19 September 2024
EMA/443964/2024
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/00010341/202312

Period covered by the PSUR: 26 December 2020 To: 25 December 2023

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Scientific conclusions

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

In view of available data on angioedema, eczema, and hepatitis B reactivation, from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between secukinumab and angioedema and eczema is at least a reasonable possibility and the causal relationship between secukinumab and hepatitis B reactivation cannot be ruled out. The PRAC concluded that the product information of products containing secukinumab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for secukinumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing secukinumab is unchanged subject to the proposed changes to the product information

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