



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 December 2014  
EMA/PRAC/189079/2014 rev3

## Timetable for the procedure

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

Ambroxol and bromhexine-containing medicinal products

Procedure no: EMEA/H/A-31/1397

Procedural step:	Date
Notification:	04 April 2014
Start of the procedure (PRAC):	April 2014 PRAC
List of questions:	10 April 2014
Submission of responses:	23 June 2014
Re-start of the procedure:	14 July 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh <sup>1</sup> :	03 August 2014
Comments:	17 August 2014
PRAC list of outstanding issues:	September, 2014 PRAC
Submission of responses to LoOI:	20 October 2014
Re-start of the procedure:	10 November 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	17 November 2014

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



<b>Procedural step:</b>	<b>Date</b>
Comments:	24 November 2014
PRAC second list of outstanding issues:	December, 2014 PRAC
Submission of responses to second LoOI:	11 December 2014
Re-start of the procedure:	15 December 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	18 December 2014
Comments:	23 December 2015
PRAC list of outstanding issues/PRAC recommendation to CMDh:	January, 2015 PRAC