

## **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:

The PRAC noted that during the current interval two serious cases, one reporting suicidal behaviour and one reporting suicidal ideation, have been received for finasteride 5 mg. Cumulatively 51 cases of suicidal ideation have been received according to the information in the summary tabulation of adverse drug reactions from post-marketing sources. Taking into account the serious reported cases and that depression is already included in section 4.8 of the summary of product characteristics (SmPC) of finasteride 5 mg, the PRAC recommended to include a warning in section 4.4 of the SmPC to inform about that mood alterations, depression and suicidal ideation have been reported with finasteride. In addition, an advice to monitor patients and to remind them to seek medical advice should they develop psychiatric symptoms should also be included.

The CMDh also noted the PRAC advice already given on the above in a work-sharing variation for finasteride 1 mg for the treatment of male pattern hair loss. PRAC considered that changes to sections 4.4 and 4.8 of the SmPC were warranted. MAHs of medicinal products containing 1 mg of finasteride indicated for the treatment of male pattern hair loss should align the product information of their products with this information within an appropriate regulatory procedure.

The CMDh agrees with the scientific conclusions made by the PRAC. As regards the 1mg strength as well, however, the CMDh considers that this change should be part of this single assessment procedure.

## **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 of finasteride 5 mg**  
(new text **underlined and in bold**, deleted text ~~strike through~~)

### Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

#### **Mood alterations and depression**

**Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.**

### Package Leaflet

Section 2

Warnings and precautions

#### **Mood alterations and depression**

**Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with <product name>. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.**

**Amendments to be included in the relevant sections of the Product Information of finasteride 1 mg**  
(new text **underlined and in bold**, deleted text ~~strike through~~)

### Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

**“Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice.”**

- Section 4.8

The adverse reaction(s) “~~depressed mood~~” should be replaced with “**depression**” added under the SOC psychiatric disorders with a frequency uncommon.

### Package leaflet:

Section 2

Warnings and precautions

**Mood alterations and depression**

**Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with <product name>. If you experience any of these symptoms stop taking <product name> and contact your doctor for further medical advice as soon as possible.**

Section 4

The adverse reaction(s) “~~depressed mood~~” should be replaced with “**depression**” with a frequency uncommon.

**Annex III**

**Timetable for the implementation of this position**

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Adoption of CMDh position:	April 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	04 June 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	03 August 2017