



08 February 2024
EMA/PRAC/194263/2023 rev.3

Timetable for the procedure

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

Hydroxyprogesterone-containing medicinal products

Procedure no: EMEA/H/A-31/1528

Procedural step:	Date:
Notification:	05 May 2023
Start of the procedure (PRAC):	May 2023 PRAC
List of questions:	12 May 2023
Submission of responses:	03 August 2023
Re-start of the procedure:	31 August 2023
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	08 September 2023
Comments:	15 September 2023
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	21 September 2023
PRAC list of outstanding issues:	28 September 2023
Submission of responses:	21 December 2023

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date:
Re-start of the procedure:	11 January 2024
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	18 January 2024
Ad-hoc expert group meeting (AHEG):	22 January 2024
Comments:	25 January 2024
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	31 January 2024
PRAC list of outstanding issues:	February 2024 PRAC
Submission of responses:	27 March 2024
Re-start of the procedure:	18 April 2024
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	22 April 2024
Comments:	30 April 2024
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	06 May 2024
PRAC list of outstanding issues or PRAC recommendation to CMDh:	May 2024 PRAC