



6 November 2014  
EMA/PRAC/261903/2014 Rev.1

## Timetable for the procedure

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

Hydroxyzine-containing medicinal products

Procedure no: EMEA/H/A-31/1400

<b>Procedural step:</b>	<b>Date</b>
Notification:	25 April 2014
Start of the procedure:	May 2014 PRAC
List of questions:	8 May 2014
Submission of responses:	19 August 2014
Re-start of the procedure:	8 September 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC:	8 October 2014
Comments:	17 October 2014
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC:	23 October 2014
PRAC discussion/PRAC list of outstanding issues:	November 2014 PRAC
Submission of responses:	2 January 2015
Re-start of the procedure:	15 January 2015



<b>Procedural step:</b>	<b>Date</b>
Rapporteur/co-rapporteur joint assessment report circulated to PRAC:	27 January 2015
Comments:	2 February 2015
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC:	5 February 2015
PRAC discussion/ PRAC recommendation:	February 2015 PRAC