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): ustekinumab

Procedure No. EMEA/H/C/PSUSA/00003085/201812

Period covered by the PSUR: 30 December 2017 – 30 December 2018

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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:

Organising pneumonia

The MAH was asked to provide a cumulative review of pulmonary fibrotic and remodelling events in the current PSUR. Considering the biological plausibility (ustekinumab already causes allergic alveolitis and eosinophilic pneumonia), the three cases suggestive of positive dechallenge and the incidence compared to the background rate, the PRAC concluded on a causal association between ustekinumab and organising pneumonia. The PRAC is also of the view that HCPs should be made aware that ustekinumab can cause organising pneumonia, as withdrawal of the drug could help to resolve the condition. Hence, an update to the SmPC is warranted in relation to organising pneumoniaas follows: update of section 4.4 of the SmPC to amend the warning on systemic and respiratory hypersensitivity reactions. Update of section 4.8 of the SmPC to add the adverse reaction organising pneumonia with a frequency very rare. The Package leaflet is updated 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.