14 September 2023
EMA/531133/2023
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): relugolix

Procedure No. EMEA/H/C/PSUSA/00010994/202301

Period covered by the PSUR: 07 July 2022 To: 07 January 2023

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Scientific conclusions

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

In view of available data on urticaria and angioedema from spontaneous reports including cases with 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 relugolix and urticaria and angioedema is at least a reasonable possibility and concluded that the product information of products containing relugolix 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 relugolix the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing relugolix is unchanged subject to the proposed changes to the product information

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