

30 September 2022 EMA/605514/2022 Stakeholders and Communication Division

## *Draft* Agenda – PCWP/HCPWP annual meeting with all eligible organisations

## 15 November 2022, 09:00hrs to 17:00hrs - meeting room: 2A

## Co-Chairs: Juan Garcia-Burgos (EMA) and Rosa Giuliani (HCPWP)

Time	Topics	Speaker	
08:45	Registration and reimbursement arrangements		
1. Introduction			
09:00	Opening remarks	Emer Cooke (EMA)	
		Juan Garcia-Burgos (EMA)	
		Rosa Giuliani (HCPWP)	
2. Patient involvement in medicines development and regulation			
09:15	2.1 Report from EMA Multistakeholder Workshop on Patient Experience Data	Rosa Gonzalez- Quevedo (EMA)	
09:35	Q&A		
09:50	CIOMS report on 'Patient involvement in the development, regulation and safe use of medicines'	François Houÿez (EURORDIS)	
		Lembit Rägo (CIOMS)	
10:20	Q&A		
10:35	Coffee break		
3. Availability and accessibility of medicines			
10:45	3.1 Task Force on availability of authorised medicines (TF AAM)		
	- Update on the TF AAM activities	Monica Dias (EMA) Hugues Malonne (HMA)	
	- Reporting of shortages by organisations	Inga Abed (EMA)	
11:15	Q&A		

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Time	Topics	Speaker	
11:30	Discussion topic		
	- Preparation for multistakeholder workshop in 2023	Monica Dias (EMA)	
	- Update on EU guidance on <u>shortage prevention</u> and <u>communication</u> to the public	Inga Abed (EMA)	
12:15	Lunch break		
13:15	3.2 Access to medicines	Valentina Barbuto (EC)	
	- "Sequential decision making": how regulatory and HTA activities interconnect under the new HTA Regulation	Michael Berntgen (EMA)	
	- The delivery under the EMA/EUnetHTA 21 work plan: focus on engagement with patients and HCPs	Stephanie Said (EunetHTA 21)	
		Anne Willemsen (EunetHTA 21)	
13:55	Q&A	Additional panellists:	
		Daniel Ritter (EunetHTA 21)	
		Maggie Galbraith (EunetHTA 21)	
14:10	Discussion topics:	Michael Berntgen (EMA)	
	<ul> <li>Role of patients and HCPs at the intersection of regulatory review and Health Technology Assessment, across the life cycle (engagement)</li> </ul>	Daniel Ritter (EunetHTA 21)	
	- Experiences and challenges by patients and HCPs in terms of access to medicines in health care systems and identification of topics where EMA/HTA cooperation could help		
14:50	Coffee break		
4. Antimicrobial resistance and other emerging health threats			
15:00	4.1 Lessons learnt from COVID-19	Melanie Carr (EMA)	
15:15	Q&A		
15:30	4.2 Preparation for multistakeholder workshop on AMR in 2023	Radu Botgros (EMA)	
16:00	Q&A		
16:45	Wrap up	Juan Garcia Burgos	
17:00	End of meeting		