01 September 2017
EMA/PRAC/366037/2017 Rev. 1

Timetable for the procedure

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

Zinbryta

Procedure number: EMEA/H/A-20/1456/C/003862/0010

Procedural step:	**Date**
Notification:	09 June 2017
Start of the procedure (PRAC):	June, 2017 PRAC
Lists of questions:	09 June 2017
Submission of responses:	20 June 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	26 June 2017
PRAC discussion:	July, 2017 PRAC
Submission of additional responses:	03 July 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	16 August 2017
Comments:	22 August 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	25 August 2017
PRAC list of outstanding issues (LoOI):	September, 2017 PRAC

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Procedural step:	**Date**
Submission of responses:	19 September 2017
Clock restart:	28 September 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	11 October 2017
Scientific Advisory Group:	12 October 2017
Comments:	16 October 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	19 October 2017
PRAC Recommendation:	November, 2017 PRAC