



22 April 2023
EMA/137738/2024

Agenda - Fourth EMA-AESGP bilateral meeting

29 April 2024 – hybrid Meeting, Webex and meeting room 0B, 10:00-12:00 CEST

Chair: Marie-Helene Pinheiro, EMA

Item	Preliminary draft agenda	Time
1.	Welcome and introduction <i>Marie-Helene Pinheiro, EMA</i>	10:00-10:10 (10')
2.	AESGP positions on One Substance One Assessment (OSOA)	10:10-10:30 (20')
BREAK		10:30-10:35 (5')
3.	MP-MD combination: Update on EMA implementation actions under MDR i.e. labelling co-packed medical devices and MDs under Rule 21 first indent	10:35-10:55 (20')
4.	AESGP work on transitioning to ePL	10:55-11:15 (20')
5.	AESGP position on new Variation Regulation revision	11:15-11:35 (20')
6.	Referral for well-established substances – reflection on recent and past experiences	11:35-11:55 (20')
7.	Conclusions Close of meeting	11:55-12:00 (5')

