



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 February 2021  
EMA/62114/2021  
Stakeholders and Communication Division

## Agenda – PCWP/HCPWP joint meeting

2 & 3 March 2021, Virtual meeting

### DAY 1: 2 March, 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	
<b>1. Introduction</b>		
13:00	1.1 Opening remarks	Kaisa Immonen (PCWP) Ulrich Jaeger (HCPWP) Juan Garcia-Burgos (EMA)
13:10	1.2 Welcome by EMA's new Executive Director	Emer Cooke (EMA)
<b>2. COVID-19 update</b>		
13:20	2.1 Update on vaccines and therapeutics 2.2 Safety surveillance 2.3 EMA's vaccine outreach strategy 2.4 Next public meeting	Marco Cavaleri (EMA) Georgy Genov (EMA) Priya Bahri (EMA) Melanie Carr (EMA) Nathalie Bere (EMA)
14:20	Q&A	All
14:40	Break	



<b>3. Medicines development and authorisation</b>		
14:50	3.1 The European Reference Network model in the European Data Space	Jordi Llinares Garcia (EMA) Martin Dorazil (EC) Rima Nabbout (EJP RD)
15:20	Q&A	All
15:40	3.2 Timely patient access to Advanced Therapy Medicinal Products (ATMPs)	Martina Schübler-Lenz (CAT)
16:00	Q&A	All
16:10	<b>Wrap up</b>	Co-Chairs
16:15	<i>End of meeting</i>	

## DAY 2: 3 March 2021, 09:45hrs to 13:15hrs 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)
<b>3. Medicines development and authorisation (continued)</b>		
10:10	3.3 Personalised medicine approaches for the next generation of medicines	Anthony Humphreys (EMA) Ejner Moltzen (ICPerMed)
10:30	Q&A	All
<b>4. Big Data</b>		
10:40	4.1 Implementation of HMA/EMA Big Data Steering Group deliverables	Peter Arlett (EMA) Nikolai Brun (HMA)
11:10	Q&A	All
11:30	<i>Break</i>	
<b>5. ICH guidance</b>		
11:40	5.1 Good Clinical Practice (E6/E8)	Fergus Sweeney (EMA)
12:00	5.2 Patient data reflection paper	Milton Bonelli (EMA)
12:10	Q&A	All

## 6. Satisfaction survey on interactions with EMA

12:30	6.1 What do the 2020 results tell us?	Maria Mavris (EMA)
12:55	<b>AOB</b>	All
13:10	<b>Wrap up</b>	Co-chairs
13:15	<i>End of meeting</i>	