EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2025
EMA/CHMP/348132/2024 rev.6

Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004

Oxbryta

Procedure no: EMEA/H/A-20/1538/C/004869/0014

Procedural step	**Date**
Notification:	26 July 2024
Start of the procedure (CHMP[1]):	29 July 2024
List of questions:	29 July 2024
Submission of responses:	12 September 2024
CHMP Opinion on temporary measures:	26 September 2024
Submission of completed responses:	22 October 2024
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	19 November 2024
Comments:	26 November 2024
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	02 December 2024
CHMP list of outstanding issues:	12 December 2024
Submission of responses:	14 March 2025
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	24 April 2025

[1] Committee for Medicinal Products for Human Use

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Procedural step	**Date**
Comments:	05 May 2025
Updated Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	12 May 2025
CHMP second list of outstanding issues:	22 May 2025
Submission of responses:	15 July 2025
Rapporteurs' joint assessment report circulated to CHMP:	25 August 2025
Ad-hoc expert group meeting (AHEG):	02 September 2025
Comments:	04 September 2025
Updated Rapporteurs' joint assessment report circulated to CHMP:	10 September 2025
CHMP third list of outstanding issues and CHMP request for PRAC[2] advice:	September, 2025 CHMP
PRAC advice to CHMP:	03 October 2025
Rapporteurs' joint assessment report circulated to CHMP:	07 October 2025
Comments:	09 October 2025
Updated Rapporteurs' joint assessment report circulated to CHMP:	10 October 2025
CHMP list of outstanding issues or CHMP opinion:	October, 2025 CHMP

[2] Pharmacovigilance Risk Assessment Committee