

Draft Agenda – PCWP/HCPWP and all eligible organisations meeting

20 November 2024, 9:00 – 17:20 (CET) Hybrid meeting - Webex/Room 1A

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

Time	Topics	Speaker
08:45	<i>Joining and technical checks</i>	
1. Welcome and introduction to joint meeting		
09:00	1.1. Highlights of 2024	Juan Garcia Burgos (EMA) and Melanie Carr (EMA)
2. Regulatory science, innovation and competitiveness		
Clinical Trials updates		
09:20	2.1. Clinical Trials in the EU: continuing the journey	Ana Zanoletty (EMA)
09:25	2.2. Feedback from ACT EU Multistakeholder Platform Annual Meeting	Ana Zanoletty (EMA) and Denis Lacombe (EORTC)
09:45	Q&A	All
09:55	2.3. Update on the Clinical Trial Information System (CTIS) public portal	Francesca Scotti (EMA)
10:10	Q&A	All
10:25	2.4. The ACT EU trial map: a dashboard for patients	IJsbrand den Rooijen (EMA)
10:40	Q&A	All
10:55	2.5. Full relaunch of Clinical Data Publication	Karen Quigley (EMA)

Time	Topics	Speaker
11:05	Q&A	All
11:15	<i>Coffee break</i>	
3. Medical Devices		
11:30	3.1. Overview of EMA activities in the area of medical devices	Silvy da Rocha (EMA)
11:40	3.2. Expert panel support for orphan medical devices	Michael Vogl (EMA)
11:55	Q&A	All
12:05	<i>Lunch break</i>	
4. Leveraging data, digitalisation and artificial intelligence		
EMA data related initiatives		
13:15	4.1. HMA/EMA joint Big Data Steering Group (BDSG) ongoing activities	Denise Umuhire (EMA) and François Domerque (EMA)
13:30	Q&A	All
13:50	4.2. Patients experience data – reflection paper and upcoming consultation	Rosa Gonzalez-Quevedo (EMA)
14:00	Q&A	All
Artificial Intelligence		
14:15	4.3. Artificial Intelligence multi-annual workplan update	Luis Pinheiro (EMA)
14:35	Q&A	All
14:50	<i>Coffee break</i>	
5. Availability and supply of medicines		
15:00	5.1. Introduction to shortages topic	Monica Dias (EMA)
15:05	5.2. Update on the publication of version 2 of the Union list of critical medicines	Joao Ferreira (EMA)
15:15	Q&A	All

Time	Topics	Speaker
15:25	5.3. Update on the new Medicine Shortage Communication (MSC) process and template	Joao Ferreira (EMA)
15:35	Q&A	All
15:45	5.4. Feedback on the Single Point of Contact (SPOC) Working Party activities on Glucagon-Like Peptide-1 (GLP-1) receptor agonists shortage management	Klaus Kruttwig (EMA)
15:55	Q&A	All
6. Communication activities at EMA		
16:05	6.1. Setting the scene	Monika Benstetter (EMA)
16:10	6.2. 'Communicating about shortages' campaign	Giulia Gabrielli (EMA) and Laure Herold (EMA)
16:25	Q&A	All
16:40	6.3. Findings of communication perception survey 2024	Violeta Pashova (EMA)
16:55	Q&A	All
17:05	6.4. 'Key User Group' for EMA corporate website	Inês Matos (EMA)
7. AOB and closing remarks		
17:10	7.1. AOB, wrap up and key information for 2025	Juan Garcia Burgos (EMA)
17:20	<i>End of meeting</i>	