



10 October 2013
EMA/PRAC/138312/2013rev2

Timetable for the procedure

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

Substances related to nicotinic acid (acipimox)

Procedure no: EMEA/H/A-31/1366

Procedural step:	Date
Notification:	27 February 2013
Start of the procedure (PRAC):	March 2013 PRAC
List of questions:	07 March 2013
Submission of responses:	02 May 2013
Re-start of the procedure:	13 May 2013
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	10 June 2013
Comments:	23 June 2013
Updated Rapporteur and Co-rapporteur assessment reports circulated to PRAC and to CMDh:	27 June 2013
PRAC list of outstanding issues:	July 2013 PRAC
Submission of responses:	02 September 2013
Re-start of the procedure:	10 September 2013

¹Committee for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Expert meeting:	06 September 2013
Joint rapporteur assessment report circulated to PRAC and to CMDh:	23 September 2013
Comments:	30 September 2013
Second PRAC list of outstanding issues:	October 2013 PRAC
Submission of responses:	18 October 2013
Re-start of the procedure:	21 October 2013
Joint rapporteur assessment report circulated to PRAC and to CMDh:	28 October 2013
Comments:	01 November 2013
PRAC recommendation:	November 2013 PRAC