



16 May 2013
EMA/PRAC/264325/2013

Timetable for the procedure

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

Diclofenac containing medicinal products

Procedure no: EMEA/H/A-31/1344

Notification:	17 October 2012
Start of the procedure (Pharmacovigilance Risk Assessment Committee (PRAC)):	November 2012 PRAC
List of Questions (LoQ):	31 October 2012
Submission of responses:	07 January 2013
Re-start of the procedure:	11 February 2013
Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	08 April 2013
Comments:	22 April 2013
Updated Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	02 May 2013
PRAC List of Outstanding Issues (LoOI)	16 May PRAC
Submission of responses in writing:	27 May 2013
Rapporteur/Co-rapporteur joint assessment report circulated to PRAC and to CMDh:	03 June 2013
Comments:	05 June 2013
Re-start of the procedure:	11 June 2013
Oral explanation / PRAC recommendation to CMDh:	June 2013 PRAC

