



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/PRAC/154221/2017 rev 3

Timetable for the procedure

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

Medicinal products containing substances related to valproate

Procedure no: EMEA/H/A-31/1454

Procedural step:	Date
Notification:	08 March 2017
Start of the procedure (PRAC):	March 2017 PRAC
List of questions:	09 March 2017
Submission of responses:	24 April 2017
Re-start of the procedure:	12 May 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	22 May 2017
Member states comments:	30 May 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	02 June 2017
PRAC list of outstanding issues or PRAC recommendation to CMDh:	June 2017 PRAC
Submission of responses:	25 August 2017

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Re-start of the procedure:	11 September 2017
Public Hearing	26 September 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ² :	06 October 2017
SAG Psychiatry	12 October 2017
SAG Neurology	12 October 2017
Stakeholders meeting	13 October 2017
QRD group consultation	19 October 2017
Member states comments:	06 November 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	20 November 2017
PRAC list of outstanding issues	30 November 2017
Submission of responses:	28 December 2017
Re-start of the procedure:	11 January 2018
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	22 January 2018
Comments:	26 January 2018
Updated joint assessment report(s) circulated to PRAC and to CMDh:	01 February 2018
PRAC recommendation to CMDh:	February 2018 PRAC

² Coordination Group for Mutual Recognition & Decentralised Procedures - Human