05 September 2019
EMA/PRAC/269913/2019 – Rev. 1

Timetable for the procedure

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

Xeljanz

EMEA/H/A-20/1485/C/4214/0017

Procedural step:	**Date**
Notification:	15 May 2019
Start of the procedure (PRAC):	May 2019 PRAC
List of questions:	20 May 2019
Submission of responses:	20 June 2019
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	16 August 2019
Comments:	23 August 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	29 August 2019
PRAC list of outstanding issues	05 September 2019
Submission of responses:	25 September 2019
Ad-hoc Expert Group meeting	10 October 2019

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Joint assessment report circulated to PRAC and CHMP	17 October 2019
Comments:	22 October 2019
Updated joint assessment report circulated to PRAC and CHMP	25 October 2019
PRAC recommendation to CHMP	31 October 2019