EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft Agenda – PCWP/HCPWP joint meeting

28 June 2023, 08:45hrs to 17:00hrs – meeting room: 2A / Webex

Co-Chairs: Juan Garcia-Burgos (EMA) and Rosa Giuliani (HCPWP)

Time	Topics	Speaker
08:30	Joining and technical checks	
08:45	Welcome and introduction to joint meeting	Juan Garcia Burgos (EMA)
1. Ongoing EMA activities		
09:00	1.1. Update on RWE including DARWIN EU®	Andrej Segec Aldo Maggioni (ESC) Elizabeth Vroom (UPPMD)
09:30	Q&A	All
09:45	1.2. Piloting the creation of electronic product information (ePI) for EU medicines	Elizabeth Scanlan (EMA)
10:00	Q&A	All
10:15	1.3. Monitoring of events and preparedness for Public Health Emergencies/Major Events	Monica Dias (EMA)
10:30	Q&A	All
10:40	1.4. Feedback on the pilot on collecting information on shortages by EMA eligible organisations	Inga Abed (EMA)
10:50	Q&A	All
11:00	1.5. Implementation of the Good practice guide on prevention and possible re-launch of the sub-group	Inga Abed (EMA)
11:10	Q&A	All
11:20	*Coffee break*	
11:45	1.6. Update on activities linked to presence of N-nitrosamines in human medicines	Antonio Azevedo (EMA) Robin Ruepp (EMA)
11:55	Q&A	
12:05	1.7. Patient Experience Data update	Rosa Gonzalez-Quevedo (EMA)
12:35	Q&A	

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Time	Topics	Speaker
12:45	*Lunch*	
2. Pharmacovigilance		
14:00	2.1. Consultation on possible outer packaging warning on opioid use disorder	Priya Bahri (EMA) Liana Gross-Martirosyan (PRAC)
14:10	Q&A	All
14:20	2.2. Report on pharmacovigilance tasks from EU Member States and EMA - 2019-2022	Aniello Santoro (EMA) Stephanie Cohen (EMA)
14:35	Q&A	All
3. Clinical trials		
14:50	3.1. ACT EU – feedback from kick off meeting of multi-stakeholder platform (MSP)	Peter Arlett (EMA)
15:10	Q&A	All
15:25	3.2. Decentralised clinical trials (DCT) • Overview of the recommendation paper and plans for the implementation phase	Ditte Zerlang Christensen (DKMA) Monique Al (CCMO)
15:40	Q&A	All
15:50	3.3. Good Clinical Practice (GCP) ICH E6 R3 • PCWP/HCPWP joint comments • Public Consultation Workshop	 Ivana Silva (EMA) Kim Pietsch (EMA) Peter Twomey (EMA)
16:05	*Coffee break*	
4. EMA communications and reporting		
16:15	4.1. Introduction to the revamp of the Human Medicines Highlights newsletter project and results of the stakeholder survey	Kaisa Immonen (EMA)
16:30	Q&A	All
16:45	4.2. Stakeholder Engagement report	Giulia Gabrielli (EMA)
16:55	Wrap up	Juan Garcia Burgos (EMA)
17:00	*End of meeting*	