



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 October 2017
EMA/MB/158073/2017 Adopted
Management Board meeting 5 October 2017

Agenda for the 97th meeting of the Management Board

Held on 5 October 2017, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/158073/2017*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 96th meeting, held on 14-15 June 2017 adopted via written procedure on 26 July 2017	For information, EMA/MB/383134/2017*
A	Points for automatic adoption	
A.1	Withdrawal of the request for derogation from the Commission rules on appraisal for middle managers Commission rules on appraisal for middle managers (adoption by analogy)	For information, EMA/MB/552174/2017, Ares(2016)6965618, Ares(2017)3520119, EMA/460261/2017, EMA/460658/2017; For adoption EMA/MB/460753/2017
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	
	3.1. Update on EMA preparedness	Oral report
	3.2. Feedback from meeting of the working groups on committees' operational preparedness for human and veterinary medicines	Oral report
	3.3. EMA Brexit Preparedness Business Continuity Plan	For information, EMA/MB/626542/2017; EMA/196585/2017*
	3.4. Phase 2 of the Business Continuity Plan	Oral report



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	3.5. Budget 2018 and Preliminary Draft Budget 2019	Oral report
	3.6. Update on communication activities	Oral report
B.4	Amending Budget 01-2017	For information & adoption, EMA/MB/163175/2017*
B.5	Revision of budget structure from financial year 2018	For information & endorsement, EMA/MB/573458/2017*
B.6	6.1 EMA Mid-year report 2017 from the Executive Director (January – June 2017)	For information, EMA/MB/635545/2017; EMA/413591/2017*
	6.2 Amendment to the 2017 Work Programme	For information, EMA/MB/640248/2017; For adoption, EMA/583016/2016*
	6.3 Transfer of appropriations in budget 2017	For information & adoption, EMA/MB/617418/2017*
B.7	Report to the Management Board on the implementation of the clinical trial Regulation (EU) No. 536/2014, in particular on the development of the clinical trial EU Portal and Database and related projects (EudraCT legacy and Safety Reporting)	For information, EMA/MB/471090/2017; EMA/443908/2017
B.8	EudraVigilance Auditable Requirements Project	For information, EMA/MB/558545/2017; EMA/558542/2017
B.9	EMA co-operation with EUnetHTA	Oral report
B.10	Report from COMP Chair	Oral report
B.11	Revision on Guidance on the classification of veterinary medicinal products indicated for minor use minor species (MUMS) / limited market	For information, EMA/MB/526899/2017; For adoption, EMA/CVMP/388694/2014-Rev.1*
B.12	Report on changes to GCP inspection fees	For information, EMA/MB/581959/2017; EMA/581984/2017
C	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/600544/2017; EMA/573994/2017
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures during the period 12 May 2017 to 12 September 2017	For information, EMA/MB/574504/2017*

C.4	Summary of transfers of appropriations in the budget 2017	For information, EMA/MB/573435/2017*
C.5	Report on ex ante and ex post evaluations (January – June 2017)	For information, EMA/MB/547813/2017, EMA/MB/548040/2017
C.6	New IAS Mission Charter	For information, EMA/MB/650295/2017; Ares(2017)4590716 - 20/09/2017

* 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.