



15 January 2014
EMA/PRAC/747322/2012 Rev.4

Timetable for the procedure

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

Diacerein-containing medicinal products

Procedure no: EMEA/H/A-31/1349

Procedural step:	Date
Notification:	22 November 2012
Start of the procedure (PRAC):	December 2012 PRAC (26-29 November 2012)
List of questions:	29 November 2012
Submission of responses:	02 May 2013
Re-start of the procedure:	13 May 2013
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	02 June 2013
Comments:	23 June 2013
Updated Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	27 June 2013
PRAC list of outstanding issues	July 2013 PRAC
Submission of responses:	27 August 2013

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



Procedural step:	Date
Rapporteur / Co-Rapporteurs' assessment reports circulated to PRAC and to CMDh:	22 October 2013
Comments from PRAC members:	28 October 2013
Oral explanation(s) /PRAC recommendation:	November 2013 PRAC
Re-examination - receipt of letter of intent from MAH by:	19 November 2013
Re-examination - Receipt of detailed grounds from MAHs:	14 January 2014
Re-examination - Start of re-examination procedure:	15 January 2014
Re-examination - Rapporteur assessment report and Co-rapporteur assessment report circulated to PRAC and to CMDh:	14 February 2014
Re-examination - PRAC members' comments on revised JAR	24 February 2014
Re-examination – Updated rapporteur assessment report and Updated co-rapporteur assessment report circulated to PRAC and to CMDh: :	27 February 2014
Re-examination - Oral explanation/PRAC final recommendation to CMDh:	March 2014 PRAC meeting