Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final report for the medicinal product(s) containing the active substance cyproterone/ethinylestradiol and concerned by the PASS final report , the scientific conclusions are as follows:

The joint survey drug utilisation final study report submitted by the MAHs, together with the joint database drug utilisation final study report submitted by the MAHs as a separate procedure (EMEA/H/N/PSR/J/0003), complies with their obligation to conduct a drug utilisation study to characterise prescribing practices for the medicinal product during typical and clinical use in representative groups of prescribers and to assess the main reason for prescription as imposed during the Article 107i procedure EMA/H/A-107i/1357 for cyproterone/ethinylestradiol containing products.

Therefore, in view of available data regarding the joint survey drug utilisation final study report, together with the joint database drug utilisation final study report submitted as a separate procedure (EMEA/H/N/PSR/J/0003), the PRAC considered that changes to the conditions of the marketing authorisation were warranted.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for the results of the study for the medicinal product(s) containing the active substance cyproterone/ethinylestradiol and concerned by the PASS final report , the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) mentioned above is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of the products concerned by this PASS final report should be varied.

Annex II

Conditions to the Marketing Authorisation(s)

Changes to be made to the conditions of the marketing authorisation(s) of medicinal product(s) containing the active substance cyproterone / ethinylestradiol concerned by the non-interventional imposed PASS final report

The marketing authorisation holder(s) shall remove the following condition(s) (new text **underlined and in bold,** deleted text ~~strike through~~)

~~The MAH(s) should provide within the risk management plan submission, a protocol for the drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription. Final study report by:~~	~~31 July 2015~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of the position

Adoption of CMDh position:	December 2016 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 January 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	29 March 2017