

12 October 2011 EMA/MB/826035/2011 Version 3.0 Adopted

Agenda for the 74th meeting of the Management Board

Held on 15 December 2011, Room 4A (09:00 - 16:00)

Chair: Kent Woods

Item	Preliminary draft agenda	Reference/Action	
Organisational topics			
1.	Draft agenda	For adoption, EMA/MB/826035/2011*	
2.	Declaration of conflicts of interest related to current agenda	Oral report	
3.	Minutes from the 73 rd meeting, held on 6 October 2011, adopted via written procedure on 23 November 2011	For information, EMA/MB/828587/2011*	
Planning and reporting topics			
4.	Highlights from the Executive Director	Oral report	
5.	Planning 2012: a. Work programme 2012 b. Implementation of Pharmacovigilance legislation	For adoption, EMA/MB/554514/2011* For endorsement, EMA/MB/901680/2011 EMA/901869/2011	
	c. Draft budget and establishment plan 2012d. ICT budgets and projects for 2012	For adoption, EMA/MB/143451/2011* For information,	
	e. Staff policy plan 2012	EMA/MB/856505/2011* EMA/MB/643417/2011*	
Governance topics			
6.	Amendments to Management Board implementing rules on the Agency's fees	For adoption, EMA/MB/239263/2011*	
7.	 EMA Conflict of interests: a. 2nd Update on the implementation of conflicts of interest policy for experts b. 2nd Update on the implementation of conflicts of interest policy for staff c. Revised Management Board conflicts of interest policy 	For discussion, EMA/MB/924270/2011 EMA/914836/2011 Oral report For adoption, EMA/MB/834867/2011	
7bis	Personnel matter EN	For adoption, 1A/MB/911958/2011Rev.1	



Item	Preliminary draft agenda	Reference/Action	
8.	Report on Agency's procurement procedure and proposed improvement action plan	For endorsement, EMA/MB/811207/2011*	
9.	IAS Strategic Audit Plan for 2012-2014 Ref. Are:	For endorsement, EMA/MB/915206/2011 s(2011)992230 - 20/09/2011	
10.	Revised Management Board Rules of procedure For adoption, EMA/MB/115339/2011/en/Rev.3*		
11.	Management Board Telematics Committee (MBTC) a. Revised Terms of reference b. MBTC Chairmanship arrangements	For adoption, EMA/907384/2011* Oral report	
11bis	Preparation for written procedures: a. Non-automatic carry-over 2011-12	For information, EMA/MB/882002/2011	
Cooperation with partners and stakeholders			
12.	Draft Reflection Paper on ethical and GCP aspects of clinical trials	For endorsement, EMA/MB/886045/2011* EMA/121340/2011*	
13.	 Interaction between EMA and Healthcare Professionals: Framework for Interaction between EMA and Healthcare Professionals Criteria to be Fulfilled by Healthcare Professionals' Organisations Involved in EMA Activities 	For endorsement, EMA/MB/903626/2011* EMA/688885/2010* EMA/161137/2011*	
14.	Financial compensation for Member States' participation in th linguistic checking of product related information: Fixed flat hourly cost for 2012	e For endorsement, EMA/MB/880875/2011*	
15.	2011 EudraVigilance-Human Mid-Year Report	For discussion, EMA/MB/902165/2011	
16.	Reflection paper on medicinal product supply shortages caused by manufacturing/ GMP compliance problems	For discussion, EMA/MB/899250/2011 EMA/INS/GMP/774201/2011	
17.	Report from the European Commission	Oral report	
18.	Report from the Heads of Medicines Agencies	Oral report	
Additional documents for information**			
19.	Minutes from the 1 st meeting of the working group on Substances of Human Origin	For information	
20.	EU Telematics update reports: a. Projects report b. Operations report c. Minutes from Management Board Telematics Committee (MBTC) meeting on 22 September 2011	For information, EMA/907269/2011 EMA/907270/2011* EMA/907383/2011	
21.	EMA preparation for the impact of the Olympic Games 2012	For information, EMA/876327/2011*	
22.	Outcome of written procedures during the period 15 Septemb 2011 to 30 November 2011	For information, EMA/MB/868582/2011*	
23.	Summary of transfers of appropriations in the budget 2011	For information, EMA.MB/902317/2011*	

^{*} 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.