



20 August 2014
EMA/PRAC/493206/2013 rev.2/corr.1

Timetable for the procedure

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

Oral bromocriptine-containing medicinal products
Procedure no: EMEA/H/A-31/1379

Procedural step:	Date
Notification:	17 July 2013
Start of the procedure (PRAC):	September 2013 PRAC
List of questions:	05 September 2013
Submission of responses:	19 December 2013
Re-start of the procedure:	06 January 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	26 January 2014
Comments:	15 February 2014
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	20 February 2014
PRAC list of outstanding issues:	March 2014 PRAC
Submission of responses:	25 April 2014
Re-start of the procedure:	12 May 2014

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	26 May 2014
Comments:	02 June 2014
Second PRAC list of outstanding issues	June 2014 PRAC
Submission of responses:	23 June 2014
Re-start of the procedure:	25 June 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	1 July 2014
Comments:	3 July 2014
PRAC recommendation to CMDh:	July 2014 PRAC