

14 June 2017 EMA/MB/1884/2017 Adopted Management Board meeting 14-15 June 2017

Agenda for the 96th meeting of the Management Board Held on 14 June 2017, Room 2A (16:30 – 18:45)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/1884/2017*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 95th meeting, held on 16 March 2017 adopted via written procedure on 28 April 2017	For information, EMA/MB/183915/2017*
4.	EMA Preparedness on Brexit - Update	Oral report
5.	Meeting of 27 April 2017	
	a) Feedback from meetingb) Deliverables	For information, EMA/MB/357943/2017; For endorsement, EMA/336491/2017 For information, EMA/MB/357655/2017; For endorsement, EMA/300951/2017, EMA/300988/2017
6.	 EMA Brexit Preparedness Business Continuity Plan Principles and methodology Launch of Phase 1 	For information, EMA/MB/358162/2017; For endorsement, EMA/322750/2017 For information, EMA/MB/370735/2017; EMA/336490/2017

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7.	Communications Plan on Brexit	Oral report
8.	Revised annual audit plan for 2017	For information, EMA/MB/257332/2017; For adoption, EMA/MB/244061/2017

Agenda for the 96th meeting of the Management Board Held on 15 June 2017, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item				
А	Points for automatic adoption			
A.1	Management Board meeting dates 2017-2019	For adoption, EMA/MB/312375/2017 Rev. 2*		
A.2	Model decision for Agencies on the policy on protecting the dignity of the person and preventing psychological and sexual harassment	For information, EMA/MB/273876/2017; EMA/338802/2010; EMA/338797/2010; For adoption, EMA/MB/854173/2016		
A.3	Derogation from Commission rules on appraisal for middle managers	For information, EMA/MB/325723/2017; C(2016)7270; EMA/301141/2017; For adoption, EMA/MB/244091/2017		
в	Points for discussion			
B.1	Highlights from 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) 2016	For information, EMA/MB/328312/2017; EMA/141860/2017*; For adoption, EMA/234192/2017*		
B.4	Item deferred			
B.5	Revised Internal Audit Charter of the Audit Capability of the European Medicines Agency	For information, EMA/MB/257563/2017; For adoption, EMA/209787/2017		
B.6	Annual report of internal audit and advisory activities at the European Medicines Agency 2016	For information, EMA/MB/257389/2017; EMA/290360/2017		
B.7	The European Medicines Agency's strategy for using cloud services	For information, EMA/MB/330200/2017; For endorsement, EMA/330193/2017		
B.8	European Medicines Web Portal (EMWP): Governance and high- level plan	For information, EMA/MB/332164/2017; For endorsement, EMA/169512/2017		
B.9	Report by the Steering Group on the Management Board data gathering initiative	Oral report		

Item		
	 Pharmacovigilance fee regulation KPI report 2016 	For information, EMA/MB/327768/2017; EMA/325900/2017
B.10	Clinical Trial EU Portal and Database	For information, EMA/MB/327139/2017 Rev 1; EMA/222592/2017
B.11	PV ADR project status update	Oral report
B.12	Annual report 2016 on the performance of the Agency's scientific procedures: Key Performance Indicators (KPIs) for medicinal products for human and veterinary use (piloted procedures only)	For information, EMA/MB/294900/2017; For endorsement,
	products for human and veterinary use (protect procedures only)	EMA/288781/2017
С	Points for information only**	
C.1	Report on EU Telematics	For information, EMA/MB/325702/2017; EMA/282408/2017
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures during the period 14 February 2017 to 11 May 2017	For information, EMA/MB/109400/2017*
C.4	Summary of transfers of appropriations in the budget 2017	For information, EMA/MB/288567/2017*
C.5	 Annual report on the EMA interactions with patients, consumers and healthcare professionals and their organisations (2016) Principles on the involvement of young patients/consumers within EMA activities 	For information, EMA/MB/308950/2017; EMA/26003/2016*; EMA/494077/2016*
C.6	Annual Report on EMA's interaction with industry stakeholders (2016)	For information, EMA/MB/343117/2017; EMA/812253/2016*

* 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.