



2 June 2021
EMA/231316/2021
Stakeholders and Communication Division

Agenda – PCWP/HCPWP joint meeting 1 & 2 June 2021, Virtual meeting

DAY 1: 1 June, 12:45hrs to 16:15hrs CET

Co-chairs: Juan Garcia-Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jaeger (HCPWP).

Time	Topics	Speaker
12:45	Joining and technical checks	
1. Introduction		
13:00	1.1 Opening remarks	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
2. Extension of EMA's mandate		
13:10	2.1 EC's legal proposal for EMA's reinforced role in crisis preparedness and how it fits with other EC strategic initiatives	Andrzej Rys (EC)
13:30	2.2 How is EMA preparing for an extended mandate	Noël Wathion (EMA) Zaide Frias (EMA)
13:45	Q&A	All
3. Communication and stakeholder engagement		
14:10	3.1 Feedback from EMA 2020 communication perception survey 3.2 Framework Strategy for external communication and stakeholder engagement	Marie-Agnes Heine (EMA)
14:30	Q&A	All
14:50	<i>Break</i>	



Time	Topics	Speaker
4. COVID-19 update		
15:00	4.1 Update on vaccines and therapeutics	Marco Cavaleri (EMA)
15:15	4.2 Safety surveillance	Georgy Genov (EMA) Catherine Cohet (EMA)
15:40	Q&A	All
16:00	Wrap up	Co-Chairs
16:15	<i>End of meeting</i>	

DAY 2: 2 June 2021, 09:45hrs to 13:00hrs CET

Co-chairs: Juan Garcia-Burgos (EMA), Kaisa Immonen (PCWP), Ulrich Jaeger (HCPWP).

Time	Topics	Speaker
09:45	Joining and technical checks	
10:00	Welcome	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
5. Scientific Advisory Groups (SAGs)		
10:10	5.1 Patient satisfaction survey	Sophie Groeneveld (EMA)
10:20	5.2 Open call for experts	Francesco Pignatti (EMA)
10:30	Q&A	All
6. Update on Big data		
10:45	6.1 Recent progress on data and analytics and looking to the future	Peter Arlett (EMA)
11:00	Q&A	All
11:15	<i>Break</i>	
7. Regulatory science research agenda		
11:25	7.1 Principles for the research agenda	Jordi Llinares (EMA) Lifang Liu (EMA)
11:40	Discussion and feedback on proposed areas for research	All
8. Electronic product information (ePI)		
12:10	8.1 Developing a common electronic standard for ePI: update on the ePI set-up project	Elizabeth Scanlan (EMA)
12:25	Q&A	All
12:40	AOB	All
12:50	Wrap up	Co-chairs
13:00	<i>End of meeting</i>	