



5 December 2013  
EMA/PRAC/418739/2013 Rev1

## Timetable for the procedure

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

Zolpidem containing medicinal products

Procedure no: EMEA/H/A-31/1377

Procedural step:	Date
Notification:	04 July 2013
Start of the procedure (PRAC):	July 2013 PRAC
List of questions:	11 July 2013
Submission of responses:	30 September 2013
Re-start of the procedure:	7 October 2013
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>1</sup> :	31 October 2013
Comments:	15 November 2013
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	21 November 2013
PRAC list of outstanding issues	5 December 2013
Submission of responses:	27 January 2014

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



Re-start of the procedure:	3 February 2014
Joint Rapporteur and co-rapporteur's assessment report circulated to PRAC and to CMDh :	19 February 2014
Comments:	24 February 2014
Updated Joint Rapporteur and Co-rapporteur's assessment report circulated to PRAC and to CMDh:	27 February 2014
PRAC list of outstanding issues or PRAC recommendation to CMDh:	March 2014 PRAC