



12 March 2020
EMA/PRAC/317693/2019 Rev 2

Timetable for the procedure

Referral under Article 31 of Directive 2001/83/EC resulting from
pharmacovigilance data

Leuprorelin-containing depot medicinal products

Procedure no: EMEA/H/A-31/1486

Procedural step:	Date
Notification:	07 June 2019
Start of the procedure (PRAC):	14 June 2019
List of questions:	14 June 2019
Submission of responses:	12 September 2019
Re-start of the procedure:	03 October 2019
Rapporteur/co-rapporteur assessment reports circulated to PRAC:	11 October 2019
Comments:	18 October 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC:	24 October 2019
PRAC list of outstanding issues	31 October 2019
Submission of responses:	23 January 2020
Re-start of the procedure:	13 February 2020
Joint assessment report(s) circulated to PRAC:	21 February 2020

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

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Procedural step:	Date
Comments:	28 February 2020
Updated joint assessment report(s) circulated to PRAC:	05 March 2020
PRAC list of outstanding issues:	12 March 2020
Submission of responses:	03 April 2020
Re-start of the procedure:	20 April 2020
Joint assessment report(s) circulated to PRAC:	27 April 2020
Comments:	01 May 2020
Updated joint assessment report(s) circulated to PRAC:	06 May 2020
PRAC list of outstanding issues or PRAC recommendation to CMDh:	May 2020 PRAC