

11 June 2025 EMA/MB/116543/2025 - Adopted Management Board

Agenda for the 128TH meeting of the Management Board

Held on 11 June 2025, Room 1C (15:00 - 18:30) Held on 12 June 2025, Room 1C (09:00 - 16:00)

Chair: Rui Santos Ivo

| Item | Title | MB action |
|------|---|---|
| 1. | Draft agenda | For adoption, EMA/MB/116543/2025* |
| 2. | Welcome African Medicines Agency Governing Board and delegation | Oral report |
| 3. | Declarations of competing interests related to the current agenda | Oral report |
| 4. | Minutes from the 127th meeting, held on 13 March 2025, adopted via written procedure | For information, EMA/MB/87893/2025* |
| 5. | Election of the Vice-Chair of the Management Board (in camera) | By ballot |
| 6. | 30 Churchill Place update (in camera) | Oral report |
| A | Points for automatic adoption | |
| A.1 | Management Board meeting dates 2026-2027 | For information & adoption, EMA/MB/164895/2025* |
| A.2 | Inflationary adjustment for rates payable to EDQM for testing and sampling activities in 2026 | For information & endorsement, EMA/MB/116543/2025 |
| В | Points for discussion | |
| B.1 | Highlights of the Executive Director | Oral report |
| B.2 | Report from the European Commission | Oral report |
| B.3 | a) Assessment of the Executive Director's Annual Activity Report (AAR) 2024 | For information, EMA/MB/175856/2025, EMA/69085/2025*; For adoption, EMA/MB/175888/2025* |
| | b) Annual accounts 2024 and launch of written procedure | For information, EMA/MB/131692/2025 |



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| B.4 | Annual report 2024 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use | For information, EMA/MB/146952/2025; For endorsement, EMA/MB/143612/2025 |
| B.5 | Report from the CHMP Chair | Oral report |
| B.6 | Update on Audit topics a) Update on MB Audits and Risks Group (MBARG) | Oral report |
| | b) Annual report of internal audit and advisory activities at the European Medicines Agency 2024 | For information, EMA/MB/51003/2025; For adoption, EMA/50992/2025 |
| | c) Internal Audit Function's half-year activities 2025 and revised 2025 Audit Plan | For adoption, EMA/MB/181090/2025 |
| B.7 | a) 2024 EMA Annual Report on the implementation of the EMA's Anti-Fraud Strategy | Oral report |
| | b) EMA Anti-Fraud Strategy and related Action Plan for 2025-2028 | For information, EMA/MB/182991/2025; For endorsement, EMA/165696/2025* |
| B.8 | Revision of EMA Code of Conduct | For information, EMA/MB/171906/2025, EMA/385894/2012; For endorsement, EMA/171864/2025* |
| B.9 | New Fee Regulation | For information, EMA/135783/2025; |
| | a) Fee Regulation Working arrangements rev. 2 | For adoption, EMA/MB/183645/2024*, |
| | b) MB Decision on the financial arrangements on remuneration for (co-)rapporteur services rev. 1 | For adoption, EMA/MB/165209/2025 |
| B.10 | Update on proposals to expand the involvement of external experts | Oral report |
| B.11 | Update on remuneration of NCA staff for EU-NTC training development and delivery | For information, EMA/MB/183903/2025 |
| B.12 | Network Data Steering Group: Update on activities Recommendations for human Product Master Data implementation and data management. | For information, EMA/MB/171350/2025; For endorsement, EMA/135628/2025* |
| B.13 | Clinical Trials in the EU: Report on operation of CTIS Policy and regulatory update including ACT EU (European Commission & EMA) | For information, EMA/MB/177235/2025, EMA/175638/2025 |
| С | Points for information only** | |

| Item | Title | MB action |
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| C.1 | Outcome of written procedures finalised during the period from 04 March to 28 May 2025 | For information, EMA/MB/114131/2025* |
| C.2 | Network Portfolio Report | For information, EMA/MB/58668/2025, EMA/158661/2025 |
| C.3 | Summary report of implementation of assigned revenue June25 | For information, EMA/177327/2025 |
| C.4 | EMA working document on buildings | For information, EMA/MB/95999/2025, EMA/95990/2025 |
| C.5 | Summary of transfers of appropriations in budget 2025 | For information, EMA/MB/177295/2025 |

^{*} 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.