

15 May 2024  
EMA/187783/2024  
Stakeholders and Communication Division

## Draft agenda – Patients and Consumers Working Party (PCWP) meeting

EMA Meeting room: EMA 2A / Webex

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

### PCWP plenary - 2 July 2024, 09:30–12:30 CEST

Time	Topics	Speakers
09:00	<i>Joining and technical checks</i>	
09:30	Welcome and introduction / Health and safety information	Marko Korenjak (PCWP) and Juan Garcia Burgos (EMA)
<b>1. Patient involvement in EMA activities</b>		
09:40	1.1. Update on patient involvement in Scientific Advice procedures 1.2. Activities involving patients/consumers during evaluation phase with CHMP	Kaisa Immonen (EMA) Maria Mavris (EMA)
09:55	Q&A	
10:10	1.3. Remuneration of experts for involvement in EMA activities	Maria Mavris (EMA)
10:20	Q&A	
<b>2. EMA International activities and patient engagement</b>		
10:35	2.1. EMA International affairs: overview of activities <ul style="list-style-type: none"><li>Support to other regions</li><li>Scope for patient engagement</li></ul>	Victoria Palmi Reig and Michiel Hendrix (EMA)
10:45	Q&A	

Time	Topics	Speakers
10:55	2.2. Collaboration with US FDA <ul style="list-style-type: none"> <li>Patient engagement cluster</li> <li>PCWP and FDA-CTTI Patient Engagement Collaborative (PEC)</li> </ul>	Maria Mavris (EMA)
11:05	Q&A	
11:15	2.3. Progress on the establishment of the African Medicines Agency	Victoria Palmi Reig and Michiel Hendrix (EMA)
11:25	Q&A	
11:30	<i>Coffee break</i>	
<b>3. PCWP operations</b>		
11:40	3.1. Outcome of the survey on the joint PCWP/HCPWP workplan actions and discussion on PCWP-specific actions	Ivana Silva (EMA)
11:50	Q&A	
12:00	3.2. Open discussion with working party members	PCWP
12:30	<i>End of PCWP plenary</i>	

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

EMA meeting room: EMA 2A / Webex

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

## Joint PCWP-HCPWP – Part 1 - 2 July 2024, 14:00-18:15 CEST

Time	Topics	Speakers
13:45	<i>Joining and technical checks</i>	
14:00	Welcome and introduction / Health and safety information	Juan Garcia Burgos (EMA)
<b>1. European Medicines Agency Network (EMAN) Strategy</b>		
14:10	1.1. Extension of the EMAN strategy to 2028	Melanie Carr (EMA)
14:25	Q&A	
<b>2. Members' voice</b>		
15:00	2.1. PCO: Analysis on Medicines Overviews for CHMP opinions	François Houyez (EURORDIS)
15:10	2.2. HCPO: Roles and Responsibilities of the GP in Prescribing in the Health Care System	Mary McCarthy (UEMO)
15:20	Q&A	
<b>3. Clinical trial activities</b>		
15:30	3.1. Clinical trials raw data pilot – interim results	Frank Pétavy and Marcia Rückbeil (EMA)
15:45	Q&A	
15:50	3.2. Update on ACT EU and Multistakeholder Platform	Ana Zanoletty (EMA) Denis Lacombe (EORTC)
16:00	Q&A	
16:10	<i>Coffee break</i>	

Time	Topics	Speakers
<b>4. Product Information</b>		
16:25	4.1. Update of the QRD template of the package leaflet	Monica Buch (EMA)
16:35	Q&A	
<b>5. Revision of EMA Guideline on Risk Assessment of Medicines on Reproduction and Lactation</b>		
16:45	5.1. Concept paper on the revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling	Dinah Duarte (EMA) Karel Allegaert (EAP)
17:00	Q&A	
<b>6. Transparency activities</b>		
17:10	6.1. Re-start of Clinical Data Publication – Update on transparency activities	Silvia Garrido-Lestache (EMA)
17:20	Q&A	
17:30	6.2. Revised CTIS transparency rules	Francesca Scotti (EMA)
17:40	Q&A	
<b>7. Update on biosimilars</b>		
17:45	7.1. Outcome of biosimilars surveys to patients, healthcare professionals, industry and Heads of Medicines Agencies (HMA)	Rosa Gonzalez-Quevedo (EMA) Diederik de Cock (EMA collaborating expert)
18:00	Q&A	All
<b>8. AOB</b>		
18:10	AOB	
18:15	<i>End of Joint PCWP-HCPWP plenary part 1</i>	

## Joint PCWP-HCPWP – Part 2 - 3 July 2024, 09:00-12:15 CEST

Time	Topics	Speakers
<b>9. Update on shortage related activities</b>		
9:00	9.1. Presentation of the activities of the Joint Action Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (Chessmen)	Nuno Simões (Infarmed) Domenico Di Giorgio (AIFA)
09:10	Q&A	
09:20	9.2. Report on progress of the Subgroup on the implementation of the Good practice guidance for patient and healthcare professional organisations on the prevention of shortages	Inga Abed (EMA)
09:30	Q&A	
09:40	9.3. Update and feedback on Multistakeholder workshop on GLP-1 RAs shortages	Klaus Kruttwig (EMA)
09:50	Q&A	
10:00	9.4. Report on “Union List of Critical Medicines” development activities	Joao Ferreira (EMA)
10:10	Q&A	
10:20	<i>Coffee break</i>	
<b>10. Vaccine related activities</b>		
10:40	10.1. Reinitiation of the vaccines outreach strategy	Melanie Carr and Marco Cavaleri (EMA)
10:55	10.2. Update on the European Vaccination Information Portal (EVIP)	Nicolas White (ECDC) Cécile Henrot and Christopher Gadd (EMA)
11:15	Q&A	
11:55	10.3. Presentation of the Vaccine Monitoring Platform	Catherine Cohet and Alessandra Buoninfante (EMA)
12:05	Q&A	

Time	Topics	Speakers
12:10	AOB	
12:15	<i>End of joint meeting</i>	