



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2022
EMA/MB/792353/2022 Noted
Management Board meeting of 06 October 2022

Outcome of written procedures finalised during the period from 08 June 2022 to 29 September 2022

Issues for consideration

This document is presented in accordance with Article 4 (5) of the Management Board rules of procedure regarding the outcome of the written procedures.

During the period from 08 June 2022 to 26 September 2022, the Board was consulted 10 times via written procedure, of which 4 consultations concerned membership in the CHMP and CVMP, and 6 additional consultations, as listed below:

- Consultation no 06/2022 on the appointment of Nadya Ognyanova Vladimirova as CVMP member as proposed by Bulgaria ended on 24 June 2022. The mandate of the nominee commenced on 25 June 2022.
- Consultation no 07/2022 on the appointment of Alexandra Branchu as CHMP alternate as proposed by Luxembourg ended on 16 August 2022. The mandate of the nominee commenced on 17 August 2022.
- Consultation no 08/2022 on the appointment of Hjalti Kristinsson as CHMP alternate as proposed by Iceland ended on 24 August 2022. The mandate of the nominee commenced on 25 August 2022.
- Consultation no 09/2022 on the appointment of Finbarr Leacy as CHMP alternate as proposed by Ireland ended on 27 September 2022. The mandate of the nominee commenced on 28 September 2022.
- Consultation procedure for the adoption of the minutes of the 115th Management Board meeting, held on 14 June 2022. The procedure was adopted.
- Consultation procedure for the endorsement of the Protocol selection and Terms of Reference for Product Owners and Subject Matters Experts ended on 15 June 2022. The procedure was endorsed.
- Consultation procedure for the endorsement of "Joint Controllership Arrangement for the EudraVigilance Human (EV)" ended on 29 June 2022. The procedure was endorsed.
- Consultation procedure for the adoption of the Agency's final accounts for the financial year 2021 ended on 27 June 2022. The procedure was adopted.



- Consultation procedure for the adoption of Revision of Fee Implementing Rules VRA veterinary medicines, including annexes ended on 20 July 2022. The procedure was adopted.
- Consultation procedure for the adoption of the Amending Budget 01/2022 (AB01-22) ended on 19 August 2022. The procedure was adopted.
- Consultation procedure for adoption of the ETF composition for the COVID-19 and monkeypox PHE ended on 30 August 2022. The procedure was adopted.

In accordance with the Board's decision of 18 March 2010 relating to the *Procedure for the consultation of the Management Board on new appointments of CHMP and CVMP members and alternates* (EMA/MB/353835/Rev.2), the Board shall be provided with a periodic overview of renewed memberships in the CHMP and CVMP. Renewed memberships also include those memberships where the member has been re-nominated as an alternate or *vice versa*:

Country	Name	Membership ¹	Committee
Croatia	Frane Božić	Member	CVMP
Croatia	Selma Arapović Džakula	Alternate	CHMP
Czechia	Tomas Radimersky	Alternate	CHMP
France	Jean-Michel Race	Alternate	CHMP
Malta	John Joseph Borg	Member	CHMP
Malta	Helen Vella	Alternate	CHMP
Netherlands	Paula Boudewina van Hennik	Alternate	CHMP
Netherlands	Johann Lodewijk Hillege	Member	CHMP
Romania	Dana Gabriela Marin	Alternate	CHMP
Spain	Sol Ruiz	Co-opted member ²	CHMP

Action requested of the Board

NOTE the presented cover note:

EMA/MB/792353/2022

Additional background

The document is intended for publication on the Agency's external website.

¹ Membership referred in this column is the membership that was indicated in the nominating correspondence.

² Co-opted members are appointed by the CHMP based on required areas of scientific expertise, following a call for nominations