

15 March 2018 EMA/MB/790/2018 Adopted Management Board meeting of 15 March 2018

Agenda for the 99th meeting of the Management Board

Held on 15 March 2018, Room 2A (08:00 - 15:00)

Chair: Christa Wirthumer-Hoche

Item				
1.	Draft agenda	For adoption, EMA/MB/790/2018*		
2.	Declarations of competing interests related to the current agenda	Oral report		
3.	a) Minutes from the 98th meeting, held on 13-14 December 2017 adopted via written procedure	For information, EMA/MB/701078/2017*		
	 b) Minutes of the Extraordinary Management Board meeting for the building approval process of EMA premises in Amsterdam 	For adoption, EMA/MB/102052/2018*		
4.	EMA Preparedness on Brexit			
	4.1. Update on EMA Brexit preparedness	Oral report		
	4.2 Update on EMA-NL collaboration for relocation to Amsterdam	Oral report		
	 Update on the negotiation of the seat agreement with the Kingdom of the Netherlands 	Oral report, endorsement of principles and mandate to finalise		
Α	Points for automatic adoption			
A.1	Management Board decision – implementing rules on telework	For information, EMA/MB/80240/2018; For adoption, EMA/MB/478899/2017		
A.2	Management Board decision – derogation from European Commission Decision C(2017) 6760 final of 16 October 2017 on Contract Agent rules	For information, EMA/MB/83105/2018; Ares(2017)5115151 – 19/10/2017;		



A.3 Management Board decision – implementing rules on Learning and Development For information, EMA/MB/30130/2018; For adoption, EMA/MB/36151/2017 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 Annual Report 2017 For information, EMA/MB/142589/2018; For adoption, EMA/MB/142589/2018; For adoption, EMA/MB/142589/2018; For adoption, EMA/MB/12018 B.4 Revised implementing rules to the Fee Regulation as of 1 April 2018 For information, EMA/MB/57356/2018* B.5 Annual review of the EMA independence policies: 2016 and 2017 Annual Report EMA/MB/1433/2018; For information, EMA/MB/39395/2018; For information & endorsement, EMA/MB/39395/2018; For information & endorsement, EMA/MB/39395/2018; For information & endorsement, EMA/MB/39395/2018; For information & EMA/MB/39395/2018; For information & EMA/MB/70289/2018; For information, EMA/MB/39395/2018; E	Item		
Learning and Development EMA/MB/81030/2018: For adoption, EMA/MB/736151/2017 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 Annual Report 2017 EMA Annual Report 2017 EMA Annual Report 2017 B Revised implementing rules to the Fee Regulation as of 1 April 2018 A Revised implementing rules to the Fee Regulation as of 1 April 2018 B.5 Annual review of the EMA independence policies: 2016 and 2017 Annual Report B.6 Proposal for streamlining the process of assessment of eligibility of patients', consumers' and healthcare professionals organisations B.7 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation EMA/MB/107646/2018, EMA/144764/2018, EMA/143047/2018, EMA/146815/2018 B.8 Bth Annual Report Veterinary MUMS/limited market For information, EMA/MB/66856/2018 For endorsement, EMA/798802/2017*			
B.1 Highlights of the Executive Director Oral report B.2 Report from the European Commission Oral report B.3 EMA Annual Report 2017 For information, EMA/MB/142589/2018: For adoption, EMA/91648/2018* B.4 Revised implementing rules to the Fee Regulation as of 1 April 2018 For information, EMA/MB/13566/2018* B.5 Annual review of the EMA independence policies: 2016 and 2017 Annual Report EMA/MB/13566/2018* B.6 Proposal for streamlining the process of assessment of eligibility of patients', consumers' and healthcare professionals organisations B.7 Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation B.8 Report to the Management Board on the implementation of EMA/MB/107646/2018. EMA/13407/2018. EMA/143047/2018. EMA/143047/2018. EMA/143047/2018. EMA/143047/2018. EMA/143047/2018. EMA/143047/2018. EMA/14308/2018; For endorsement, EMA/14216/2018. EMA/14308/3018; For endorsement, EMA/14216/2018. EMA/14308/3018; For endorsement, EMA/14216/2018. EMA/14308/3018; For endorsement, EMA/1435853/2018. EMA/158533/2018. EMA/168353/2018. EMA/158533/2018. EMA/158553/2018. EMA/158553/20	A.3	·	EMA/MB/81030/2018; For adoption,
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	B.8	8th Annual Report Veterinary MUMS/limited market	EMA/MB/66856/2018; For endorsement,
	B.9	Report from the CAT Chair	

B.10	EVVET Access policy update	For information, EMA/MB/74862/2018
С	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/111032/2018; EMA/58551/2018
C.2	Feedback from the Heads of Medicines Agencies	
C.3	2017 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2017	For information, EMA/MB/92046/2018; EMA/7552/2018*
C.4	Sixth six-monthly report on ex ante and ex post evaluation of projects for the period 1 July to 31 December 2017	For information, EMA/MB/21882/2018; EMA/21884/2018
C.5	Outcome of written procedures finalised during the period from 21 November 2017 to 21 February 2018	For information, EMA/MB/114032/2018*
C.6	Summary of transfers of appropriations in budgets 2017 & 2018	For information, EMA/MB/1127/2018*

^{*} 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.