



12 June 2019  
EMA/MB/157340/2019 Adopted  
Management Board meeting of 12-13 June 2019

## Agenda for the 104<sup>th</sup> meeting of the Management Board

Held on 12 June 2019, Room 2D (14:30 – 19:00)

Held on 13 June 2019, Room 2D (09:00 – 16:00)

Chairperson: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/157340/2019*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 103rd meeting, held on 21 March 2019 adopted via written procedure	For information, EMA/MB/188256/2019*
4.	EMA Preparedness on Brexit	Oral report
	4.1. Update on EMA Brexit preparedness	
	4.1.1. Progress report on operational aspects	For information/ discussion
	4.1.2. Status update on EMA staff retention and priorities for reintroducing EMA activities for 2 <sup>nd</sup> half of 2019	For information/ discussion
	4.2. Update on EMA-NL Authorities collaboration for relocation to Amsterdam	
	4.2.1. Relocation to the final EMA premises	For information/ discussion
5.	Update on 30 Churchill Place	For discussion
<b>A</b>	<b>Points for automatic adoption</b>	
A.1	Management Board meeting dates 2020-2021	For information & adoption, EMA/MB/198583/2019*
A.2	Internal rules on possible restrictions of data subjects' rights in administrative inquiries, investigations and disciplinary proceedings	For information, EMA/MB/293415/2019; For adoption, EMA/183213/2019



<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	Assessment of the Executive Director's Annual Activity Report (AAR) 2018	For information, EMA/MB/276306/2019; EMA/112688/2019*; For adoption, EMA/240861/2019*
B.4	Preparation for the written procedure on the Amending Budget 2019	For information, EMA/MB/281638/2019
B.5	Rules for reimbursement of expenses for delegates attending meetings	For information, EMA/MB/252390/2019; For adoption, EMA/MB/279597/2018, rev.2*
B.6	Revision of the Financial Regulation of the European Medicines Agency  a) Revision of the Financial Regulation  b) Revision of budget structure and nomenclature from 1st July 2019	For information, EMA/MB/911309/2019;  For adoption, EMA/MB/911312/2019* For information & endorsement, EMA/MB/186752/2019
B.7	Annual report of internal audit and advisory activities at the European Medicines Agency 2018	For information, EMA/MB/258484/2019; EMA/MB/790888/2018
B.8	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation a) Interim report on CTIS development	For discussion, EMA/MB/245561/2019, EMA/245562/2019
B.9	2nd EC report on the performance of pharmacovigilance tasks by the EU Member States and the EMA (2015-2018) – preparation for a written procedure	For discussion, EMA/MB/286639/2019
B.10	Implementation of the new veterinary medicines legislation a) Resources/governance	Oral report
B.11	Deliverables from the HMA/EMA Task Force on the Availability of Authorised Medicines  <ul style="list-style-type: none"> <li>• Draft Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)</li> <li>• Draft Best practices for public communication on medicines' availability issues</li> </ul>	For information, EMA/MB/288386/2019, EMA/299737/2019  For adoption, EMA/674304/2018*  For adoption, EMA/632473/2018*
B.12	Annual report 2018 on Key Performance Indicators (KPIs) for evaluation, post-authorisation, inspection and scientific advice procedures for medicinal products for human and veterinary use	For information, EMA/MB/265471/2019; For endorsement, EMA/258793/2019

B.13	Outcomes of the <i>Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use</i>	Oral report
B.14	Update on EudraLink and secure communication	Oral report
B.15	Interim update on the activities of the HMA-EMA Joint Big Data Taskforce	Oral report
<b>C</b>	<b>Points for information**</b>	
C.1	Report on EU Telematics	For information, EMA/MB/270904/2019, EMA/255216/2019
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 23 February 2019 to 16 May 2019	For information, EMA/MB/270926/2019*
C.4	Summary of transfers of appropriations	For information, EMA/MB/245070/2019*

\* 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.