EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): toremifene

Procedure No. EMEA/H/C/PSUSA/00002999/201709

Period covered by the PSUR: 1 October 2014 to 30 September 2017

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Scientific conclusions

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

Cumulatively 18 cases reporting Adverse Drug Reactions (ADRs) of hepatic steatosis (16) and of non-alcoholic steatohepatitis (NASH) (2) with toremifene were identified by the MAH. Six of them were serious. Diagnosis of hepatic steatosis/NASH was supported by liver biopsy for 3 cases. Latency period (documented for 7 reports) varied from 4 months to 2 years. Confounding factors were present for 2 cases. Positive dechallenge was reported in four cases and in one of these cases also rechallenge was positive. Based on this review it is agreed to amend the ADR table in section 4.8 of Fareston EU SmPC to add the ADR hepatic steatosis, with frequency unknown. There is no need to update the package leaflet, considering that the ADR of hepatitis is already mentioned with "frequency not known".

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 toremifene the CHMP is of the opinion that the benefit-risk 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.