16 March 2017
EMA/MB/1181/2017 V.4 Adopted
Management Board meeting 16 March 2017

Agenda for the 95th meeting of the Management Board

Held on 16 March 2017, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/1181/2017*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 94th meeting, held on 14-15 December 2016 adopted via written procedure on 3 February 2017	For information, EMA/MB/862367/2016*
A	**Points for automatic adoption**	
A.1	Repeal of Long term and short term contract agent rules	For information, EMA/MB/76149/2017; For adoption, EMA/MB/66252/2017
A.2	Derogation from Commission rules (Middle management rules, Function of Adviser, Learning & Development strategy)	For information, EMA/MB/58698/2017, C(2016) 3288, C(2016) 3827, C(2016) 3828, C(2016) 3855 with Annex, C(2016) 3214, EMA/MB/84839/2017; For adoption, EMA/MB/58145/2017
B	**Points for discussion**	
B.1	Highlights from the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	EMA preparedness on Brexit	Oral report

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B.4	EMA Annual Report 2016	For information, EMA/MB/133379/2017; For adoption, EMA/77204/2017*
B.5	Revised implementing rules to the Fee Regulation as of 1 April 2017 – Inflationary 1.2% increase of general fees from 1 April 2017 and of Pharmacovigilance fees from 1 July 2017	For information, EMA/MB/97414/2017; For adoption, EMA/MB/97423/2017*
B.6	Appointment of new Accounting Officer of the European Medicines Agency	For information, EMA/MB/27835/2017; For adoption, EMA/MB/27838/2017*
B.7	Revision of rules for reimbursement of expenses for delegates attending meetings	For information, EMA/MB/144135/2017; For adoption, EMA/MB/144136/2017*
B.8	Framework of collaboration between the EMA and academia	For information, EMA/MB/125458/2017, EMA/124964/2017, EMA/58661/2017; For adoption, EMA/125511/2017*
B.9	Report by the Steering Group on the Management Board data gathering initiative	For information, EMA/MB/134040/2017, EMA/174166/2017
B.10	Policy on external sources reporting potential regulatory improprieties	For information, EMA/MB/68192/2017; For endorsement, EMA/283205/2013*
B.11	Report from CVMP Chair	Oral report
B.12	a) Clinical Trial EU Portal and Database b) Preparation for audit	For information, EMA/MB/123839/2017, EMA/52673/2017; For information, EMA/MB/171044/2017; For endorsement, EMA/170854/2017
B.13	Pharmacovigilance Programme: Update on the EudraVigilance Auditable Requirements Project	For information, EMA/MB/60610/2017
B.14	Update on PSUR Repository	Oral report
B.15	7th Annual Report Veterinary MUMS/limited market	For information, EMA/MB/29936/2017; For endorsement, EMA/868034/2016*

B.16	Composition of the Paediatric Committee – Joint membership	For information, EMA/MB/124057/2017; Ref. Ares(2017)446809 - 27/01/2017; EMA/139965/2017
C	**Points for information only****	
C.1	Report on EU Telematics	For information, EMA/MB/98968/2017, EMA/98876/2017
C.2	Feedback from the Heads of Medicines Agencies	
C.3	2016 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2016	For information, EMA/MB/122153/2017, EMA/9942/2017*
C.4	Outcome of written procedures finalised during the period from 17 November 2016 to 16 February 2017	For information, EMA/MB/27995/2017*
C.5	Third six-monthly report on ex ante and ex post evaluation of projects for the period 1 July to 31 December 2016	For information, EMA/MB/49397/2017, EMA/49388/2017
C.6	Summary of transfers of appropriations in budget 2016	For information, EMA/MB/124297/2017*
C.7	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2016	For information, EMA/MB/27750/2017

* 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.