



16 March 2023  
EMA/MB/948302/2022  
Management Board

## Agenda for the 119 meeting of the Management Board

Held on 16 March 2023, WebEx (09:00 – 15:00)

Chairperson: Lorraine Nolan

Item		
1.	Draft agenda	For adoption, EMA/MB/948302/2022*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 118 <sup>th</sup> meeting, held on 14-15 December 2022 to be adopted via written procedure	EMA/MB/17597/2023*
<b>A</b>	<b>Points for automatic adoption</b>	
A.1	Update on impact of inflation rate on delegate reimbursement rules	For information & adoption, EMA/MB/74833/2023; EMA/MB/279597/2018, rev.4*
<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	EMA Annual Report 2022	For information, EMA/MB/70226/2023; For adoption, EMA/46734/2023*
B.4	2022 EMA Annual Report on Independence	For information, EMA/MB/88253/2023; For endorsement, EMA/2588/2023*
B.5	Revised implementing rules to the Fee Regulation as of 1 April 2023	For information, EMA/MB/700128/2022; For adoption, EMA/MB/622516/2022*
B.6	Review of activities of the Working Parties of the EMA - Update from the MB Review Group	For information, EMA/MB/94231/2023
B.7	3rd EC report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2019-2022) – update on status of preparation and next steps	For information, EMA/MB/87854/2023
B.8	Report from the CVMP Chair	Oral report



B.9	Update on Agile transformation and Network portfolio	For information, EMA/MB/94296/2023; EMA/93979/2023
B.10	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/66824/2023; EMA/76948/2023
B.11	Update on Accelerating Clinical Trials in the EU (ACT EU)	Oral report
B.12	Big Data Steering Group progress report	Oral report
<b>C</b>	<b>Points for information only**</b>	
C.1	Outcome of written procedures finalised during the period from 06 December 2022 to 08 March 2023	For information, EMA/MB/948919/2022*
C.2	Feedback from the Heads of Medicines Agencies	
C.3	2022 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2022	For information, EMA/MB/66824/2023; EMA/900566/2022*
C.4	Fifteenth six-monthly report on <i>ex ante</i> and retroactive evaluation of projects for the period 1 July to 31 December 2022	For information, EMA/MB/26674/2023; EMA/26675/2023
C.5	EMA working document on buildings	For information, EMA/MB/72500/2023 EMA/71459/2023
C.6	Summary of transfers of appropriations in budget	For information, EMA/MB/99789/2023
C.7	ECA Annual report on EU agencies for the financial year 2021 <a href="https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2021/AGENCIES_2021_EN.pdf">https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2021/AGENCIES_2021_EN.pdf</a>	For information

\* 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.