12 December 2018
EMA/MB/297576/2018 Adopted
Management Board meeting of 12-13 December 2018

Agenda for the 102nd meeting of the Management Board

Held on 12 December 2018, Room 2A (14:30 – 19:00)
Held on 13 December 2018, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/297576/2018*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 101st meeting, held on 4 October 2018 adopted via written procedure	For information, EMA/MB/690649/2018*
4.	EMA Preparedness on Brexit	Oral report
	4.1. Update on EMA Brexit preparedness	For information/discussion
	4.2. Update on EMA-NL collaboration for relocation to Amsterdam	For information/discussion
	4.3. Report on the EMA Management Board delegation visit to the future EMA premises	For information, EMA/MB/841077/2018; EMA/8050171/2018*
A	**Points for automatic adoption / endorsement**	
A.1	Financial compensation and workload estimation of the revised EMA organisation of translations of product related information	For information, EMA/MB/781386/2018* For endorsement, EMA/781387/2018
B	**Points for discussion**	
B.1	Clinical Trials Information System required by the Clinical Trial Regulation	
	a) Update on the CTIS Project	For information, EMA/MB/744007/2018; EMA/743977/2018
	b) Update from the EU CTR Coordination group	Oral report

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Item		
	Recommendation of the EU CTR Coordination Group on options to ensure CTIS delivery	For endorsement
B.2	Revised policy for classification and incentives for veterinary medicinal products indicated for minor use minor species (MUMS)/limited market and revised guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS)/limited market	For information, EMA/MB/706300/2018; For adoption, EMA/308411/2014-Rev.1*; EMA/CVMP/388694/2014-Rev.2*
B.3	Revision of the EVVET Access policy	For information, EMA/MB/697834/2018; For adoption, EMA/113700/2008-Rev.1*
B.4	Impact of the new veterinary medicines legislation	Oral report
B.5	Highlights of the Executive Director	Oral report
B.6	Report from the European Commission	Oral report
B.7	Yearly revision of the EMA Information Management Strategy and Information Management Strategic Plan	For information, EMA/MB/831845/2018; For endorsement, EMA/502708/2018*; EMA/831036/2018
B.8	Programming a) Programming 2019-2021, including 2019 work programme, budget, establishment plan b) Draft programming 2019-2022 c) Preparation for written procedure on non-automatic carry-over of appropriations from 2018 to 2019 for EvVet3 project	For information, EMA/MB/831121/2018 For adoption, EMA/73195/2018*; EMA/MB/847697/2018* For information, EMA/639690/2018 For information, EMA/MB/844868/2018
B.9	Revision of rules for reimbursement of expenses for delegates attending meetings	For information, EMA/MB/804662/2018; For adoption, EMA/MB/279597/2018*
B.10	Audit Strategy and Annual Audit Plan a) Audit Strategy 2019 – 2021 and Annual Audit Plan for 2019 b) Final Audit Report on Signal Management conducted in 2018 by the IAS	For information, EMA/MB/758750/2017; For adoption, EMA/803113/2017 For information, EMA/MB/797878/2018; EXT/797887/2018

Item		
	c) Report to the Management Board on Pharmacovigilance Audits carried out at EMA from 1st July 2016 to 30th June 2018	For information, EMA/MB/826417/2018; For endorsement, EMA/703195/2018
B.11	Revision of the Internal Control Framework - 2018	For information, EMA/804508/2018; For adoption, EMA/11654/2018
B.12	Improving completeness of Art 57 database	For information, EMA/MB/788636/2018; For endorsement, EMA/788639/2018
B.13	Communication on EMA regulatory processes	For information, EMA/MB/840333/2018; EMA/103813/2018
B.14	HMA-EMA Joint Big Data Taskforce Report	For information, EMA/MB/796769/2018; EMA/799916/2018
B.15	Implementation of medical devices and in-vitro diagnostic regulations	Oral report
B.16	EMA's Regulatory Science to 2025	Oral report
B.17	Annual report on the implementation of the EMA's Anti-Fraud Strategy a) Intellectual property rights for EMA staff members	For information, EMA/MB/856579/2018 For adoption, EMA/259494/2016, Rev. 1*
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/810771/2018; EMA/766615/2018
C.2	Feedback from the Heads of Medicines Agencies	EXT/860318/2018
C.3	Outcome of written procedures finalised during the period from 11 September 2018 to 23 November 2018	For information, EMA/MB/810142/2018*
C.4	Summary of the transfers of appropriation 2018	For information, EMA/MB/832177/2018*

* 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.