EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 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): pegcetacoplan

Procedure No. EMEA/H/C/PSUSA/00010974/202311

Period covered by the PSUR:
14/05/2023 To: 13/11/2023

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Scientific conclusions

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

In view of available data on spontaneous reports including in some cases with a close temporal relationship and positive rechallenge, the PRAC Rapporteur considers, that a causal relationship between pegcetacoplan and urticaria is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing pegcetacoplan 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 pegcetacoplan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pegcetacoplan 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.