



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 July 2014  
EMA/PRAC/606970/2013 Rev.2

## Timetable for the procedure

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

Substances related to valproate  
Procedure no: EMEA/H/A-31/1387

Procedural step:	Date
Notification:	07 October 2013
Start of the procedure (PRAC):	October 2013 PRAC
List of questions:	10 October 2013
Submission of responses:	03 February 2014
Re-start of the procedure:	10 February 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>1</sup> :	02 March 2014
Comments:	16 March 2014
Updated rapporteur/co- rapporteur assessment reports circulated to PRAC and to CMDh:	27 March 2014
PRAC list of outstanding issues:	10 April 2014

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<sup>1</sup> Coordination Group for Mutual Recognition & Decentralised Procedures - Human



<b>Procedural step:</b>	<b>Date</b>
Submission of responses:	30 May 2014
Re-start of the procedure:	11 June 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	26 June 2014
Comments:	1 July 2014
Updated rapporteur and co-rapporteur's assessment reports circulated to PRAC and to CMDh:	4 July 2014
PRAC list of outstanding issues	10 July 2014
Submission of responses:	20 August 2014
Re-start of the procedure:	10 September 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	19 September 2014
Comments:	24 September 2014
Updated rapporteur and co-rapporteur's assessment reports circulated to PRAC and to CMDh:	1 October 2014
Neurology Scientific Advisory Group meeting	3 October 2014
PRAC list of outstanding issues or PRAC recommendation to CMDh:	October 2014 PRAC