

13 February 2025
EMA/PRAC/414468/2024 rev1

Timetable for the procedure

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

Finasteride- and dutasteride-containing medicinal products

Procedure no: EMEA/H/A-31/1539

Procedural step:	Date:
Notification:	13 September 2024
Start of the procedure (PRAC ¹):	October 2024 PRAC
List of questions:	03 October 2024
Submission of responses:	10 December 2024
Re-start of the procedure:	02 January 2025
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ² :	23 January 2025
Comments:	30 January 2025
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	05 February 2025
PRAC list of outstanding issues:	February 2025 PRAC
Submission of responses:	13 March 2025
Re-start of the procedure:	03 April 2025

¹ Pharmacovigilance Risk Assessment Committee

² Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date:
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	14 April 2025
Comments:	22 April 2025
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	29 April 2025
PRAC list of outstanding issues or PRAC recommendation to CMDh:	May 2025 PRAC