



10 July 2014
EMA/PRAC/178709/2014 Rev.1

Timetable for the procedure

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

Testosterone containing medicinal products

Procedure no: EMEA/H/A-31/1396

Procedural step:	Date
Notification:	27 March 2014
Start of the procedure (PRAC):	April, 2014 PRAC
List of questions:	10 April 2014
Submission of responses:	20 May 2014
Re-start of the procedure:	9 June 2014
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	20 June 2014
Comments:	27 June 2014
PRAC list of outstanding issues:	10 July 2014
Submission of responses:	1 September 2014
Re-start of the procedure:	9 September 2014

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	25 September 2014
Comments:	1 October 2014
PRAC list of outstanding issues or PRAC recommendation to CMDh:	October 2014