All
9:55	9.3. Best practices - stakeholders' engagement	Kaisa Immonen (EMA)
10:05	Q&A	All
10:20	<i>Coffee break</i>	
10. Reflection from PCWP and HCPWP co-chairs		
10:40	10.1. End of mandate comments from PCWP and HCPWP Co-Chairs	Marko Korenjak (PCWP) Rosa Giuliani (HCPWP)
10:50	Q&A	
Looking ahead into 2025		
11:00	10.2. Call for new mandate 2025-2028	Maria Bonafonte (EMA)
11:05	Q&A	All
11:10	10.3. Highlights of PCWP/HCPWP 2023-2025 mandate	Maria Mavris (EMA)
11:20	Q&A	All
11. Ecosystem information management		
11:30	Stakeholder listening pilot	Rosa Gonzalez-Quevedo (EMA)
11:45	Update on misinformation framework activities	Sophie Labbe (EMA)
12:00	Q&A	All
12:20	<i>Lunch break</i>	
12. Communication activities		
13:30	12.1. Update on communication campaigns	Giulia Gabrielli (EMA) Camelia Enachioiu (EMA)
13:45	Q&A	

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13. One Health approach		
14:00	13.1. Cross-agency One Health Task Force – a framework for action	Ana Vidal (EMA)
14:20	Q&A	All
14:30	<i>Coffee break</i>	
14. Members' voice		
14:45	14.1. Patients organisations	
15:00	Q&A	
15:10	14.2. HCPs organisations Risks on the misuse of medicines	Jorge Batista (PGEU)
15:25	Q&A	All
15:35	AOB	Juan Garcia Burgos (EMA)
15:50	<i>End of meeting</i>	