



22 February 2023  
EMA/MB/817029/2022  
Management Board meeting of 14-15 December 2022

## Agenda for the 118<sup>th</sup> meeting of the Management Board

Held on 14 December 2022, Room 1C (15:00 – 18:30)

Held on 15 December 2022, Room 1C (09:00 – 16:00)

Chairperson: Lorraine Nolan

Item		
1.	Draft agenda	For adoption, EMA/MB/817029/2022*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 117 <sup>th</sup> meeting, held on 6 October 2022 adopted by written procedure	EMA/MB/815892/2022*
<b>A</b>	<b>Points for automatic adoption/endorsement</b>	
A.1	Revision of budget remarks for budget 2023	For automatic endorsement, EMA/MB/222626/2022
A.2	Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2023	For automatic endorsement, EMA/MB/858314/2022
<b>B</b>	<b>Points for discussion</b>	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Programming 2023-2026  a) Final programming document 2023-2025 b) Preliminary programming document 2024-2026  c) Discontinuation of EMA Business Continuity Plan (EMA BCP)	For information, EMA/MB/914739/2022, EMA/MB/855412/2022;  For adoption, EMA/727092/2022,* EMA/MB/914861/2022*
B.4	Agile transformation and Portfolio progress update	For information, EMA/MB/895452/2022; EMA/922756/2022
B.5	Audit strategy/plan 2023-2025	For information, EMA/MB/867727/2022;  For adoption,



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		EMA/560352/2022
B.6	Biennial report on pharmacovigilance audits	For information, EMA/MB/735666/2022; For endorsement, EMA/735668/2022;
B.7	Result of an Independent external validation of AF-AUD's self-assessment 2022	Oral report
B.8	Update on the implementation of Veterinary Medicinal Products Regulation	Oral report
B.9	Big Data Steering Group progress report	Oral report
B.10	Report to the Management Board on the operation of CTIS and the Clinical Trial Regulation <ul style="list-style-type: none"> <li>CTIS planning 2023-2024</li> <li>Open letter on EMA's proposed deferral of publication of clinical trial protocols</li> </ul>	For information, EMA/MB/806898/2022; EMA/806900/2022 For endorsement, EMA/916770/2022; For information, EXT/836727/2022; EMA/836729/2022
B.11	Update on Accelerating Clinical Trials in the EU (ACT EU)	Oral report
B.12	Report from CAT chair	Oral report
B.13	Update on implementation activities of EMA's extended mandate – Chapter IV on experts panels	Oral report
B.14	HMA/EMA Task Force on availability of medicines update	Oral report
B.15	Annual report on the implementation of the EMA's Anti-Fraud Strategy	Oral report
B.16	Report on the implementation by EMA of the EU Data Protection Regulation	Oral report
<b>C</b>	<b>Points for information only**</b>	
C.1	Feedback from the Heads of Medicines Agencies	
C.2	a) Outcome of written procedures finalised during the period from 30 September 2022 to 5 December 2022 including <ul style="list-style-type: none"> <li>EMA policy on the handling of declarations of interests of scientific committees' members and experts (Policy 0044)</li> <li>EMA policy on the handling of competing interests of Management Board members (Policy 0058)</li> <li>European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by Management Board members</li> <li>European Medicines Agency breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts</li> </ul> b) Preparation for a written procedure on the adoption of the MB Decision on rules concerning the handling of declared interests of EMA staff	For information, EMA/MB/794683/2022; *  For information, EMA/MB/916902/2022

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C.3	a) summary of transfers in budget 2022 b) summary of implementation of assigned revenue	For information, EMA/900086/2022; EMA/MB/779499/2022
C.4	Revised rules governing the secondment of national experts to the EMA	For information, EMA/194397/2022
C.5	EMA's multilingual policy	For information, EMA/MB/887791/2022; EMA/723437/2022*

\* 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.