



16 December 2020  
EMA/MB/547010/2020 Adopted  
Management Board meeting of 16-17 December 2020

## Agenda for the 110<sup>th</sup> meeting of the Management Board

Held on 16 December 2020, Room 1C (13:00 – 16:00)

Held on 17 December 2020, Room 1C (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/547010/2020*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 109 <sup>th</sup> meeting, held on 1 October 2020 adopted by written procedure	For information, EMA/MB/519858/2020*
4.	COVID-19 <ul style="list-style-type: none"><li>EMA Status Report</li><li>OPEN project</li></ul>	For information & discussion  EMA/MB/688840/2020; EMA/691780/2020
5.	Aplidin General Court Judgment and impact on the EMA handling of competing interests	For endorsement, EMA/MB/689087/2020
6.	Update on 30 Churchill Place	Oral report
7.	Update on Brexit	For information
<b>A</b>	<b>Points for automatic adoption/endorsement</b>	
A.1	Revision of budget remarks for budget 2021	For information & endorsement, EMA/MB/116730/2020
A.2	Financial compensation and workload estimation of the EMA organisation of translations of product related information	For information, EMA/MB/623265/2020*; For endorsement, EMA/623334/2020
<b>B</b>	<b>Points for discussion</b>	
B.1	a) Audit strategy 2021-2023 and audit plan 2021	For information, EMA/MB/622416/2020; For adoption, EMA/MB/434298/2020
	b) Report to the Management Board on Pharmacovigilance audits carried out in the	For information, EMA/MB/608386/2020;



Item		
	European Medicines Agency from 1 July 2018 to 30 June 2020	For endorsement, EMA/MB/597112/2020
B.2	Review of activities of the Working Parties of the EMA High-level implementation plan	For information, EMA/MB/650729/2020, EMA/650033/2020; For endorsement, EMA/634100/2020
B.3	Information Management governance review	Oral report
B.4	Annual report on the implementation of the EMA's Anti-Fraud Strategy	For information, EMA/627416/2020
B.5	Report on the implementation by EMA of the EU Data Protection Regulation	For information, EMA/627417/2020
B.6	Highlights of the Executive Director	Oral report
B.7	Report from the European Commission	Oral report
	a) Commission legal proposal for extending the mandate of the European Medicines Agency	For information, EMA/MB/651887/2020
B.8	Programming 2021-2024  a) Final programming document 2021-2023 b) Preliminary programming document 2022-2024	For information, EMA/MB/663790/2020, EMA/592220/2020; For adoption, EMA/380399/2020*, EMA/MB/664792/2020*
B.9	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation  a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation  b) Mandate of the Monitoring Subgroup of the Clinical Trial Regulation Coordination group	For information, EMA/MB/594006/2020, rev.1  For information, EMA/MB/594004/2020  For endorsement, EXT/613767/2020
B.10	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.11	Union Product Database (UPD) Access Policy under the Veterinary Medicinal Products Regulation (VMP-Reg)	For information, EMA/MB/631606/2020, EMA/633343/2020; For adoption, EMA/632902/2020
B.12	Big Data Steering Group workplan update  DARWIN EU implementation approach	For information, EMA/MB/617432/2020; For information & discussion, EMA/636401/2020*
B.13	Renewal of the cooperation agreements between the NCAs and EMA	For information, EMA/MB/642653/2020; EMA/641097/2020

<b>C</b>	<b>Points for information only**</b>	
C.1	Report on EU Telematics	For information, EMA/MB/578488/2020, EMA/569531/2020
C.2	Feedback from the Heads of Medicines Agencies	
C.3	Outcome of written procedures finalised during the period from 16 September 2020 to 26 November 2020	For information, EMA/MB/640539/2020*;
C.4	a) Summary of transfers of appropriations 2020	For information EMA/MB/585327/2020*
	b) Summary report on implementation of assigned revenue	For information, EMA/MB/586754/2020
C.5	Biennial Report on EMA's interaction with industry stakeholders (2018-2019)	For information, EMA/MB/628469/2020, EMA/623780/2019*
C.6	Stakeholder engagement biennial report: engaging with patients, consumers, healthcare professionals and academia (2018-2019)	For information, EMA/MB/624477/2020, EMA/124131/2020*

\* 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.