05 February 2025
EMA/MB/501393/2024 - Adopted
Management Board

Agenda for the 126th meeting of the Management Board

Held on 11 December 2024, Room 1C (14:00 – 18:30hrs)

Held on 12 December 2024, Room 1C (09:00 – 16:00hrs)

Chairperson: Lorraine Nolan

Item	Title	**MB action**
1.	Draft agenda	For adoption, EMA/MB/501393/2024*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 125th meeting, held on 3 October 2024 adopted by written procedure	For adoption*, EMA/MB/449773/2024
4.	30 Churchill Place • EMA Update • IAS: audit on Management of the lease of 30CP	Oral report
A	**Points for automatic adoption/endorsement**	
A.1	Revision of budget remarks for budget 2025	For endorsement, EMA/MB/539471/2024
A.2	Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2025	For endorsement, EMA/MB/148596/2024
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Programming 2025-2028 a) Final programming document 2025-2027 b) Preliminary programming document 2026-2028	For information, EMA/MB/548847/2024, EMA/MB/500033/2024, EMA/486596/2024; For adoption, EMA/348813/2024*, EMA/538371/2024
B.4	Audit topics	

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Item	Title	MB action
	a) MBARG update b) 2025 Audit Annual Plan and Audit Strategy 2025-2027 c) 6th biennial report on Pharmacovigilance audits	Oral report, For information, EMA/MB/337502/2024; For adoption, EMA/337503/2024; For information, EMA/MB/530557/2024; For adoption, EMA/320999/2024
B.5	Revision of EMA independence policies: • Outcome of public consultation • Revised Policy 0044 (Committee members and experts) and revised Policy 0058 (Management Board members)	For information, EMA/MB/543764/2024 EMA/543492/2024*; For adoption, EMA/54457/2024*, EMA/MB/89817/2024*
B.6	Clinical Data Publication (CDP) Relaunch Strategy – Step 2	For endorsement, EMA/MB/557989
B.7	New EMA Fee Regulation implementation: a) Revision of the Fee Regulation Working Arrangements b) MB Decision on the common format for reporting performance information	For information, EMA/MB/5394742024, Ares(2024)8652210; For adoption, EMA/539474/2024*; For information, EMA/MB/557930/2024; For adoption, EMA/557929/2024
B.8	Update on the preparations for implementation of the Health Technology Assessment (HTA) Regulation: • EC activities • EMA activities	Oral report
B.9	Update on the implementation of the Veterinary Medicinal Products Regulation	Oral report
B.10	Update of HMA/EMA Task Force on Availability (TF-AAM), including Union list of critical medicines	Oral report
B.11	Clinical Trials in the EU: • ACT EU (EMA) • Report to the Management Board on operation of CTIS (EMA) • transition to Clinical Trial Regulation (European Commission)	For information, EMA/MB/551429/2024, EMA/MB/501393/2024
B.12	Big Data Steering Group progress report	Oral report
B.13	Report on the data protection activities by EMA in accordance with the EU Data Protection Regulation	Oral report

Item	Title	MB action
C	**Points for information only****	
C.1	Outcome of written procedures finalised during the period from 26 September to 4 December 2024	EMA/MB/454481/2024*
C.2	a) summary of transfers in budget 2024 b) summary of implementation of assigned revenue	For information, EMA/MB/559501/2024, EMA/MB/559904/2024
C.3	Network portfolio report	For information, EMA/MB/544528/2024, EMA/MB/544497/2024

* Documents marked with a star * are intended for publication on the external website.
** Documents in *'Points for information only'* section are not intended for discussion unless specifically requested.