



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 June 2023
EMA/PRAC/702489/2022 rev.4

Timetable for the procedure

Referral under Article 31 of Directive 2001/83/EC resulting from
pharmacovigilance data

Topiramate-containing medicinal products

Procedure no: EMEA/H/A-31/1520

Procedural step:	Date
Notification:	22 August 2022
Start of the procedure (PRAC):	September 2022 PRAC
List of questions:	01 September 2022
Submission of responses:	12 October 2022
Re-start of the procedure:	03 November 2022
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	11 November 2022
Comments:	18 November 2022
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	23 November 2022
PRAC list of outstanding issues:	01 December 2022
Submission of responses:	23 January 2023
Re-start of the procedure:	16 February 2023

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Procedural step:	Date
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	21 February 2023
Scientific Advisory Group on Neurology (SAG-N) meeting:	01 March 2023
Comments:	03 March 2023
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	09 March 2023
PRAC Second list of outstanding issues:	16 March 2023
Submission of responses:	19 April 2023
Re-start of the procedure:	11 May 2023
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	17 May 2023
Comments:	25 May 2023
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	01 June 2023
PRAC list of outstanding issues:	08 June 2023
Submission of responses:	10 July 2023
Re-start of the procedure:	03 August 2023
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	11 August 2023
Comments:	18 August 2023
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	23 August 2023
PRAC recommendation to CMDh:	September, 2023 PRAC (31 August 2023)