



03 May 2023
EMA/901780/2022
Stakeholders and Communication Division

Draft Agenda – PCWP/HCPWP joint meeting

19 and 20 September 2023, virtual meeting (WebEx)

DAY 1: 19 September, 13:30–17:50 CEST

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

Time	Topics	Speaker
13:15	Joining and technical checks	
Introduction		
13:30	Welcome and opening remarks	Juan Garcia-Burgos (EMA) Rosa Giuliani (HCPWP) Marko Korenjak (PCWP)
1. Patient and HCP representatives in EMA groups		
13:45	1.1. Emergency Task Force (ETF)	Jose Drabwell (IPOPI) Anita Simonds (ERS)
	1.2. HMA/EMA Joint Big Data Steering Group (BDSG)	George Paliouras (WDO) Ioana Agache (EAACI)
	1.3. Medicines Shortages Steering Group (MSSG)	Charlotte Roffiaen (EPHA) Piera Polidori (EAHP)
14:15	Q&A / discussion	All
2. Crisis preparedness and management		
14:45	2.1. Clinical trials in emergency situations	Manuela Mura (EMA)
15:00	Q&A	All
15:15	<i>Coffee break</i>	
3. Big Data		
15:30	3.1. Big Data Steering Group updates	Denise Umuhire (EMA) Kelly Plueschke (EMA)
15:50	Q&A	All

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Time	Topics	Speaker
4. Medicine shortages		
16:05	4.1. Results from surveys on medicine shortages	Inga Abed (EMA) Stephanie Marschler (EMA)
16:20	Q&A	All
16:30	4.2. EU list of critical medicines	Joao Francisco Ferreira (EMA)
16:40	Q&A	All
16:50	4.3. Update on preparedness activities	Emilija Matelytė (EMA)
17:00	Q&A	All
5. Patient information on medicines		
17:10	5.1. Publication on ' <i>Communication of anticancer drug benefits and related uncertainties to patients and clinicians</i> '	Courtney Davis (HAI)
17:20	Q&A	All
17:30	5.2. Revision of QRD template for package leaflet (PL) improvement	Monica Buch (EMA) Alexios Skarlatos (EMA)
17:40	Q&A	All
17:50	<i>End of meeting</i>	

DAY 2: 20 September, 09:30–13:00 CEST

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

Time	Topics	Speaker
09:15	Joining and technical checks	
Introduction		
09:30	Welcome	Juan Garcia-Burgos (EMA) Rosa Giuliani (HCPWP) Marko Korenjak (PCWP)
6. Clinical trials		
09:45	6.1. ICH E21 Concept paper on inclusion of pregnant and breastfeeding individuals in clinical trials	Corinne De Vries (EMA)
10:00	Q&A	All
10:15	6.2. ACT EU Multi-stakeholder platform (MSP) advisory group update	Ana Zanoletty (EMA) Maria Filancia (EMA)
10:30	Q&A	All
7. EMA communications		
10:45	7.1. Social media strategy	Camelia Enachioiu (EMA)
11:00	Q&A	All
11:15	7.2. Mis- and disinformation	Sophie Labbé (EMA)
11:30	Q&A	All
8. Working party updates		
12:00	8.1. Feedback from joint meeting of US PEC and EU PCWP and topic for 2024	Maria Mavris (EMA)
12:10	8.2. ICH E6 R3 update	Ivana Silva (EMA)
12:30	Q&A	
12:50	Wrap up	Co-chairs
13:00	<i>End of meeting</i>	