3 October 2019
EMA/PRAC/218954/2019 rev.2

Timetable for the procedure

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

Lemtrada

Procedure number: EMEA/H/A-20/1483/C/3718/0028

Procedural step:	**Date**
Notification:	10 April 2019
Start of the procedure (PRAC):	April, 2019 PRAC
List of questions:	11 April 2019
Submission of responses:	23 May 2019
Re-start of the procedure:	13 June 2019
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	21 June 2019
Comments:	28 June 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	4 July 2019
PRAC list of outstanding issues:	July, 2019 PRAC
Submission of responses:	5 August 2019

[1] Committee for Medicinal Products for Human Use

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Procedural step:	**Date**
Re-start of the procedure:	7 August 2019
Rapporteur / co-rapporteur joint assessment report circulated to PRAC and to CHMP:	30 August 2019
Scientific Advisory Group meeting	5 September 2019
Comments:	13 September 2019
Updated rapporteur / co-rapporteur joint assessment report circulated to PRAC and to CHMP:	20 September 2019
2nd PRAC list of outstanding issues:	October, 2019 PRAC
Submission of responses:	9 October 2019
Re-start of the procedure:	14 October 2019
Rapporteur / co-rapporteur joint assessment report circulated to PRAC and to CHMP:	18 October 2019
Comments:	23 October 2019
Updated rapporteur / co-rapporteur joint assessment report circulated to PRAC and to CHMP:	25 October 2019
PRAC recommendation to CHMP:	November, 2019 PRAC