16 March 2022
EMA/MB/30014/2022 Adopted
Management Board meeting of 16-17 March 2022

Draft agenda for the 115th meeting of the Management Board

Held on 16 March 2022, Room 1C/WebEx (15:00 – 18:30)

Held on 17 March 2022, Room 1C/WebEx (09:00 – 16:00)

Chairperson: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/30014/2022*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Election of the Chair of the Management Board ***(in camera to take place on Thursday 17 March at 09:00am CET)***	By ballot
4.	Minutes from the 114th meeting, held on 15-16 December 2021 adopted via written procedure	EMA/MB/761948/2021*
5.	Update on regulatory and coordinating actions arising from the war in Ukraine	For information
6.	EMA extended mandate – Regulation (EU) 2022/123	
	i. European Commission update on Health Union package	Oral update
	ii. EMA update on implementation activities:	
	a. Chapter II: Monitoring and mitigating shortages of critical medicinal products and management of major events including:	For information & discussion, EMA/MB/105513/2022;
	○ Draft Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) Rules of Procedure	For information, EMA/41493/2022;
	b. Chapter IV: Monitoring and mitigating shortages of critical medical devices	For information, EMA/MB/105513/2022;

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	c. Chapter III: Medicinal products with the potential to address public health emergencies, including:	For information & discussion, EMA/MB/105513/2022;
	○ Emergency Task Force (ETF) composition ○ Draft Emergency Task Force Rules of Procedure	For adoption, EMA/555794/2021*; For information, EMA/336551/2021;
	d. Chapter IV: Support for the Expert Panels on medical devices	For information, EMA/MB/105513/2022;
	iii. Stakeholders engagement plan	For information, EMA/MB/105513/2022, EMA/359462/2021
7.	COVID-19 • EMA Status Report	For information
A	**Points for automatic adoption**	
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	EMA Annual Report 2021	For information, EMA/MB/107705/2022; For adoption, EMA/74495/2022*
B.4	2021 EMA Annual Report on Independence	For information, EMA/MB/149373/2022; For endorsement, EMA/759921/2021*
B.5	Revised implementing rules to the Fee Regulation as of 1 April 2022	For information, EMA/MB/407922/2021; For adoption, EMA/MB/408059/2021*
B.6	Composition of the Paediatric Committee – Joint PDCO/CHMP membership	For information EMA/MB/64247/2022, Ref. Ares(2017)446809 - 27/01/2017, EMA/64249/2022
B.7	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/64550/2022, EMA/64551/2022
B.8	Update on Accelerating Clinical Trials in the EU (ACT EU)	Oral report
B.9	Update on implementation of Veterinary Medicinal Products Regulation	Oral report
B.10	12th Annual Veterinary MUMS/limited market Report	For information, EMA/MB/52895/2022; For endorsement, EMA/573681/2021*
B.11	Big Data Steering Group progress report	Oral report

B.12	OPEN Pilot: one-year review and recommendations	For information, EMA/MB/113300/2022; For endorsement, EMA/6881/2022
B.13	Agile transformation progress update	For information, EMA/MB/126686/2022
B.14	Stakeholder engagement biennial report: engaging with patients, consumers, healthcare professionals and academia	For information, EMA/MB/138446/2022, EMA/562976/2021*
C	**Points for information only****	
C.1	Report on EU Telematics	For information EMA/MB/116589/2022 EMA/116590/2022
C.2	Feedback from the Heads of Medicines Agencies	
C.3	2021 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission Reporting period: 1 January to 31 December 2021	For information, EMA/MB/93986/2022, EMA/719862/2021*
C.4	13th six-monthly report on ex ante and retroactive evaluation of projects for the period 1 July to 31 December 2021	For information, EMA/MB/60814/2022, EMA/60815/2022
C.5	Preparation for written procedure on opinion on the Agency annual accounts for the financial year 2021	For information, EMA/MB/34530/2022
C.6	Outcome of written procedures finalised during the period from 25 November 2021 to 18 February 2022	EMA/MB/149565/2022*
C.7	Summary of transfers of appropriations in budget 2021 and 2022	For information, EMA/MB/58837/2022*
C.8	EMA working document on buildings 2022	For information, EMA/MB/61235/2022, EMA/61223/2022

* 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.