



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2015
EMA/PRAC/180087/2014 Rev.2

Timetable for the procedure

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

Codeine containing medicinal products and for the treatment of cough and/or cold in paediatric patients

Procedure no: EMEA/H/A-31/1394

Procedural step:	Date
Notification:	02 April 2014
Start of the procedure (PRAC):	April, 2014 PRAC
List of questions:	10 April 2014
Submission of responses:	14 August 2014
Re-start of the procedure:	08 September 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	8 October 2014
Comments:	17 October 2014
Rapporteur/co-rapporteur updated assessment report(s) circulated to PRAC and to CMDh:	23 October 2014
PRAC list of outstanding issues:	November, 2014 PRAC
Submission of responses:	8 December 2014
Submission of responses from HCPOs ² :	6 January 2015

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human

² Healthcare Professionals' Organisations



Procedural step:	Date
Re-start of the procedure:	12 January 2015
Rapporteur/co-rapporteur assessment report circulated to PRAC and to CMDh:	23 January 2015
Comments:	30 January 2015
PRAC list of outstanding issues:	12 February 2015
Submission of responses:	24 February 2015
Re-start of the procedure:	27 February 2015
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	4 March 2015
Comments:	6 March 2015
PRAC recommendation:	March, 2015 PRAC