



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/691595/2019
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): ospemifene

Procedure No. EMEA/H/C/PSUSA/00010340/201902

Period covered by the PSUR: 25/02/2018 To: 25/02/2019



Scientific conclusions

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

Based on a review of data from clinical trials and post-marketing reporting, the PRAC considers that a causal relationship between ospemifene and the adverse reaction vaginal bleeding cannot be ruled out and therefore recommends an updated to section 4.8 of the SmPC. The PL is updated in accordance.

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 ospemifene the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ospemifene 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.