



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 March 2020
EMA/633892/2019
Stakeholders and Communication Division

Agenda – PCWP/HCPWP joint meeting

3 March 2020, 08:30hrs to 17:30hrs – meeting room: 2C

Co-chairs: Kaisa Immonen (EPF); Ulrich Jaeger (EHA)

Time	Topics/ DAY 1	Speaker
08:30	Registration and reimbursement arrangements	
8:45	Welcome and introduction / Health and safety information	M. Carr (EMA)
1. Strategies for future activities		
09:00	1.1 EMA recommendations from the Regulatory Science Strategy to 2025 – implications for patients and healthcare professionals	A. Humphreys (EMA)
09:45	1.2 European Medicines Regulatory Network Strategy to 2025 – introduction on the route to joint strategy, stakeholder consultation process, timelines	M. Carr (EMA)
10:00	1.2.1 Theme 1: Availability and accessibility of medicines Discussion and Q&A	M. Berntgen (EMA)
10:15	1.2.2 Theme 2: Data analytics, digital tools and digital transformation	P. Arlett (EMA)
10:30	1.2.3 Theme 3: Innovation Discussion and Q&A	A. Humphreys (EMA)
10:45	<i>Coffee break</i>	
11:00	1.2.4 Theme 4: Antimicrobial resistance (AMR) Discussion and Q&A	M. Cavaleri (EMA)
11:15	1.2.5 Theme 5: Supply Chain Challenges Discussion and Q&A	B. Cuddy (EMA)

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11:30	1.2.6 Theme 6: Sustainability of the Network and Operational Excellence Discussion and Q&A	M. Lenihan (EMA)
11:45	1.2.7 Next steps	M. Carr (EMA)
12:00	Lunch	
2. Nitrosamine impurities		
13:00	2.1 Update on activities related to presence of nitrosamine impurities in medicines	N. Wathion (EMA)
13:20	Q&A / Discussion	All
3. HMA/EMA Task Force on Availability of authorised medicines		
13:30	3.1 Update on the activities of the HMA/EMA Task Force	J. Ferreira (EMA)
13:50	Q&A / Discussion	All
4. Renovation of ICH guidelines on general considerations for clinical trials and good clinical practice		
14:15	4.1 What is changing and how is EMA contributing?	F. Sweeney (EMA)
14:45	Q&A / Discussion	All
15:15	Coffee Break	
5. Big data, data sharing and data protection		
15:30	5.1 Survey on rare disease patient perspectives on data sharing and data protection	S. Courbier (Eurordis)
15:50	5.2 Health29; Patient data platform	E. Vroom (UPPMD)/ J. Isla (DSEF)
16:10	5.3 HMA/EMA Big data task force recommendations and future actions	N. Brun (HMA)/ P. Arlett (EMA)
16:30	Q&A Discussion	All
17:30	Closure of first day	

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4 March 2020, 09:00hrs to 16:00hrs – meeting room: 2C

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Time	Topics/ DAY 2	Speaker
6. Feedback from committee members		
09:00	COMP	T. Leest
	PRAC	V. Hivert/R. Anderson
	CAT	K. Breen
	CHMP	C. Prieto/ F. Ventura
	PDCO	J. Taminiau
	HMPC	S. Bager
7. Electronic product information (ePI)		
10:00	7.1 Update on electronic product information for EU medicines	E. Scanlan (EMA)
10:20	Q&A / Discussion	All
10:45	Coffee break	
8. CIOMS guidelines on patient involvement in development and safe use of medicines		
11:00	8.1. Global Guidance on patient involvement	L. Răgo (CIOMS)
11:30	8.2. Incorporating EMA and patient organisations’ experience	F. Houyez (Eurordis)
11:45	Q&A / Discussion	All
12:00	Lunch	
9. Shortages		
13:00	9.1 Sharing real examples to identify specific areas where action is needed	J. de Belie (PGEU)
13:30	9.2 Summary of discussions related with developing a concept paper on best practices to prevent shortages	C Roffiaen (EPHA)
14:00	Coffee break	

Time	Topics/ DAY 2	Speaker
14:15	9.3 Discussion on revision of the common position between patients', consumers, and healthcare professionals' organisations on supply shortages of medicines	F. Houyez (EURORDIS)
14:45	9.4 Reflection on topics and timelines for a follow up multi-stakeholder workshop	All
15:30	AOB / upcoming meeting dates	
16:00	<i>End of meeting</i>	