28 June 2017
EMA/213892/2017
Stakeholders and Communication Division

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

27 June 2017, 08:30hrs to 17:30hrs – 28 June 2017, 08:45hrs to 13:30hrs
meeting room: 3E

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

27 June 2017		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. Involvement in EMA activities			
09:00	1.1 EMA preparedness on Brexit	For information	N. Wathion (EMA)
09:45	1.2 Proposal for revision of PCWP/HCPWP mandates and rules of procedure	For discussion	I. Silva (EMA)
10:15	1.3 Principles and practical considerations for streamlining process for re-assessment of eligibility status of organisations	For discussion	S. Benefice / N. Bere (EMA)
10:50	*Coffee Break*		
11:10	1.4 Work-plans 2018/19 • Proposal for drafting process • Draft structure of single work-plan • Drafting group	For discussion	I. Silva (EMA)
11:50	1.5 Topic Groups update	For discussion	N. Bere (EMA)

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27 June 2017		Action	Speaker
12:30	*Lunch*		
2. Access to medicines			
13:30	2.1 Conditional marketing authorisation: 10 year report	For information	Z. Sebris (EMA)
14:00	2.2 EUnetHTA • Introduction to EUnetHTA activities • EMA/EUnetHTA work-plan 2017-2020 • Exploring synergies with PCWP/HCPWP work-plan 2018-2019	For discussion	M. Mujoomdar (EUnetHTA)
15:00	2.3 HMA/EMA Taskforce on availability of authorised medicines • Introduction to the taskforce • Exploring synergies with PCWP/HCPWP work-plan 2018-2019	For discussion	B. Cuddy (EMA)
16:00	*Coffee break*		
16:20	2.4 PRIME update after workshop	For information	Z. Hanaizi (EMA)
3. Pharmacovigilance			
16:50	3.1 Additional monitoring impact analysis • Goals and objectives • Survey to patients and healthcare professionals	For discussion	J. Januskiene (EMA)
17:30	*End of day*		

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4. Cross Agency activities			
08:45	4.1 EMA framework of collaboration with academia – action plan	For information	M. Ensini (EMA)
09:05	4.2 EMA training for patients – facts and figures	For information and discussion	M. Mavris (EMA)
5. Committee feedback			
09:30	5.1 CHMP	For information	F. Ventura (CHMP)
	5.2 COMP		D. O'Connor (COMP)
	5.3 CAT		K. Breen (CAT)
	5.4 HMPC		S. Madsen (HMPC)
	5.5 PRAC		A. Zeijden (PRAC)
6. Members voice			
10:00	6.1 Patient Access Partnership (PACT)	For information	S. Hasardzhiev (EPF)
10:20	6.2 Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS)	For information	M. Lepeska (HAI)
10:40	*Coffee break*		
7. Product Information			
11:00	7.1 European Commission's report on the shortcomings of product information • Introduction to concrete areas of work for EMA • Improving patient input in developing and testing of PLs • Electronic SmPC/PL formats	For discussion	K. Kurgonaitė (EC)
8. AOB			
13:30	*End of meeting*		