



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 March 2012
EMA/MB/47692/2012 Adopted

Agenda for the 75th meeting of the Management Board

21 March 2012, Room 4A (Wednesday 21st; from 14:00 – 19:00 hrs)

Chairperson: Sir Kent Woods

Item		Mins
Opening	Sir Kent Woods	14:00 – 14:05
Introduction	Guido Rasi, Executive Director	14:05 – 14:15
Session 1	<ul style="list-style-type: none">A discussion on the concept of public hearing and transparency<ul style="list-style-type: none">Extracts from FDA video recordings of public hearings;Patients' interest for public hearings on medicines in Europe (François Houyez from Eurordis)	14:15 – 15:15
	<ul style="list-style-type: none">A discussion on the publication of agendas and minutes	15:15 – 15:30
	<i>Tea and coffee break (4th floor open area)</i>	15:30 – 15:45
Session 2	<ul style="list-style-type: none">An update on the implementation of pharmacovigilance legislation in the countdown to 2 July 2012	15:45 – 16:00
	<ul style="list-style-type: none">A discussion on PRAC Rapporteur appointment (follow up to February HMA meeting)	16:00 – 17:00
<i>Tea and coffee break (4th floor open area)</i>		17:00 – 17:15
Session 3	<ul style="list-style-type: none">Adaptive licensing: a useful approach for drug licensing in the EU? (presentation by Hans-Georg Eichler)	17:15 – 18:00
<i>Dinner (3rd floor restaurant)</i>		18:00 – 19:00



Agenda for the 75th meeting of the Management Board

22 March 2012, Room 4A (Thursday 22nd; from 09:00 – 16:00 hrs)

Chairperson: Sir Kent Woods

Item	Preliminary draft agenda	Action/Reference
Organisational topics		
1.	Draft agenda	For adoption, EMA/MB/47692/2012*
2.	Declaration of conflicts of interest related to current agenda	Oral report
3.	Minutes from the 74 th meeting, held on 15 December 2011 and adopted via written procedure on 9 February 2012	For information, EMA/MB/33634/2012*
4.	Organisation of Management Board meetings	For adoption, EMA/MB/131620/2012*
Planning and reporting topics		
5.	Highlights from the Executive Director	Oral report
6.	Annual report 2011	For adoption, EMA/MB/977044/2011*
7.	Work Programme and preliminary draft budget 2013: a) Preliminary draft work programme b) Preliminary draft budget c) Information and communication technology d) Project 2014	For adoption, EMA/MB/945561/2011 EMA/MB/121516/2012 For information, EMA/MB/82882/2012 EMA/MB/955795/2012
8.	Amendments to Management Board implementing rules on the Agency's fees	For adoption, EMA/MB/13210/2012*
9.	Amending Budget 01-2012 for changes to entry grade for a post	For adoption, MB/EMA/155755/2012
Governance topics		
10.	EMA Conflict of interests: a. 2 nd update on implementation b. Revised conflicts of interest policy for experts c. Breach of trust policy d. Revised Management Board conflicts of interest policy e. 2 nd Update on the implementation of conflicts of interest policy for staff	For discussion, EMA/154547/2012 For endorsement, EMA/513078/2010* For endorsement, EMA/154320/2012* For adoption, EMA/MB/64234/2012* Oral report
11.	Pharmacovigilance and Risk Assessment Committee (PRAC) a) Consultation procedure on final composition b) Overview of nominations received	For adoption, EMA/MB/139702/2012* For information, EMA/MB/146762/2012
12.	Appointment of Michael Lenihan as the Agency's accounting officer	For adoption, EMA/MB/124276/2012*

Item	Preliminary draft agenda	Action/Reference
Cooperation with partners and stakeholders		
13.	Report from the European Commission	Oral report
14.	Report from the Heads of Medicines Agencies	Oral report
15.	Report on performance of National Competent Authorities (NCAs) against newly established Key Performance Indicators (KPIs)	For information, EMA/112052/2012
Additional documents for information**		
16.	Annual report 2011 of the Agency's Audit Advisory Committee	For information, EMA/135591/2012
17.	Annual report 2011 of the Agency's Internal Audit	For information, EMA/135587/2012
18.	Performance of the Agency's scientific procedures: Survey 2011 for medicinal products for human use	For information, EMA/MB/157253/2012*
19.	EU Telematics strategy update: a. Project report b. Operational report c. Minutes from Management Board Telematics Committee (MBTC) from the meeting on 14 February 2012	For information, EMA/185199/2012 EMA/189200/2012* EMA/177625/2012
20.	Outcome of written procedures during the period 25 November 2010 to 29 February 2012	For information, EMA/MB/2671/2012*
21.	Summary of transfers of appropriations in the budget 2011	For information, EMA/MB/115063/2012*
22.	Overview of implementing rules to Staff Regulations signed by the MB Chair during the period from 7 October 2011 to 29 February 2012	For information, EMA/MB/137391/2012*

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

** Documents in *Additional documents for information* section are not indented for discussion unless specifically requested