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/00010341/201712

Period covered by the PSUR: 26 December 2016 – 25 December 2017

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Scientific conclusions

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

The review of the current evidence identified several cases reporting exacerbations and “de novo” cases for inflammatory bowel disease, Crohn’s disease and ulcerative colitis. Furthermore, the available extensive literature supports the fact that a potential role of secukinumab cannot be fully excluded based on the mechanism of action, an inhibitor of IL-17. The Product Information should be updated to include a broader medical concept such as “Inflammatory bowel disease (Crohn’s disease and ulcerative colitis)”. With the evidence gathered so far, the inclusion of “de novo cases” in the warning is also warranted.

In addition, the review of the important identified risk of *infections and infestations* revealed that although the reporting of cases remain stable over PSUR periods, there is a cumulative number of 5,105 cases (30% serious, 1,594/5,105) reported for the safety concern of “*infections and infestations”*. Therefore, the SmPC section 4.4 should be updated to reflect that serious infections have already been reported in the post-marketing setting. A proposal to re-arrange the section (4.4) is also endorsed.

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.