



06 March 2014
EMA/PRAC/290691/2013 rev3

Timetable for the procedure

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

Renin-angiotensin system (RAS)-acting agents

Procedure no: EMEA/HA/31/1370

Procedural step:	Date
Notification:	17 April 2013
Start of the procedure (PRAC):	May 2013 PRAC
List of questions:	16 May 2013
Submission of responses:	02 September 2013
Re-start of the procedure:	09 September 2013
Co-rapporteur assessment reports circulated to Overall Rapporteur:	17 October 2013
Overall Rapporteur assessment report circulated to PRAC and to CHMP:	24 October 2013
Comments:	29 October 2013
PRAC list of outstanding issues:	November 2013 PRAC
Submission of responses:	10 January 2014
Re-start of the procedure:	07 February 2014
Co-rapporteur assessment reports circulated to Overall Rapporteur:	10 February 2014



Procedural step:	Date
SAG meeting:	11 February 2014
Overall Rapporteur assessment report circulated to PRAC and to CHMP:	20 February 2014
Comments:	25 February 2014
PRAC second list of outstanding issue / Oral explanation:	March 2014 PRAC
Submission of responses:	17 March 2014
Re-start of the procedure:	18 March 2014
Rapporteur joint assessment report circulated to PRAC:	26 March 2014
Comments:	31 March 2014
PRAC recommendation:	April 2014 PRAC