



6 June 2018
EMA/MB/802/2018 Adopted
Management Board meeting of 6-7 June 2018

Agenda for the 100th meeting of the Management Board Held on 6 June 2018, Room 2A (15:30 – 18:45)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/802/2018 *
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 99th meeting, held on 15 March 2018 adopted via written procedure	For information, EMA/MB/167407/2018*
4.	EMA Preparedness on Brexit	
4.1.	Update on EMA Brexit preparedness	
4.1.1	Progress report on operational aspects	For information
4.1.2	EMA Brexit Preparedness Business Continuity Plan - Next phases (principles and methodology)	For information/endorsement, EMA/MB/377647/2018; EMA/MB/377647/2018
4.1.3	Staff Retention Support Measures – Progress report	For information
4.2	Update on EMA-NL collaboration for relocation to Amsterdam	
4.2.1	Progress report on the EMA-NL collaboration	For information
4.2.2	Physical relocation to Amsterdam	For information
4.2.3	EMA in the Spark building	For information



Agenda for the 100th meeting of the Management Board

Held on 7 June 2018, Room 2A (08:00 – 15:00)

A	Points for automatic adoption	
A.1	Management Board meeting dates 2019-2021	For adoption, EMA/MB/173925/2018*
A.2	Management Board decision – New mission rules	For information, EMA/MB/270800/2018; C(2017) 5323; For adoption, EMA/MB/811544/2017
A.3	Management Board decision – Revised Guidelines on whistleblowing	For information, EMA/MB/270945/2018; For adoption, EMA/MB/232598/2018
A.4	Management Board decision – Model rules on middle management	For information, EMA/MB/303342/2018; For adoption, EMA/MB/299672/2018
A.5	Management Board decision – Model rules on function of adviser	For information, EMA/MB/303679/2018; For adoption, EMA/MB/296715/2018
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) 2017	For information, EMA/MB/303373/2018; EMA/26967/2018*; For adoption, EMA/269259/2018*
B.4	Internal Audit Capability of EMA: a) 2017 External Quality Assessment of the Internal Audit Capability of EMA (AF-Audit) and the improvement action plan b) Annual report of internal audit and advisory activities at the European Medicines Agency 2017	 For information, EMA/MB/128702/2018; EXT/240011/2018; EMA/5026/2018 For information, EMA/MB/150028/2018; EMA/263956/2018

B.5	Internal Audit Service – EC (IAS)	
	a) IAS audit report on implementation of the new pharmacovigilance fees regulation in EMA	For information, EMA/MB/241166/2018; Ares(2018)395370
	b) IAS Organisational Independence of the Auditor	For information, EMA/MB/127459/2018; Ares(2018)540491
	c) Update of the Mutual Expectations Paper of the Internal Audit Service of the EC (IAS)	For information, EMA/MB/130742/2018; Ares(2018)2199778; Ares(2018)230286
B.6	a) Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/287259/2018; EMA/259890/2018
	b) Report of step 1 of the external review of the project	For information, EMA/MB/276100/2018; EMA/281388/2018; EMA/364559/2018
B.7	Impact of the new veterinary medicines legislation: Executive Summary	Oral report
B.8	Public Hearings: lessons learnt	For information, EMA/MB/280649/2018; EMA/751919/2017*
B.9	European Medicines Agency and Member States joint report to the European Commission on the experience with the list of products subject to additional monitoring	For information, EMA/MB/153820/2018; EMA/153015/2018
B.10	Management Board liaison on PRAC composition 2018	For information, EMA/MB/268963/2018; EMA/MB/43845/2015; EMA/411582/2015; For discussion & recommendation, EMA/269031/2018
C	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/367349/2018; EMA/274245/2018
C.2	Feedback from the Heads of Medicines Agencies	EXT/373022/2018
C.3	Outcome of written procedures finalised during the period from 22 February 2018 to 21 May 2018	For information, EMA/MB/296208/2018*
C.4	Summary of the transfers of appropriation 2018	For information, EMA/MB/225499/2018*
C.5	Stakeholder Engagement report: engaging with patients, consumers, healthcare professionals and academia	For information, EMA/MB/271765/2018; EMA/676772/2017*

C.6	Annual Report on EMA's interaction with industry stakeholders (2017)	For information, EMA/MB/291747/2018; EMA/80771/2018*
C.7	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2017	For information, EMA/MB/263403/2018

* 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.