



11 July 2013
EMA/PRAC/744203/2012 –Rev 2

Timetable for the procedure

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

Short Acting Beta Agonists (SABAs) (INNs: terbutaline, salbutamol, hexoprenaline, ritodrine, fenoterol, isoxsuprine) containing medicinal products authorised in obstetric indication(s)

Procedure no: EMEA/H/A-31/1347

Procedural step:	Date
Notification:	27 November 2012
Start of the procedure (PRAC):	December 2012 PRAC (26-29 November 2012)
List of questions:	29 November 2012
Submission of responses:	11 March 2013
Re-start of the procedure:	18 March 2013
Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	24 April 2013
Comments:	30 April 2013
PRAC list of outstanding issues	May 2013 PRAC meeting (13-16 May 2013)
Submission of responses:	03 June 2013
Re-start of the procedure:	10 June 2013

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



Procedural step:	Date
Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	24 June 2013
Comments	01 July 2013
Oral Explanations / PRAC recommendation to CMDh:	September 2013 PRAC