02 October 2025
EMA/MB/261306/2025 - Adopted
Management Board

Agenda for the 129TH meeting of the Management Board

Held on 2 October 2025, Virtual (09:00 – 14:00hrs)

Chairperson: Rui Santos Ivo

Item	Title	MB action
1.	Draft agenda	For adoption, EMA/MB/261306/2025*
2.	Declarations of competing interests related to the agenda	Oral report
3.	Minutes from the 128th meeting, held on 11-12 June 2025, adopted via written procedure	For information, EMA/MB/189883/2025*
A	**Points for automatic adoption**	
A.1	EMA decision on adoption, by analogy, of Commission decision C(2025) 2495 of 13.5.2025 – guide to missions and authorised travel	For information & adoption, EMA/MB/283583/2025, EMA/MB/283584/2025*
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Update on Medical Device (MD) and *In- Vitro* Diagnostic Medical Device (IVD) activities: • update on EMA activities • EC Policy update on MD/IVD legislation	Oral report
B.4	EMA Mid-year report 2025 from the Executive Director (January – June 2025)	For information, EMA/MB/308954/2025, EMA/283452/2025*
B.5	Environmental (PESTLE) analysis - navigating the future	Oral report
B.6	Involvement of external experts to support EU regulatory network activities	For endorsement, EMA/MB/290390/2025
B.7	Revision to the Cooperation Agreement (CA) between EMA and the National Competent Authorities (NCAs) • Addendum 1 to the CA	For information, EMA/MB/306542/2025, EMA/306728/2025; For adoption, EMA/146931/2025
B.8	Update from Network Data Steering Group (NDSG):	For information, EMA/MB/300628/2025;

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Item	Title	MB action
	• Network Data Strategy • Update AI Network plan	For endorsement, EMA/128369/2025*; Oral report
B.9	Clinical trials in the EU: • CTIS modernisation roadmap • ACT EU highlights	For information, EMA/MB/301991/2025, EMA/MB/301991/2025
B.10	Update on international activities: • International Coalition of Medicines Regulatory Authorities (ICMRA) activities 2019-2025 • Proposal to expand 'OPEN Framework' scope	For information, EMA/MB/305339/2025; Oral report; For endorsement, EMA/309905/2025
C	**Points for information only****	
C.1	Outcome of written procedures finalised during the period from 29 May to 22 September 2025	For information, EMA/MB/206039/2025*
C.2	Revision of EMA rules governing the secondment of national experts (SNEs) to EMA	For information, EMA/MB/298201/2025, EMA/85885/2025
C.3	Multinational Assessment Teams (MNAT) Guide to rapporteurs and coordinators	For information, EMA/MB/293347/2025 EMA/486654/2016
C.4	Summary of transfers of appropriations in budget 2025	For information, EMA/307851/2025
C.5	20TH monthly report on *ex ante* and retroactive evaluation of projects for the period 1 January to 30 June 2025	For information, EMA/MB/288085/2025 EMA/236334/2025
C.6	Network Portfolio Report	For information, EMA/MB/304792/2025, EMA/304813/2025

* Documents marked with a star * are intended for publication on the external website.
** Documents in *Additional documents for information* section are not intended for discussion unless specifically request