



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2024
EMA/CHMP/352892/2023 rev.7 corr.1

Timetable for the procedure

Referral under Article 20 of Regulation (EC) No 726/2004

Procedure no: EMEA/H/C/003687/A20/0065

Mysimba

Procedural step	Date
Notification:	01 September 2023
Start of the procedure (CHMP ¹):	14 September 2023
List of questions ² :	30 May 2024
Submission of responses:	18 October 2024
Re-start of the procedure:	14 November 2024
Rapporteur/co-rapporteur assessment reports circulated to CHMP:	21 November 2024
Comments:	28 November 2024
Updated rapporteur/co-rapporteur assessment reports circulated to CHMP:	04 December 2024
CHMP list of outstanding issues:	12 December 2024
Submission of responses:	06 February 2025

¹ Committee for Medicinal Products for Human Use

² At the May 2024 CHMP meeting, a new Rapporteur was appointed and the procedure was reset to day 1. This entailed that the procedural steps that had taken place between 14 September 2023 and 30 May 2024 were annulled.

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Procedural step	Date
Re-start of the procedure:	27 February 2025
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	06 March 2025
Comments:	13 March 2025
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	19 March 2025
CHMP list of outstanding issues or CHMP opinion:	March CHMP