

18 April 2022 EMA/157813/2023

Agenda - Fourth EMA-AESGP bilateral meeting

18 April 2023 - hybrid Meeting, 16:20-17:30 CEST

Chair: Marie-Helene Pinheiro, EMA

Item	Preliminary draft agenda	Time
1.	Welcome and introduction	5′
	Introductory Remarks	
2.	Pharma review – ePI (both content and telematics side)	15′
3.	Combination products	15′
4.	Experience with Borderline Guidance	10'
5.	EMA implementation actions under the MDR:	10'
6.	Well Established Use legal basis	10'
7.	Conclusions and next steps Close of meeting	5′

