



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2025
EMA/MB/331769/2025
Management Board

DRAFT Agenda for the 130th meeting of the Management Board

Held on 17 December 2025, Room 1C (14:00 – 18:30hrs)

Held on 18 December 2025, Room 1C (09:00 – 16:00hrs)

Chairperson: Rui Santos Ivo

Item	Title	MB action
1.	Draft agenda	For adoption, EMA/MB/331769/2025*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 129 TH meeting, held on 2 October 2025 adopted by written procedure	For information, EMA/MB/313357/2025*
A	Points for automatic adoption/endorsement	
A.1	Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2026	For endorsement, EMA/MB/293332/2025
A.2	Revised composition of the ETF for preparedness	For information, EMA/MB/377945/2025; For endorsement, EMA/206184/2025*
B	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Report from PDCO chair	Oral report
B.4	Selection procedure for the next EMA Executive Director	For information, EMA/MB/
B.5	Preparation for implementation of the new EU pharmaceutical legislation, once adopted	For information, EMA/MB/378997/2025; For endorsement, EMA/378998/2025
B.6	Programming 2026-2029	For information, EMA/MB/372981/2025, EMA/MB/354198/2025;

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Item	Title	MB action
	a) Final programming document 2026-2028 and 2026 budget b) Preliminary programming document 2027-2029 c) Preparation of a written procedure for non-automatic carry-over of appropriations from 2025 to 2026	For adoption, EMA/366818/2025*, EMA/354245/2025; For information, EMA/343092/2025, EMA/MB/358368/2025
B.7	New Fee Regulation implementation: update on the time collection data by procedure types in accordance with Annex VI to Regulation (EU) 2024/568	For information, EMA/MB/359144/2025, EMA/MB/359047/2025
B.8	Audit topics a) Revised composition of Management Board Audit and Risks Group (MBARG) b) MBARG activities c) Updated Internal audit charter of the EMA's internal audit capability d) EMA 2026 risk-based audit plan and 2026–2028 strategic audit plan	For adoption, EMA/MB/374864/2025 For information, EMA/MB/356789/2025 For information, EMA/MB/360449/2025; For adoption, EMA/209787/2017 For information, EMA/MB/258509/2025; For adoption, EMA/258521/2025
B.9	Breach of trust procedures for scientific committee members and experts and for Management Board members	For information, EMA/MB/359463/2025; For adoption, EMA/MB/309079/2012*, EMA/154320/2012*
B.10	Report on the data protection activities by EMA in accordance with the EU Data Protection Regulation	For information, EMA/MB/37871/2025; For endorsement, EMA/137320/2022*
B.11	DARWIN EU update	Oral report
B.12	Update from Network Data Steering Group (NDSG)	Oral report
B.13	Clinical trials in the EU: <ul style="list-style-type: none"> • Legislative update • CTIS report and update • ACT EU highlights 	For information, EMA/MB/375961/2025, EMA/375941/2025,
B.14	Technology Capability Investment Plan (TCIP) to 2028	For information, EMA/MB/377957/2025, EMA/379954/2025*

Item	Title	MB action
B.15	2025 EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy	For information, EMA/MB/381088/2025, EMA/380151/2025
C	Points for information only**	
C.1	Outcome of written procedures finalised during the period from 23 September to 03 December 2025	For information, EMA/MB/316806/2025*
C.2	a) summary of transfers in budget 2025 b) summary of implementation of assigned revenue	For information, EMA/MB/379882/2025 EMA/MB/379888/2025
C.3	Network portfolio report	For information,
C.4	Guidance on handling of EMA scientific committees, Management Board or other EMA group members' intention to engage in occupational activities	For information, EMA/MB/381019/2025, EMA/366830/2024*
C.5	2024 Environmental Statement (under the standard of the EU Eco-Management and Audit Scheme)	For information, EMA/MB/376660/2025, EMA/379205/2025*
C.6	European Court of Auditors Annual report on EU agencies for the 2024 financial year (section 3.19 - EMA)	For information, EMA/MB/357668/2025

* 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 requested.