

6 October 2016 EMA/MB/440637/2016 v.4 Adopted Management Board meeting of 6 October 2016

## Agenda for the 93rd meeting of the Management Board Held on 6<sup>th</sup> October 2016, Room 2A (08:00 – 15:00)

Chair: Christa Wirthumer-Hoche

Item			
1.	Draft agenda	For adoption, EMA/MB/440637/2016*	
2.	Declaration of competing of interest related to current agenda	Oral report	
3.	Minutes from the 92nd meeting, held on 16 June 2016 adopted via written procedure on 27 July 2016	For information, EMA/MB/421228/2016*	
4.	Election of the Vice-Chair of the Management Board (in camera)	By ballot For information, EMA/MB/453034/2016; EMA/MB/453036/2016	
A	Points for automatic adoption/endorsement		
A.1	European Commission part-time rules	For information, EMA/MB/566944/2016; C(2015) 9720; For adoption, EMA/MB/463031/2016	
A.2	Revised rules on working time	For information, EMA/MB/566910/2016; For adoption, EMA/MB/562311/2016	
В	Points for discussion		
B.1	Highlights from the Executive Director	Oral report	
B.2	Report from the European Commission	Oral report	
B.3	EMA mid-year report 2016 from the Executive Director (January - June 2016)	For information, EMA/MB/614902/2016; EMA/469742/2016*	
B.4	Amendment to the Procurement Plan (Annex 5) of the Work Programme 2016	For information, EMA/MB/629515/2016;	



Item			
		For adoption,	
		Annex 5 of EMA/92499/2016	
B.5	Amending budget 01-2016	For adoption, EMA/MB/572210/2015*	
B.6	Revision of budget structure from financial year 2017	For information &	
		endorsement,	
		EMA/MB/404323/2016*	
B.7	Annual review of the EMA independence policies and	For information,	
	ensuing actions	EMA/MB/608752/2016;	
		EMA/MB/655150/2016;	
		EMA/175527/2016*	
	EMA policy on the handling of declarations of interests of	For adoption,	
	scientific committees' members and experts (Policy 0044)	EMA/626261/2014, Rev. 1*	
	EMA policy on the handling of competing interests of	For adoption,	
	Management Board members (Policy 0058)	EMA/MB/715362/2015, Rev. 1*	
B.8	Decision on rules concerning the handling of declared	For information,	
	interests of EMA staff	EMA/MB/608567/2016;	
		For adoption,	
		EMA/259494/2016 *	
B.9	Report on changes to GCP inspections fees as of 1 August	For information,	
	2015	EMA/MB/365399/2016;	
		EMA/INS/GCP/264055/2016	
B.10	Pharmacovigilance Programme: Update on the	For information,	
	EudraVigilance Auditable Requirements Project	EMA/MB/587863/2016;	
		EMA/452911/2015;	
		EMA/325783/2016;	
		EMA/835422/2016	
B.11	Reflection paper on the development of the European	For information,	
	Medicines web portal	EMA/MB/607095/2016;	
		EMA/MB/654700/2016;	
		For adoption, EMA/585981/2016*	
D 12	Papart on dry run of Public Haarings	Oral report	
B.12 B.13	Report on dry-run of Public Hearings Clinical Trial EU Portal and Database	Oral report	
B.13		For information,	
D. 14	Report by the Steering Group on the Management Board data gathering initiative	EMA/MB/630665/2016;	
	data gathering initiative	EMA/655001/2016	
B.15	Multinational assessment team concept – The next phase –	For information,	
D. 13	Broadening the concept to the post-authorisation phase	EMA/MB/619857/2016;	
	2. data	For discussion,	
		EMA/619544/2016	

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С	Points for information only * *	
C.1	Report on EU Telematics	For information,
		EMA/MB/600489/2016;
		EMA/MB/588736/2016
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures during the period 12 May	For information,
	2016 to 6 September 2016	EMA/MB/607820/2016*
C.4	Summary of transfer of appropriations in the budget 2016	For information
		EMA/MB/577322/2016*
C.5	EudraVigilance Veterinary / Signal Detection and on-going	For information,
	related Veterinary-IT projects	EMA/MB/600445/2016;
		EMA/13787/2009*
C.6	Report on ex ante and ex post evaluations (January - June	For information,
	2016)	EMA/MB/490849/2016;
		EMA/490850/2016

<sup>\*</sup> 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.