

10 July 2014 EMA/PRAC/746118/2013 Rev.2

Timetable of procedure

Review under Article 20 of Regulation (EC) No 726/2004

Iclusig (ponatinib)

Procedure no: EMEA/H/C/002695/A-20/0003

Notification:	27 November 2013
Start of procedure (PRAC):	05 December 2013
List of questions:	05 December 2013
Submission of responses:	3 March 2014
Re-start of the procedure:	10 March 2014
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	07 April 2014
Comments:	22 April 2014
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	28 April 2014
Adoption of List of outstanding issues	08 May 2014
Submission of responses:	06 June 2014
Joint Rapporteurs' assessment report circulated to PRAC and to CHMP:	24 June 2014
Comments:	01 July 2014
Updated Joint Rapporteurs' assessment report circulated to PRAC and to CHMP:	04 July 2014
Adoption of List of outstanding issues	10 July 2014



Submission of responses:	4 August 2014
Joint Rapporteurs' assessment report circulated to PRAC and to CHMP:	3 September 2014
Scientific Advisory Group meeting:	10 September 2014
Comments:	19 September 2014
Updated Joint Rapporteurs' assessment report circulated to PRAC and to CHMP:	26 September 2014
Adoption of List of outstanding issues / PRAC recommendation to CHMP:	October 2014 PRAC