



12 March 2015  
EMA/PRAC/332908/2014 Rev.2

## Timetable for the procedure

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

Ibuprofen and dexibuprofen containing medicinal products (systemic formulations)

Procedure no: EMEA/H/A-31/1401

<b>Procedural step:</b>	<b>Date</b>
Notification:	09 June 2014
Start of the procedure (PRAC):	June 2014 PRAC
List of questions:	13 June 2014
Submission of responses:	29 September 2014
Re-start of the procedure:	06 October 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>1</sup> :	14 November 2014
Comments:	21 November 2014
PRAC list of outstanding issues:	04 December 2014
Submission of responses to LoOI:	20 January 2015
Re-start of the procedure:	09 February 2015

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



<b>Procedural step:</b>	<b>Date</b>
Joint assessment report circulated to PRAC and to CMDh:	17 February 2015
Comments:	27 February 2015
PRAC list of outstanding issues:	12 March 2015
Submission of responses to LoOI2:	20 March 2015
Re-start of the procedure:	26 March 2015
Joint assessment report circulated to PRAC and to CMDh:	30 March 2015
Comments:	01 April 2015
PRAC list of outstanding issues/PRAC recommendation to CMDh:	April 2015 PRAC