16 September 2021
EMA/CHMP/684614/2021
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): ustekinumab

Procedure No. EMEA/H/C/PSUSA/00003085/202012

Period covered by the PSUR: from 01/01/2020 to 31/12/2020

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Scientific conclusions

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

In view of available data on opportunistic infections from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC Rapporteur concluded that the product information of products containing ustekinumab should be amended accordingly.

In view of available data on bullous pemphigoid from the literature and spontaneous reports including in some cases a close temporal relationship, positive de-challenge, and positive re-challenge, the PRAC Rapporteur considers a causal relationship between ustekinumab and bullous pemphigoid is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing ustekinumab should be amended accordingly.

In view of available data from the literature on excretion of ustekinumab in breastmilk, the PRAC Rapporteur concluded that the product information of products containing ustekinumab should be amended accordingly.

In view of available data on serious infusion related reactions from spontaneous reports, the PRAC Rapporteur concluded that the product information of products containing ustekinumab concentrate for solution for infusion should be amended accordingly.

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 ustekinumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ustekinumab 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.