



18 May 2012
EMA/MB/92770/2012 Adopted

Agenda for the 76th meeting of the Management Board

Thursday, 7 June 2012 in room 4A (from 09:00 – 16:00)

Chair: Sir Kent Woods

Item	Preliminary draft agenda	Action/Reference
1.	Draft agenda	For adoption, EMA/MB/92770/2012*
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Minutes from the 75 th meeting, held on 21-22 March 2012	For adoption, EMA/MB/221361/2012*
4.	Changes to the Management Board meetings organisation	For adoption, EMA/MB/251300/2012*
Block A: Adoption without presentation		
A.1.	Revised Implementing Rules to the Fee Regulation (Item moved to C.5.b)	
Block B: Discussion items with presentation		
B.1.	Highlights from Executive Director	Oral report
B.2.	a. Executive Director's Annual Activity Report (AAR) 2011	EMA/MB/326083/2012 For discussion, EMA/MB/878723/2012
	b. Analysis and Assessment of the AAR 2011	For adoption, EMA/MB/326427/2012*
B.3.	Report from the European Commission	Oral report
B.4.	Management Board breach of trust procedure	For adoption, EMA/MB/309079/2012*
B.5.	Report from the Management Board sub-group on procurement procedures	For endorsement, EMA/MB/236859/2012 EMA/269255/2012; EMA/269247/2012
B.6.	Pharmacovigilance legislation	For discussion, EMA/MB/347576/2012
	a. Pharmacovigilance Risk Assessment Committee (PRAC) rapporteur appointment principles	For discussion, EMA/MB/345767/2012;
	b. Countdown to July 2012; the establishment and functioning of the PRAC	EMA/315258/2012
	c. Final composition of the Pharmacovigilance and Risk Assessment Committee (PRAC)	For information, EMA/329643/2012
B.7.	Management Board meeting dates 2013	For adoption, EMA/MB/325685/2012*



Item	Preliminary draft agenda	Action/Reference
B.8	Annual EudraVigilance status report 2011 a. Human b. Veterinary	For endorsement, EMA/MB/144431/2012; EMA/144430/2012* For information, EMA/322615/2012*
B.9	Committee on Herbal Medicinal Products; Report on Action plan for herbal medicines 2010-2011	For endorsement EMA/MB/347231/201* EMA/HMPC/45679/2012*
B.10	Management Board appointment to the Management Board Telematics Committee (MBTC)	Oral report
Block C: Information items**		
C.1	a. Report on the Agency's discharge 2010 b. Annual Internal Audit Report (IAS) 2011 c. Agency's improvement action plan on open recommendations from the IAS audit	For information, P7_TA-PROV(2012)0175 Ares(2012)577449 EMA/MB/321840/2012
C.2	Annual EudraVigilance status report 2011 – Human (Item moved to B.8.a)	
C.3	Update report on the Agency's implementation of the EU Telematics strategy: a. Projects report b. Operations report c. Minutes of MBTC from March 2012 meeting	For information, EMA/310159/2012 EMA/310155/2012* EMA/310498/2012
C.4	Outcome of written procedures during the period between 1 March 2012 and 17 May 2012	For information, EMA/MB/326836/2012*
C.5	Preparation for written procedures: a. On opinion of the Agency's annual accounts for the year ended 31 December 2011 b. Revised Implementing Rules to the Fee Regulations	For information, EMA/MB/323132/2012 EMA/MB/361662/2012

* Documents marked with a star * are intended for publication on the external web site

** Documents in Block C are for information only. These documents are not intended for discussion unless specifically requested