



4 October 2018  
EMA/MB/297556/2018 Adopted  
Management Board meeting of 4 October 2018

## Agenda for the 101<sup>st</sup> meeting of the Management Board

Held on 4 October 2018, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/297556/2018*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 100th meeting, held on 6-7 June 2018 adopted via written procedure	For information, EMA/MB/395034/2018*
4.	EMA Preparedness on Brexit	Oral report
	4.1. Update on EMA Brexit preparedness	For information/discussion
	4.1.1. Progress report on operational aspects	For information/discussion
	4.1.2. Preparation for 2019 and 2020 WP, including impact and phasing-out of BCP	For information/discussion
	4.1.3. EMA Brexit Preparedness Business Continuity Plan – Phase 3 implementation plan	For information, EMA/MB/680226/2018; EMA/DED/660449/2018
	4.1.4. Facilitation of END relocation	For information
	4.2. Update on EMA-NL collaboration for relocation to Amsterdam	Oral report
	4.2.1. Progress report on the relocation to the Netherlands	For information



<b>A Points for automatic adoption</b>		
A.1	Management Board decision – Model rules on Temporary posting	For information, EMA/MB/391744/2018; EXT/742466/2017; For adoption, EMA/MB/809113/2017
A.2	Management Board decision - Outside activities and occupational activities after leaving the Service	For information, EMA/MB/572454/2018 EXT/617512/2018; For adoption, EMA/MB/568497/2018
A.3	Revision of budget structure from financial year 2019	For information & endorsement, EMA/MB/225635/2018
<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	Revision of EMA breach of trust procedure for competing interests of and disclosure of confidential information by scientific committees' members and experts	For information, EMA/MB/641199/2018; For endorsement, EMA/MB/154320/2012, Rev. 2*
B.4	EMA policy on access to documents	For information, EMA/MB/523307/2018; For adoption, EMA/729522/2016, Rev. 1*; For endorsement, EMA/127362/2006, Rev. 1*; EMA/183710/2016*
B.5	EU Telematics Strategy 2020 – 2025 Concept Paper	For information, EMA/MB/593498/2018; For endorsement, EMA/586125/2018
B.6	Clinical Trials Information System Required by the Clinical Trial Regulation <ul style="list-style-type: none"> <li>a) Update on the CTIS Project</li> <li>b) Report on the Independent External Review of the Project</li> <li>c) Report from the EU CTR Coordination Group</li> </ul>	<p>For information, EMA/MB/552613/2018; EMA/552137/2018; EXT/INS/GCP/370512/2018; EMA/504594/2018</p> <p>For information, EMA/MB/652420/2018; EXT/652463/2018; EXT/652445/2018; EXT/652475/2018</p> <p>Oral report</p>

B.7	Update on the pilot of signal detection in EudraVigilance by marketing authorisation holders	For information, EMA/MB/493254/2018*
B.8	Annual report 2017 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use (piloted procedures only)	For information, EMA/MB/543319/2018; For endorsement, EMA/479531/2018
B.9	Ernst & Young study on MA procedures	Oral report
B.10	EMA Mid-year report 2018 from the Executive Director (January – June 2018)	For information, EMA/MB/600269/2018; EMA/449860/2018*
B.11	Report from SAWP Chair	Oral report
B.12	Impact of the new veterinary medicines legislation	Oral report
<b>C</b>	<b>Points for information only**</b>	
C.1	Report on EU Telematics	For information, EMA/MB/634092/2018; EMA/573646/2018
C.2	Feedback from the Heads of Medicines Agencies	EXT/671688/2018
C.3	Outcome of written procedures finalised during the period from 22 May 2018 to 10 September 2018	For information, EMA/MB/540105/2018*
C.4	Summary of transfers of appropriations in budget 2018	For information, EMA/MB/584626/2018*

\* 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.