25 January 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): follitropin beta

Procedure No. EMEA/H/C/PSUSA/00001465/202305

Period covered by the PSUR:
01/05/2020 To: 01/05/2023

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Scientific conclusions

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

In view of available data on **anaphylactic reaction** from spontaneous reports, including cases with a close temporal association, the PRAC considers a causal relationship between follitropin beta and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing follitropin beta 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 follitropin beta the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing follitropin beta 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.