

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	Joining and technical checks	
09:30	Welcome and introduction / Health and safety information	Marko Korenjak (PCWP) and Juan Garcia Burgos (EMA)
1. Patient involvement in EMA activities		
09:40	1.1. Update on patient involvement in Scientific Advice procedures	Kaisa Immonen (EMA)
	1.2. Activities involving patients/consumers during evaluation phase with CHMP	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	
2. EMA Inter	rnational activities and patient engagement	
10:35	2.1. EMA International affairs: overview of activities	Victoria Palmi Reig
	Support to other regions	and Michiel Hendrix (EMA)
	Scope for patient engagement	, , , , , , , , , , , , , , , , , , ,
10:45	Q&A	

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Time	Topics	Speakers
10:55	2.2. Collaboration with US FDA	Maria Mavris (EMA)
	Patient engagement cluster	
	<ul> <li>PCWP and FDA-CTTI Patient Engagement Collaborative (PEC)</li> </ul>	
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	Coffee break	
3. PCWP ope	erations	
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	End of PCWP plenary	

## 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

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

Time	Topics	Speakers	
4. Product	4. Product Information		
16:25	4.1. Update of the QRD template of the package leaflet	Monica Buch (EMA)	
16:35	Q&A		
5. Revision	5. Revision of EMA Guideline on Risk Assessment of Medicines on Reproduction and Lactation		
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		
6. Transpa	rency activities		
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		
7. Update	on biosimilars		
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	
8. AOB			
18:10	AOB		
18:15	End of Joint PCWP-HCPWP plenary part 1		

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

9. Update or shortage related activities       Nuno Simões (Infarmed)         9:00       2.1. Presentation of the activities of the Joint Action Coordination and Harmonisation of the Existing Systems agains Shortages of Medicines – European Network (Chessmen)       Nuno Simões (Infarmed)         09:100       Q&A       Domenico Di Giorgio (AIFA)         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       Inga Abed (EMA)         09:40       9.3. Update and feedback on Multistakeholder workshop on GLP-1 RAs shortages       Klaus Kruttwig (EMA)         10:00       9.4. Report on "Union List of Critical Medicines" development activities       Joao Ferreira (EMA)         10:10       Q&A       Infarmed)         10:20       Caffee break       Infarmed)         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       Nicolas White (EDC)         11:15       Q&A       Infarmed)       Catherine Cohet and Alessandra Buoninfante (EMA)         11:15       Q&A       Infarmed)       Marco Cavaleri (ENA)         11:15       Q&A       Infarmed)       Catherine Cohet and Alessandra B	Time	Topics	Speakers	
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and Alessandra Buoninfante (EMA)	11:15	Q&A		
12:05 Q&A	11:55	10.3. Presentation of the Vaccine Monitoring Platform	and Alessandra	
	12:05	Q&A		

Time	Topics	Speakers
12:10	AOB	
12:15	End of joint meeting	