



11 July 2019  
EMA/PRAC/214200/2019 rev1

## 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

<b>Procedural step:</b>	<b>Date</b>
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 <sup>1</sup> :	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

<sup>1</sup> Coordination Group for Mutual Recognition & Decentralised Procedures - Human



<b>Procedural step:</b>	<b>Date</b>
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>2</sup> :	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 list of outstanding issues or PRAC recommendation to CMDh:	October 2019 PRAC

---

<sup>2</sup> Coordination Group for Mutual Recognition & Decentralised Procedures - Human