25 April 2024
EMA/CHMP/448947/2023 Rev. 4

Timetable for the procedure

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

Ocaliva

Procedure no: EMEA/H/A-20/1531/C/004093/0045

Procedural step	**Date**
Notification:	12 October 2023
Start of the procedure (CHMP[1]):	October 2023 CHMP
List of questions:	12 October 2023
Submission of responses:	01 December 2023
Re-start of the procedure:	26 December 2023
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	05 January 2024
Comments:	11 January 2024
Updated rapporteur/co-rapporteur assessment reports circulated to CHMP:	17 January 2024
CHMP list of outstanding issues:	25 January 2024

[1] Committee for Medicinal Products for Human Use

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Procedural step	**Date**
Submission of responses:	07 March 2024
Re-start of the procedure:	28 March 2024
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	04 April 2024
Comments:	11 April 2024
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	17 April 2024
CHMP list of outstanding issues:	25 April 2024
Submission of responses:	28 May 2024
Re-start of the procedure:	30 May 2024
Ad-hoc expert group meeting (AHEG):	TBD
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	11 June 2024
Comments:	17 June 2024
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	19 June 2024
CHMP opinion:	June 2024 CHMP