

25 September 2018
EMA/610994/2018
Stakeholders and Communication Division

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

25 September 2018, 13:15hrs to 18:00hrs meeting room: 2A

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

25 September 2018 (PCWP/HCPWP joint session)		Action	Speaker
13:15	Registration and reimbursement arrangements (HCPWP only)		
13:30	Welcome and introduction / Health and safety information Disclosure of interests / Adoption of the agenda Points for information, including: • Update since April 2018 • EMA preparedness on Brexit and relocation – impact in PCWP and HCPWP activities		J. Garcia-Burgos (EMA)
1. EMA perception survey			
14:00	1.1 Results of the 2017 EMA perception survey	For information/discussion	E. Scanlan (EMA)
2. EMA regulatory science to 2025			
14:30	2.1 Background to the initiative and future consultation process	For information/discussion	A. Humphreys (EMA)
3. Pharmacovigilance			
15:00	3.1 Feedback from the 12 th Stakeholder Forum on Pharmacovigilance	For information	H. Sundseth (EIWH) R. Anderson (PGEU)
15:10	3.2 Updates on Good Pharmacovigilance Practices (GVP), in particular Population-specific considerations GVP P III –	For information/discussion	P. Bahri (EMA)

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	pregnancy/breastfeeding, GVP P IV - pediatrics and GVP P V – geriatrics Highlights from the PRAC Pharmacovigilance Impact project work on engagement of patients and healthcare professionals, in particular a proposed conceptualisation of engagement in pharmacovigilance and feedback from a case study on valproate		
4. Digital media and health			
15:35	4.1 Follow up by PCWP/HCPWP topic group on digital media and health	For information/ discussion	D. Singer (EACPT) C. Enachioiu (EMA)
16:15	Coffee Break		
5. Electronic product information			
16:30	5.1 Update on ongoing work	For information	A. Skarlatos (EMA)
16:45	5.2 EC/HMA/EMA multi-stakeholder workshop - feedback by PCWP/HCPWP participants at preparatory meeting, draft programme and points for discussion	For discussion	C. Cabrita (BEUC)/ I. Silva (EMA)
6. Access to medicines			
17:15	6.1 Update on ongoing work on availability of authorised medicines	For information	E. Martinez / M. Dias (EMA)
17:30	6.2 Preparation for the HMA/EMA multi- stakeholder workshop on availability of authorised medicines– contribution from PCWP and HCPWP	For discussion	I. Abed / I. Silva (EMA)
7. AOB			
18:00	End of meeting		