



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2018
EMA/775204/2017
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

17 April 2018, 08:30hrs to 17:30hrs – 18 April 2018, 08:30hrs to 16:30hrs
meeting room: 3A

Co-Chairs: Juan Garcia-Burgos (EMA), Kaisa Immonen (PCWP), Gonzalo Calvo (HCPWP)

17 April 2018		Action	Speaker
08:30	Registration and reimbursement arrangements		
08:45	Welcome and introduction / Health and safety information Disclosure of interests / Adoption of the agenda		J. Garcia-Burgos (EMA)
1. Digital media and health			
09:00	1.1 Perspectives from the European Commission	For information	K. Neubauer (EC)
2. Real world evidence – what have we learnt lately at EMA?			
09:30	2.1 An introduction to the concept and how is it relevant for the medicines regulatory system		H-G. Eichler (EMA)
10:00	2.2 Learnings from a series of workshops	For information	A. Cave (EMA)
10:25	2.3 How are real-world evidence and patient registries used in benefit-risk evaluation to support early access to medicines	For information	J. Moseley (EMA)
10:50	<i>Coffee Break</i>		
11:10	<ul style="list-style-type: none">Discussion points– Identify points of concern/reflection	For discussion	K. Breen (Digital media & health topic group)



17 April 2018		Action	Speaker
	<p>from patients and healthcare professionals;</p> <ul style="list-style-type: none"> – Reflect on how to address identified concerns and best communicate to patients and healthcare professionals in a clear and comprehensible manner. 		
3. Electronic product information			
12:00	3.1 Towards electronic product information in the EU	For information	A. Skarlatos (EMA)
12:20	3.2 Mapping EU initiatives on electronic product information	For discussion	C. Hernandez (HMA WG Support for better use of medicines)
13:15	<i>Lunch</i>		
4. mHealth – recent learnings and trends			
14:00	4.1 Findings from the WebRADR project	For information	V. Newbould (EMA)
14:30	4.2 Trends in marketing authorisation applications	For information	F. Cerreta/ A. Skarlatos (EMA)
15:00	<ul style="list-style-type: none"> • Discussion points <ul style="list-style-type: none"> – Identify points of concern/reflection from patients and healthcare professionals; – Reflect on the need for a guideline for patients on how to assess open mHealth apps solutions. 	For discussion	K. Apostolidis (Digital media & health topic group)
15:45	<i>Coffee break</i>		
5. Social media – focusing on increased outreach			
16:00	5.1 EMA's approach to social media	For information	M. Benstetter (EMA)
16:30	5.2 Outreach to targeted audiences	For discussion	C. Morton (Digital media & health topic group)
17:15	Wrap-up		
17:30	<i>End of day</i>		

18 April 2018		Action	Speaker
08:30	Introduction to Day 2 and review of: <ul style="list-style-type: none"> • Actions from previous meetings • Draft proposals open for consultation • Outcome of written procedures 		J. Garcia-Burgos (EMA)
6. EMA relocation			
09:00	6.1 Update on business continuity and EMA relocation	For information	N. Wathion (EMA)
7. European Immunisation Week			
09:40	7.1 Update on EMA communication activities	For information	C. Enachioiu (EMA)
10:00	<i>Coffee Break</i>		
8. Transparency and clinical trials			
10:20	8.1 Clinical data publication policy – experience since Oct 2016 and Technical Anonymization Group	For information	K. Quigley/ M. Dias (EMA)
11:00	8.2 Implementation of Clinical Trial Regulation – update on EU-CT portal and database	For information	L. Pioppo (EMA)
9. Pharmacovigilance			
11:35	9.1 Findings of the EMA survey on awareness of the ‘additional monitoring’ concept and next steps	For discussion	J. Januskiene (EMA)
10. EMA corporate website			
12:15	10.1 Relaunch of EMA corporate website	For information	AC. Schmidt (EMA)
12:30	<i>Lunch</i>		
11. Access to medicines			
13:15	11.1 EMA-HMA collaboration on shortages and availability of medicines: stakeholder input	For discussion	R. Gonzalez-Quevedo (EMA) A. Byrholt Hansen (DMA) Y. Knudsen (NOMA)
14:15	11.2 EMA-EUnetHTA collaboration: mutual learning concerning practices for engagement with patients and healthcare professionals in assessment activities	For discussion	A. Willemsen / C. Guilhaume (EUnetHTA)

18 April 2018		Action	Speaker
15:00	<i>Coffee break</i>		
12. Committee feedback			
15:15	12.1 COMP	For information	
	12.2 CAT		
	12.3 PRAC		
	12.4 CHMP		
	12.5 PDCO		
	12.6 HMPC		
13. Members voice			
16:00	13.1 Online training for MS nurses project, MS Nurse Professional	For information	A. Antonovici (EMSP)
14. AOB			
16:30	<i>End of meeting</i>		