



21 March 2019
EMA/MB/916015/2019 Adopted
Management Board meeting of 21 March 2019

Agenda for the 103rd meeting of the Management Board

Held on 21 March 2019, Room 2D (09:00-16:00)

Chairperson: Vice-chair

Item		
1.	Draft agenda	For adoption, EMA/MB/916015/2019 *
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Election of the Chair of the Management Board (<i>in camera</i>)	By ballot For information, EMA/MB/916040/2019; EMA/MB/13585/2019

Chairperson: Elected chair

4.	Minutes from the 102nd meeting, held on 12-13 December 2018 adopted via written procedure	For information, EMA/MB/877601/2018*
5.	EMA Preparedness on Brexit	Oral report
5.1.	Update on EMA Brexit preparedness	For information/discussion
– 5.1.1.	Progress report on operational aspects	For information/discussion
– 5.1.2.	Status update on EMA staff retention and ensuing impact on the 2019 EMA Work Plan	For information/discussion
5.2.	Update on EMA-NL collaboration for relocation to Amsterdam	For information/discussion
– 5.2.1.	Status report on EMA-Dutch Authorities collaboration	For information/discussion
– 5.2.2.	EMA physical relocation: First experiences and next phase	For information/discussion

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	5.3 Revision of rules for reimbursement of expenses for delegates attending meetings	For information, EMA/MB/166807/2019 For adoption, EMA/MB/279597/2018, rev.1*
	5.4 Amending Budget 01-2019	For adoption, EMA/MB/171445/2019*
6.	Update on judgment of 30 Churchill Place	For discussion
	6.1. Management Board Decision on transfer of appropriations in budget 2019	For information, EMA/MB/135539/2019; For adoption, EMA/MB/135526/2019
A	Points for automatic adoption	
B	Points for discussion	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Vacancy notice for the Executive Director's function	For information/discussion, EMA/MB/145888/2019; EXT/144734/2019
B.4	EMA Annual Report 2018	For information, EMA/MB/104102/2019; For adoption, EMA/85499/2019*
B.5	Revised implementing rules to the Fee Regulation as of 1 April 2019	For information, EMA/MB/909606/2019; For adoption, EMA/MB/909612/2019*
B.6	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/102914/2019; EMA/84532/2019
B.7	2 nd EC report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2015-2018)	For information/discussion, EMA/MB/107241/2019
B.8	Implementation of the new veterinary medicines legislation	For information, EMA/MB/180984/2019; Ref. Ares(2019)1335557 - 27/02/2019; EMA/149791/2019
B.9	9th Annual Report Veterinary MUMS/limited market	For information, EMA/MB/125805/2019; For endorsement, EMA/713390/2018*
B.10	Report from the PDCO Chair	Oral report
B.11	Composition of the Paediatric Committee – Joint membership	For information, EMA/MB/101857/2019; Ref. Ares(2017)446809 - 27/01/2017; EMA/101960/2019

B.12	EMA Policy on the Publication of Clinical Data: Revision of the Terms of Use: third party contractual rights	For information, EMA/MB/139474/2019; For adoption, EMA/144064/2019, Rev. 1
B.13	Preparation for a written procedure for the adoption of the Revision of the breach of trust procedure on declarations of competing interests for Management Board members	Oral report
C	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/93695/2019; EMA/4422/2019
C.2	Feedback from the Heads of Medicines Agencies	EXT/175868/2019
C.3	2018 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2018	EMA/MB/124139/2019 EMA/906394/2019*
C.4	Report on ex ante and ex post evaluation of projects for the period 1 January to 31 December 2018	For information, EMA/MB/101123/2019; EMA/101122/2019
C.5	Outcome of written procedures finalised during the period from 24 November 2018 to 22 February 2019	For information, EMA/MB/112294/2019*
C.6	Summary of the transfers of appropriation	For information, EMA/MB/129665/2019*
C.7	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2018	For information, EMA/MB/56107/2019
C.8	Revised Executive Directors decision on rules governing the secondment of national experts to the EMA	For information, EMA/MB/130004/2019; EMA/145199/2019 *

* 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.