Editor's note: This English translation was done by a third party. The original report can be accessed here.

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 on the PSUR(s) for finasteride, the scientific conclusions are as follows:

Based on the reported cases of anxiety related to the treatment with finasteride 1 mg indicated for male pattern hair loss (MPHL) and finasteride 5 mg indicated for benign prostate hyperplasia, and also taking into account that a high prevalence of anxiety in patients with MPHL has been confirmed, the PRAC considered that the adverse drug reaction anxiety should be included in section 4.8 of the summary of product characteristics of all finasteride containing products with a frequency not known. The package leaflet is updated accordingly.

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 finasteride the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing finasteride is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing finasteride are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~).

Summary of Product Characteristics

- Section 4.8

[The following adverse reaction should be added under the SOC Psychiatric disorders with a frequency "not known"]

Anxiety

Package Leaflet

- Section 4: Possible side effects

[The following text should be added as follows]

Frequency unknown

[…]

Anxiety

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	9 June 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	8 August 2018