EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 October 2019
EMA/MB/414950/2019 Adopted
Management Board meeting of 3 October 2019

Agenda of the 105th meeting of the Management Board

Held on 3 October 2019, Room 2D (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/414950/2019*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Election of the Vice-Chair of the Management Board *(in camera)*	By ballot For information, EMA/MB/474899/2019; EMA/MB/417113/2019
4.	Minutes from the 104th meeting, held on 12-13 June 2019 adopted via written procedure	EMA/MB/335139/2019*
5.	EMA Preparedness on Brexit	Oral report
	5.1. Update on EMA Brexit preparedness	Oral report
	5.2. Update on EMA-NL Authorities collaboration for relocation to Amsterdam	Oral report
	5.3. Preparation for written procedure of the Amending budget/transfer of titles	For information
A	**Points for automatic adoption**	
A.1	Management Board decision – Model rules on Type of posts and post titles	For information, EMA/MB/39245/2019; EXT/55349/2014; For adoption, EMA/MB/907298/2019

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A.2	Management Board decision – model rules on the engagement of Contract Agents	For information, EMA/MB/422605/2019; EXT/5948/2018; For adoption, EMA/MB/263274/2019
A.3	Revised charter of (financial) tasks and responsibilities of the Executive Director and the accounting officer as of 1 July 2019	For information, EMA/MB/414768/2019; For adoption, EMA/MB/414689/2019*; EMA/MB/414778/2019*
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 2019 from the Executive Director (January – June 2019)	For information, EMA/MB/485721/2019; EMA/443839/2019*
B.4	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation a) Report on CTIS development b) The Report of the EU Clinical Trial Regulation Coordination group	 For information, EMA/MB/477430/2019; EMA/486126/2019 For endorsement, EXT/524158/2019
B.5	Update on the pilot of signal detection in EudraVigilance by marketing authorisation holders	For information, EMA/MB/488796/2019
B.6	Implementation of the new veterinary medicines legislation – Proposed governance for the implementation of Regulation 2019/6 ('NVR')	Oral report For information, EMA/MB/488796/2019; For endorsement, EMA/521954/2019
B.7	Review of activities of the Working Parties of the EMA	For discussion/endorsement
B.8	EMA Regulatory Science Strategy to 2025	Oral report
B.9	Report from the Director of the Internal Audit Service EC (IAS) and Director of the European Court of Auditors (ECA)	Oral report
B.10	Update of the Annual Audit Plan 2019	For information, EMA/MB/505995/2019; For adoption, EMA/505946/2019
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/485665/2019; EMA/484836/2019

C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 17 May 2019 to 16 September 2019	For information, EMA/MB/498499/2019*
C.4	Summary of transfers of appropriations in budget 2019	For information, EMA/MB/447289/2019*
C.5	Eighth six-monthly report on ex ante and ex post evaluation of projects for the period 1 January to 30 June 2019	For information, EMA/MB/397874/2019; EMA/397875/2019

* 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.