30 May 2024
EMA/354722/2024
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): toremifene

Procedure No. EMEA/H/C/PSUSA/00002999/202309

Period covered by the PSUR:
01/10/2020 To: 30/09/2023

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Scientific conclusions

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

In view of available data on hypertriglyceridaemia from the literature and spontaneous cases including some 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 toremifene and hypertriglyceridaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing torefemifene 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 toremifene the CHMP is of the opinion that the benefitrisk balance of the medicinal product(s) containing toremifene 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.