Ord, Kathryn

From: uk-h.pharmacovigilance
Sent: 10 June 2019 20:26
To: #UK PRAC Delegates; #VRMM Benefit Risk Management Group; #VRMM_Post-Authorisation Signal Unit
Cc: Branch, Sarah; [redacted] Morgan, Sarah; [redacted] Raine, Dr June
Subject: FW: PRAC: Draft#1 of the April 2019 minutes for your review by: Wedn 12/06/2019, 4pm CET
Attachments: Draft#1 Minutes of PRAC meeting on 8-11 April 2019.doc

Sensitivity: Confidential

Dear all,

Please see attached the draft minutes of the April PRAC 2019.

Thanks,
[redacted]

From: PRAC secretariat <PRACsecretariat@ema.europa.eu>
Sent: 10 June 2019 16:10
Subject: PRAC: Draft#1 of the April 2019 minutes for your review by: Wedn 12/06/2019, 4pm CET
Sensitivity: Confidential

CONFIDENTIAL

Dear all

With some important delays, please find attached **draft#1** of the **minutes** of the **April 2019 PRAC** meeting.

We would be grateful if you could review them and kindly circulate your comments in track-changes to All Human Pharmacovigilance [redacted] by **Wednesday 12 June 2019, 4pm CET**.

Please include your comments in the latest commented version circulated. This helps us, PRAC Secretariat, to consolidate draft#2 that will be tabled for adoption before the end of the plenary meeting.

FYI - The **May 2019 PRAC minutes** will be circulated tomorrow/Wednesday – and also due for adoption at this week's PRAC.

Thanks in advance.

Kind regards
PRAC Secretariat

PRAC Secretariat
Scientific Committees Support

European Medicines Agency
[redacted] 6 | 1083 HS Amsterdam | The Netherlands
PRACsecretariat @ema.europa.eu | www.ema.europa.eu

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2019
EMA/PRAC/322778/2019 **CONFIDENTIAL**
Inspections, Human Medicines Pharmacovigilance and Committees Division
Yellow marked text = CONFIDENTIAL – will not appear on the website, will be deleted before publication

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft#1 Minutes of the meeting on 08 – 11 April 2019

Chair: Sabine Straus – Vice-Chair: Martin Huber

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in the minutes is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scope listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also change during the course of the review. Additional details on some of these procedures will be published in the PRAC meeting highlights once the procedures are finalised.

Of note, the minutes are a working document primarily designed for PRAC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006, Rev. 1).

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15.3.7. [redacted]

16.1.1. [redacted]

[redacted]

6.3.1. Finasteride (NAP) - PSUSA/00001392/201808

Applicant(s): various

PRAC Lead: [redacted]

EMA resources: RMS: [redacted]

Scope: Evaluation of a PSUSA procedure

Background

Finasteride is an inhibitor of type II 5 alfa reductase indicated, in the 5 mg strength, for the treatment of treatment of benign prostatic hyperplasia and for prevention of urologic events

to reduce the risk of acute urinary retention as well as to reduce the risk of surgery. It is also indicated, in the 1 mg strength, for the treatment of male pattern hair loss.

Based on the assessment of the PSUR(s), the PRAC reviewed the benefit-risk balance of nationally authorised medicine(s) containing finasteride and issued a recommendation on their marketing authorisation(s).

Summary of recommendation(s) and conclusions

- Based on the review of the data on safety and efficacy, the benefit-risk balance of finasteride-containing medicinal products in the approved indication(s) remains unchanged.
- The current terms of the marketing authorisation(s) should be maintained.
- In the next PSUR, MAHs should closely monitor the persistence of psychiatric events after discontinuation of finasteride together with a discussion on biological plausibility of these events, possible risk factors for persistence of these events. In addition, the MAHs should closely monitor cases of suicide and self-injury taking into account medical history and concurrent medical condition and risk factors, muscle-related events and rhabdomyolysis. Finally, the MAHs should conduct a thorough literature search[42] and present a discussion of the findings.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC. The requirement to submit PSUR(s) for products referred to in Articles 10(1), 10a, 16a of Directive 2001/83/EC does not apply any longer. The EURD list is updated accordingly.

[redacted]

[42]Including: Lee et al. Adverse sexual effects of treatment with finasteride or dutasteride for male androgenetic alopecia: a systematic review and meta-analysis. Acta Dermato-Venereologica. 2019; 99: 12-17
Baas et al. A Review of the FEARS data on 5-alpha reductase inhibitors: implication for post finasteride syndrome. Urology. 2018; 120:143-149
Fertig et al. Sexual side effects of 5-α-reductase inhibitors finasteride and dutasteride: a comprehensive review. Dermatol Online J. 2017; 23(11)