17 June 2021
EMA/MB/196797/2021 Adopted
Management Board meeting of 17 June 2021

Agenda for the 112th meeting of the Management Board

Held on 17 June 2021, Room 1C (09:00 – 16:00)

Chairperson: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/196797/2021*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 111th meeting, held on 11 March 2021 adopted via written procedure	For information, EMA/MB/153834/2021*
4.	COVID-19 • EMA Status Report	For information & discussion
A.	**Points for automatic adoption**	
A.1	Management Board meeting dates 2022-2023	For information & adoption, EMA/MB/196921/2021*
B.	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Assessment of the Executive Director's Annual Activity Report (AAR) 2020	For information, EMA/MB/277559/2021, Rev.1, EMA/81758/2021, Rev.1*; For adoption, EMA/233043/2021*
B.4	Revised implementing rules to the Fee Regulation as of 28 January 2022	For information, EMA/MB/64673/2021; For adoption, EMA/MB/52454/2021*
B.5	Annual report of internal audit and advisory activities at the European Medicines Agency 2020 • Organisational independence of the Internal Auditor	For information, EMA/MB/237754/2021, EMA/50919/2021 For information, Ares (2021)1134437

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Item		
B.6	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/255108/2021, Rev.1
	a) Minutes from the Extraordinary Management Board meeting of 21 April 2021 adopted via written procedure	For information, EMA/MB/243718/2021*
	b) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation	For information, EMA/MB/255110/2021
	c) Joint Controllership Arrangement (regarding personal data protection) for CTIS	For information, EMA/MB/422912/2020, EXT/160261/2019
	d) Approach to negotiating agreement on the Joint Controllership Arrangement for EMA to negotiate with member states and sponsors	For endorsement, EMA/MB/297428/2021
B.7	Information Management governance review	For information, EMA/MB/273382/2021; For endorsement, EMA/250013/2021
B.8	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.9	Big Data Steering Group update and progress report on DARWIN EU implementation	For information, EMA/MB/291650/2021, EMA/298378/2021
B.10	Management Board liaison on PRAC composition – Liaison after 9 years of PRAC in 2021	For information & endorsement, EMA/MB/157966/2021; For endorsement, EMA/MB/275601/2021, For information, EMA/MB/43845/2015, EMA/411582/2015
C.	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/249517/2021, EMA/249544/2021
C.2	Feedback from the Heads of Medicines Agencies	For information, EXT/321688/2021
C.3	Outcome of written procedures finalised during the period from 13 February 2021 to 25 May 2021	For information, MA/MB/315817/2021*
C.4	a. Summary of transfers of appropriations	For information, EMA/MB/241961/2021*

Item		
	b. Preparation for written procedure on the adoption of transfer of provisional appropriations within budget 2021	For information, EMA/MB/257659/2021
C.5	Summary of implementation of assigned revenue	For information, EMA/MB/252487/2021
C.6	EudraVigilance access policy for medicines for veterinary use	For information, EMA/MB/226594/2021, EMA/113700/2008-Rev.2*
C.7	Framework strategy for external communication and stakeholder engagement 2021-2025	For information, EMA/MB/292994/2021, EMA/579063/2020

* 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.