EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2024
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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): mepolizumab

Procedure No. EMEA/H/C/PSUSA/00010456/202309

Period covered by the PSUR:
24/03/2023 To: 23/09/2023

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Scientific conclusions

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

In view of available data on herpes zoster and arthralgia from clinical trials, the literature and spontaneous cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between mepolizumab and herpes zoster and between mepolizumab and arthralgia is at least a reasonable possibility. The PRAC concluded that the product information of products containing mepolizumab 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(s)

On the basis of the scientific conclusions for mepolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mepolizumab 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.