EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): secukinumab

Procedure No. EMEA/H/C/PSUSA/00010341/201606

Period covered by the PSUR: 26 December 2015 to 25 June 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for secukinumab, the scientific conclusions of CHMP are as follows:

Taking into account cases of candidiasis and candida infections reported with secukinumab from clinical trials, spontaneous reporting and postmarketing surveillance, including a number of serious cases, cases with positive de-challenge and one case of positive re-challenge, the term mucosal and cutaneous candidiasis is added to the list of adverse drug reactions with frequency not known. Taking into account that oesophageal candidiasis was considered serious in nearly half of the reported cases, that it represents more than 10% of the reported candidiasis and that it usually requires systemic treatment while oral candidiasis will receive local treatment, reference to oesophageal candidiasis should be specifically included in order to highlight the specific reaction.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing secukinumab were warranted.

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

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.