



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2019
EMA/PRAC/371761/2019 Rev 1

Timetable for the procedure

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

Cyproterone-containing medicinal products

Procedure no: EMEA/H/A-31/1488

Procedural step:	Date
Notification:	02 July 2019
Start of the procedure (PRAC):	July 2019 PRAC
List of questions:	11 July 2019
Submission of responses:	12 September 2019
Re-start of the procedure:	03 October 2019
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	11 October 2019
Comments:	18 October 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	24 October 2019
PRAC list of outstanding issues:	31 October 2019
Submission of responses:	26 December 2019
Re-start of the procedure:	16 January 2020

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human

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Procedural step:	Date
Joint assessment report(s) circulated to PRAC and to CMDh:	24 January 2020
Comments:	31 January 2020
Updated joint assessment report(s) circulated to PRAC and to CMDh	06 February 2020
PRAC list of outstanding issues: or PRAC recommendation to CMDh	February 2020 PRAC