



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 January 2020  
EMA/PRAC/484544/2019 Rev.1

## Timetable for the procedure

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

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Procedure number: EMEA/H/A-20/1489/C/2275/0030

Procedural step:	Date
Notification:	3 September 2019
Start of the procedure (PRAC):	September 2019 PRAC
List of questions:	5 September 2019
Submission of responses:	14 November 2019
Re-start of the procedure:	10 December 2019
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP <sup>1</sup> :	13 December 2019
Comments:	20 December 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	7 January 2020
PRAC list of outstanding issues:	16 January 2020

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<sup>1</sup> Committee for Medicinal Products for Human Use



<b>Procedural step:</b>	<b>Date</b>
Submission of responses:	24 February 2020
Re-start of the procedure:	20 March 2020
Joint assessment report circulated to PRAC and to CHMP	24 March 2020
Comments:	01 April 2020
Updated joint assessment report circulated to PRAC and to CHMP	06 April 2020
PRAC list of outstanding issues or PRAC recommendation to CHMP	April 2020 PRAC