



12 December 2019
EMA/PRAC/214200/2019 rev2

Timetable for the procedure

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

Estradiol-containing (0.01% w/w) medicinal products for topical use

Procedure no: EMEA/H/A-31/1482

Procedural step:	Date
Notification:	4 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 CMDh ¹ :	21 June 2019
Comments:	28 June 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	4 July 2019
PRAC list of outstanding issues:	11 July 2019
Submission of responses:	15 August 2019
Re-start of the procedure:	5 September 2019

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ² :	13 September 2019
Ad-hoc expert group meeting:	17 September 2019
Comments:	20 September 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	26 September 2019
PRAC PRAC recommendation to CMDh:	October 2019 PRAC
Re-examination - Receipt of letter of intent from MAH:	23 October 2019
Re-examination - Receipt of detailed grounds from MAH:	9 December 2019
Re-examination - Start of re-examination procedure:	10 December 2019
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	6 January 2020
Re-examination - Comments:	8 January 2020
Re-examination - Joint Assessment Report:	10 January 2020
Re-examination - Oral explanation/PRAC final recommendation:	PRAC January 2020

² Coordination Group for Mutual Recognition & Decentralised Procedures - Human