7 October 2021
EMA/MB/218267/2021 Adopted
Management Board meeting of 7 October 2021

Agenda of the 113th meeting of the Management Board

Held on 7 October 2021, Room 1C + Webex (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/218267/2021*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 112th meeting, held on 17 June 2021 adopted via written procedure	For information, EMA/MB/345297/2021*
4.	Covid-19 a) EMA Status Report b) Feedback on lessons learned	 For information/discussion For information/discussion
A	**Points for automatic adoption**	
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	EMA Mid-year report 2021 from the Executive Director (January – June 2021)	For information, EMA/MB/501841/2021, EMA/352298/2021*
B.4	Amendments to the existing Rules of Procedure of EMA Management Board and Scientific Committees	For information, EMA/MB/439109/2021 – Rev. 2, EMA /439108/2021 – Rev.1, EMA/366005/2021*; For adoption, EMA/MB/439109/2021 – Rev.2, EMA/MB/115339/2004/en/Rev.8*
B.5	Amending budget 01, amending appropriations in budget 2021	For information, EMA/MB/457635/2021; For adoption, EMA/MB/458302/2021*
B.6	Cooperation agreement and Key Performance Indicators	For information, EMA/MB/472842/2021, Rev.1, EMA/MB/339083/2021;

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		
	a) Revision of Cooperation agreement and Key Performance Indicators for the implementation of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6	For adoption, EMA/MB/504321/2021
	b) Annual report 2020 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/400732/2021; For endorsement, EMA/MB/399014/2021
B.7	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/458573/2021
	a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation	For information, EMA/MB/458574/2021 For information, EMA/MB/473854/2021
	b) Report of the EU Clinical Trial Regulation Coordination group	For information, EXT/553140/2021
	c) CTIS Joint Controllership Arrangement (JCA)	For endorsement & information, EMA/MB/422912/2020
B.8	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.9	Review of activities of the Working Parties of the EMA	For information, EMA/MB/525082/2021;
	• High-level recommendations for stakeholder engagement	For adoption, EMA/377662/2021
	• Update from the Implementation Task Force	Oral report
B.10	Big Data Steering Group update and progress report on the use of Real World Evidence in EMA committee decision-making (including DARWIN EU)	For information, EMA/512714/2021
B.11	Information Management (IM) Agile governance reporting	Oral report
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/518862/2021, EMA/518667/2021
C.2	Feedback from the Heads of Medicines Agencies	EXT/553703/2021
C.3	Outcome of written procedures finalised during the period from 26 May 2021 to 13 September 2021	For information, EMA/MB/520127/2021*
C.4	Summary of transfers of appropriations in budget 2021	For information, EMA/MB/457657/2021*

Item		
C.5	Twelfth six-monthly report on ex ante and ex post evaluation of projects for the period 1 January to 30 June 2021	For information, EMA/MB/481513/2021, EMA/481514/2021

* 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.