

11 March 2021 EMA/MB/34198/2021 Adopted Management Board meeting of 11 March 2021

Agenda for the 111th meeting of the Management Board

Held on 11 March 2021, Room 1C (09:00-16:00)

Chairperson: Christa Wirthumer-Hoche

Item			
1.	Draft agenda	For adoption,	
		EMA/MB/34198/2021*	
2.	Declarations of competing interests related to the current agenda	Oral report	
3.	Minutes from the 110th meeting, held on 16-17	For information,	
	December 2020 adopted via written procedure	EMA/MB/695181/2020*	
4.	COVID-19 • EMA Status Report	For information & discussion	
5.	Aplidin General Court Judgment	Oral report	
6.	Update on 30 Churchill Place	Oral report	
7.	Update on Brexit	Oral report	
A	Points for automatic adoption		
A.1	Management Board decision – amendment to	For information,	
	Commission decision on transfer of pension rights	EMA/MB/46155/2021,	
		EXT/644244/2020,	
		EXT/644221/2020;	
		For adoption,	
		EMA/MB/44358/2021	
В	Points for discussion		
B.1	Highlights of the Executive Director	Oral report	
B.2	Report from the European Commission	Oral report	
		For information,	
		EXT/146060/2021,	
		EXT/147893/2021,	
		EXT/147894/2021	



B.3	EMA Annual Report 2020	For information, EMA/MB/74231/2021, EMA/706919/2020*
B.4	2020 EMA Annual Report on Independence	For information, EMA/MB/116532/2021; For endorsement, EMA/34780/2021*
B.5	Revised implementing rules to the Fee Regulation as of 1 April 2021	For information, EMA/MB/506725/2020; For adoption, EMA/MB/316533/2020*
B.6	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/44296/2021
	a) Summary Report from 23 February 2021 meeting	For information, EMA/MB/118548/2021
	 b) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation 	For information, EMA/MB/44297/2021
	 c) Update on planning for go-live and post- go-live, planned go-live date and update from EU Clinical Trials Coordination Group 	For information, EXT/143080/2021
B.7	Review of activities of the Working Parties of the EMA	For information, EMA/125403/2021, Rev.1; For endorsement, EMA/MB/125024/2021, Rev.1; For information, EMA/MB/134823/2021
B.8	Update on Commission legal proposal for extending the mandate of the European Medicines Agency	Oral report
B.9	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
B.10	11th Annual Report Veterinary MUMS/limited market	For information, EMA/MB/83320/2021, Rev.1; For endorsement, EMA/553359/2020, Rev.1*
B.11	Information Management governance review	For information, EMA/143069/2021

B.12	Big Data Steering Group update	For information, EMA/MB/84860/2021,Rev.1
	a) Big Data Steering Group 2020 activities	For information,
	report, for information	EMA/48625/2021*
	b) DARWIN EU Advisory Board: mandate	For adoption, EMA/87192/2021
B.13	Revision of the EMA Anti-Fraud Strategy and	For information,
	related Action Plan for the next 3-year period	EMA/MB/108779/2021 rev.1,
		EMA/111152/2021;
		For adoption
D 14	Duana untian for the southern number of une on unitian	EMA/128273/2021*
B.14	Preparation for the written procedure on revision of budget remarks	For information, EMA/MB/136279/2021
С	Points for information only**	LMA/Mb/130273/2021
C.1	Report on EU Telematics	For information,
0.1	report on to relements	EMA/MB/27703/2021;
		EMA/27657/2021
C.2	Feedback from the Heads of Medicines Agencies	
C.3	2020 Annual Report on EudraVigilance for the	For information,
	European Parliament, the Council and the	EMA/MB/80733/2021;
	Commission Reporting period: 1 January to 31 December 2020	EMA/620104/2020*
C.4	11^{th} six-monthly report on ex ante and retroactive	For information,
	evaluation of projects for the period 1 July to 31	EMA/MB/58488/2021;
	December 2020	EMA/58487/2021
C.5	Preparation for written procedure on opinion on	For information,
	the Agency annual accounts for the financial year 2020	EMA/MB/53054/2021
C.6	Outcome of written procedures finalised during the	For information,
	period from 26 November 2020 to 12 February 2021	EMA/MB/81947/2021*
C.7	Summary of transfers of appropriations in budget	For information,
	2020	EMA/MB/76157/2021*

^{*} 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.