



7 June 2023
EMA/MB/129985/2023 - Adopted
Management Board meeting of 7-8 June 2023

Agenda for the 120th meeting of the Management Board

Held on 7 June 2023, Room 1C (15:00 – 18:30)

Held on 8 June 2023, Room 1C (09:00 – 16:00)

Chairperson: Lorraine Nolan

Item		
1.	Draft agenda	For adoption, EMA/MB/129985/2023*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 119 th meeting, held on 16 March 2023 adopted via written procedure	For information, EMA/MB/225645/2023*
4.	Information session on European Commission proposals for revision of EU pharmaceutical legislation	Oral report
A.	Points for automatic adoption	
A.1	Management Board meeting dates 2024-2025	For information & adoption, EMA/MB/38032/2023*
B.	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	<ul style="list-style-type: none">Assessment of the Executive Director's Annual Activity Report (AAR) 2022	For information, EMA/MB/239468/2023; EMA/137754/2023*; For adoption, EMA/MB/209000/2023;
	<ul style="list-style-type: none">Annual accounts and launch of written procedure	For information, EMA/MB/60027/2023;



Item		
B.4	<ul style="list-style-type: none"> Annual report 2022 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection, and scientific advice procedures for medicinal products for human and veterinary use Overview of Rapporteurships 	<p>For information, EMA/MB/202946/2023; For endorsement, EMA/174448/2023;</p> <p>Oral report</p>
B.5	Remuneration of training development	<p>For information, EMA/MB/243436/2023; For adoption, EMA/243422/2023*</p>
B.6	Annual report of internal audit and advisory activities at the European Medicines Agency 2022	<p>For information, EMA/MB/178511/2023; For adoption, EMA/74278/2023</p>
B.7	MB Decision on the establishment of Management Board Audits and Risks Group' ('MBARG')	<p>For information, EMA/MB/164148/2023; For adoption, EMA/MB/105013/2023</p>
B.8	Update on Agile transformation and Network portfolio	<p>For information, EMA/MB/253058/202; EMA/253049/2023</p>
B.9	<ul style="list-style-type: none"> Network data governance: revised EU Network Data Board (EUNDB) and Big Data Steering group (BDSG) mandates Report from the Big Data Steering Group, including, the experience with Real World Evidence (RWE) studies 	<p>For information, EMA/MB/226451/2023; EMA/239258/2023*; For endorsement, EMA/96104/2023*; EMA/96120/2023*;</p> <p>Oral report</p>
B.10	<p>Clinical Trials in the EU</p> <p>a) Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation</p> <p>b) Update on Accelerating Clinical Trials in the EU (ACT EU)</p>	<p>For information, EMA/MB/238741/2023; EMA/238743/2023;</p> <p>Oral report</p>
B.11	<p>Beating Cancer</p> <ul style="list-style-type: none"> Cancer Medicines Forum (CMF) – presentation by the representatives of doctors' organisations Cancer medicines as pathfinder – EMA initiatives 	Oral report
B.12	Report from the CHMP Chair	Oral report
C.	Points for information only**	
C.1	Feedback from the Heads of Medicines Agencies	

Item		
C.2	Outcome of written procedures finalised during the period from 09 March 2023 to 02 June 2023	For information, EMA/MB/106869/2023*
C.3	Summary of implementation of assigned revenue	For information, EMA/MB/240843/2023
C.4	Security Policy (Policy 0076)	For information, EMA/1016/2023

* Documents marked with a star * are intended for publication on the external website.

** Documents listed under section C '*Points for information only*' are not intended for discussion, unless specifically requested.