



09 June 2017
EMA/PRAC/154221/2017 Rev. 1

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 CMDh2:	06 October 2017
SAG Psychiatry/Neurology	<i>To be confirmed</i>
Stakeholders meeting	<i>To be confirmed</i>
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 or PRAC recommendation to CMDh:	December 2017 PRAC (27-30 November 2017)

² Coordination Group for Mutual Recognition & Decentralised Procedures - Human