Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for relugolix / estradiol / norethisterone acetate, the scientific conclusions of CHMP are as follows:

In view of available data on urticaria and angioedema from clinical trials and spontaneous reports including cases with 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 the combination relugolix/estradiol/norethisterone acetate and urticaria and angioedema is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing the combination relugolix/estradiol/norethisterone acetate 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 relugolix / estradiol / norethisterone acetate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing relugolix / estradiol / norethisterone acetate 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.