09 June 2016
EMA/PRAC/196144/2016 Rev. 1

Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

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Procedure no: EMEA/H/A-20/1439/C/3843/0023

Procedural step:	**Date**
Notification:	11 March 2016
Start of the procedure (PRAC):	March 2016 PRAC
List of questions:	17 March 2016
Submission of responses:	07 April 2016
Re-start of the procedure:	13 April 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	09 May 2016
Comments:	16 May 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	01 June 2016
PRAC list of outstanding issues:	June 2016 PRAC
Submission of responses:	15 June 2016
Re-start of the procedure:	20 June 2016

[1] Committee for Medicinal Products for Human Use

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Procedural step:	**Date**
Rapporteur/co-rapporteur joint assessment reports circulated to PRAC and to CHMP:	24 June 2016
Comments:	29 June 2016
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	01 July 2016
PRAC recommendation to CHMP:	July 2016 PRAC