



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 February 2013
Patient Health Protection
EMA/PRAC/69142/2013 – rev 1

Timetable for the procedure

Procedure under Article 107i of Directive 2001/83/EC

Cyproterone acetate/ethinylestradiol (2mg/0.035mg) containing medicinal products

Procedure no: EMEA/H/A-107i/1357

Procedural step:	Date
Notification:	04 February 2013
Start of the procedure (PRAC):	February 2013 PRAC
List of questions:	08 February 2013
Submission of responses:	11 March 2013
Start of assessment:	18 March 2013
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ :	05 April 2013
First PRAC discussion:	April 2013 PRAC (8 – 11 April 2013)
Comments:	21 April 2013
<i>Ad-hoc</i> expert meeting:	26 April 2013
Updated rapporteur/co-rapporteur/joint assessment report(s):	02 May 2013
Oral explanation/PRAC recommendation to CMDh:	May 2013 PRAC

¹ Co-ordination Group for Mutual Recognition & Decentralised Procedures - Human

