EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/PRAC/791197/2017 Rev. 2

Timetable for the procedure

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

Esmya

Procedure number: EMEA/H/A-20/1460/C/2041/0043

Procedural step	**Date**
Notification:	30 November 2017
Start of the procedure (PRAC):	December 2017 PRAC (27-30 November 2017)
List of questions:	30 November 2017
Submission of responses:	12 January 2018
Re-start of the procedure:	08 February 2018
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	21 February 2018
Comments:	27 February 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	01 March 2018
PRAC list of outstanding issues (LoOI):	08 March 2018
Submission of responses:	02 April 2018
Re-start of the procedure:	16 April 2018

[1] Committee for Medicinal Products for Human Use

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Procedural step	Date
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[2]	30 April 2018
Ad-hoc experts meeting:	03 May 2018
Comments:	07 May 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	09 May 2018
PRAC recommendation to CHMP	May 2018 PRAC (14-17 May 2018)

[2] Committee for Medicinal Products for Human Use