

11 April 2013 EMA/PRAC/209863/2013

Timetable for the procedure

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

Almitrine containing medicinal products Procedure no: EMEA/H/A-31/1346

Procedural step:	Date
Notification:	27 November 2012
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Start of the procedure (PRAC):	December 2012 PRAC (held on 26-29 November
	2012)
List of questions:	29 November 2012
Submission of responses:	04 February 2013
Re-start of the procedure:	11 February 2013
Rapporteur/co-rapporteur assessment report(s)	03 March 2013
circulated to PRAC and to CMDh ¹ :	
Comments:	17 March 2013
PRAC list of outstanding issues for oral	April 2013 PRAC
explanation:	
Oral Explanation:	May 2013 PRAC
PRAC recommendation to CMDh:	



¹ Co-ordination Group for Mutual Recognition & Decentralised Procedures - Human