



11 April 2013
EMA/PRAC/184919/2013

Timetable for the procedure

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

Codeine containing medicinal products used for pain in children

Procedure no: EMEA/H/A-31/1342

Procedural step:	Date
Notification:	03 October 2012
Start of the procedure (Pharmacovigilance Risk Assessment Committee (PRAC)):	October 2012 PRAC
List of Questions (LoQ):	03 October 2012
Amended notification:	22 October 2012
Submission of responses:	07 January 2013
Re-start of the procedure:	11 February 2013
Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	04 March 2013
Comments:	18 March 2013

¹ Co-ordination Group for Mutual Recognition & Decentralised Procedures - Human



Updated Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	28 March 2013
PRAC List of Outstanding Issues (LoOI):	11 April 2013
Submission of responses:	02 May 2013
Re-start of the procedure:	13 May 2013
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh ¹ :	22 May 2013
Comments:	29 May 2013
Updated Rapporteur/ co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	3 June 2013
PRAC recommendation:	June 2013 PRAC