



14 January 2016
EMA/PRAC/293314/2015 rev4

Timetable for the procedure

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

Tysabri EMEA/H/A-20/1416/C/000603/0083

Procedural step:	Date
Notification:	29 April 2015
Start of the procedure (PRAC):	May 2015 PRAC
List of questions:	07 May 2015
Submission of responses:	30 July 2015
Re-start of the procedure:	13 August 2015
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP ¹ :	26 August 2015
Comments:	02 September 2015
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	04 September 2015
PRAC list of outstanding issues or PRAC recommendation to CHMP:	10 September 2015
Submission of responses:	9 October 2015
Re-start of the procedure:	12 October 2015

¹ Committee for Medicinal Products for Human Use



Procedural step:	Date
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	31 October 2015
Scientific Advisory Group meeting:	06 November 2015
Comments:	20 November 2015
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	26 November 2015
PRAC list of outstanding issues or PRAC recommendation to CHMP:	December 2015 PRAC
Submission of responses:	10 December 2015
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	15 December 2015
Submission of additional responses:	18 December 2015
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	04 January 2016
Comments:	06 January 2016
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	07 January 2016
PRAC list of outstanding issues or PRAC recommendation to CHMP:	14 January 2016
Submission of responses:	22 January 2016
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	29 January 2016
Comments:	03 February 2016
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	05 February 2016
PRAC list of outstanding issues or PRAC recommendation to CHMP:	February 2016 PRAC