



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 December 2017  
EMA/MB/611419/2017 Adopted  
Management Board meeting of 13-14 December 2017

## Agenda for the 98th meeting of the Management Board

Held on 13 December 2017, Room 2A (13:00 – 19:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/611419/2017*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 97th meeting, held on 5 October 2017 adopted via written procedure	EMA/MB/660406/2017*
4.	Outline of the offer made by the Netherlands to host the EMA in Amsterdam including EMA impact assessment	Oral report For information
	4.1. Authority to the Executive Director to accept one of the options offered by the Dutch Government for the EMA temporary premises in Amsterdam	For information, EMA/MB/827245/2017 For adoption
5.	Presentation from the Netherlands including how it will meet EMA requirements	Oral report For information
	EMA Preparedness on Brexit	
	6.1. Update on EMA preparedness	Oral report For information
	6.2 Collaboration framework between the Netherlands and EMA	Oral report For information
	6.3. High-level roadmap for relocating EMA to Amsterdam	Oral report For information
	6.4. Building requirements in the context of the building approval process	Oral report For information



<ul style="list-style-type: none"> <li>– Preparation for written procedure of building approval process</li> </ul>	
6.5. Working groups on committees' operational preparedness for human and veterinary medicines	
6.5.1 Feedback from the working group meetings and the 15 November 2017 EU27 Information meeting	Oral report For information
6.5.2 Outcome from the working groups	For information, EMA/MB/824752/2017; For endorsement, EMA/MB/816950/2017
6.6. Staff Retention Support Measures	
a) Overview of Staff Retention Support Package	Oral report
b) Executive Decision on Relocation visits	For information, EMA/MB/772574/2017; EMA/744063/2017
c) Update on rules on Teleworking	Oral report
6.7. Communication activities	Oral report

# Agenda for the 98th meeting of the Management Board

Held on 14 December 2017, Room 2A (08:00 – 15:00)

Item		
<b>A</b>	<b>Points for automatic adoption</b>	
A.1	Financial compensation and workload estimation of the revised EMA organisation of translations of product related information	For information, EMA/MB/731638/2017;  For endorsement, EMA/732995/2017*
<b>B</b>	<b>Points for discussion</b>	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Programming <ul style="list-style-type: none"> <li>a) Programming 2018-2020, including 2018 work programme, budget, establishment plan</li> <li>b) Draft programming 2019-2021</li> </ul>	For information, EMA/MB/770050/2017  For adoption, EMA/417705/2017*; EMA/MB/799068/2017*  For information, EMA/800271/2017
B.4	Audit Strategy and Annual Audit Plan 2018	For information, EMA/MB/768580/2017;  For adoption, EMA/716214/2017
B.5	<ul style="list-style-type: none"> <li>a) Report to the Management Board on the implementation of the clinical trial Regulation (EU) No. 536/2014, in particular on the development of the clinical trial EU Portal and Database and related projects (EudraCT legacy and Safety Reporting)</li> <li>b) Report on the state of play, as of 1 December 2017, of the progress and revised planning for further development of the EU Portal and Database</li> </ul>	For information, EMA/MB/689288/2017; EMA/687143/2017  For information, EMA/MB/692978/2017;  For discussion, EMA/692972/2017
B.6	EudraVigilance Auditable Requirements project update	For information, EMA/MB/792430/2017 EMA/779748/2017
B.7	Information Management Strategy 2018-2020 and Information Management Strategic Plan 2018-2020	For information, EMA/MB/711126/2017;  For endorsement, EMA/232224/2017, EMA/302624/2017

B.8	Revision of the Anti-fraud Strategy and new action plan 2018-2020	For information, EMA/MB/811979/2017; For adoption, EMA/812072/2017*
B.9	Preparation for written procedure on non-automatic carry-over of appropriations from 2017 to 2018 for various IT projects	For information, EMA/MB/800148/2017
<b>C</b>	<b>Points for information only**</b>	
C.1	Report on EU Telematics	For information, EMA/MB/781734/2017, EMA/706184/2017
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 13 September 2017 to 20 November 2017	For information, EMA/MB/771195/2017*
C.4	Summary of the transfers of appropriation 2017	For information, EMA/MB/794050/2017*
C.5	Report on the annual accounts of the European Medicines Agency for the financial year 2016	For information, EMA/MB/775352/2017, CH4089422EN05 dated 19.09.2017*, EXT/51775/2017

\* 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.