



06 November 2015
EMA/PRAC/290163/2015 rev. 2

Timetable for the procedure

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

Inhaled corticosteroids containing medicinal products indicated in the treatment of chronic obstructive
pulmonary disease

Procedure no: EMEA/H/A-31/1415

Procedural step:	Date
Notification:	27 April 2015
Start of the procedure (PRAC):	May 2015 PRAC
List of questions:	07 May 2015
Submission of responses:	27 August 2015
Re-start of the procedure:	10 September 2015
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP ¹ :	20 October 2015
Comments:	27 October 2015
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	30 October 2015
PRAC list of outstanding issues:	November 2015 PRAC

¹ Committee for Medicinal Products for Human Use



Procedural step:	Date
Submission of responses:	08 January 2016
Re-start of the procedure:	14 January 2016
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	02 March 2016
Comments:	09 March 2016
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	11 March 2016
PRAC list of outstanding issues or PRAC recommendation:	March 2016 PRAC