EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
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Committee for Medicinal Products for Human Use (CHMP)

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

Active substance(s): olanzapine

Procedure No. EMEA/H/C/PSUSA/00010540/201903

Period covered by the PSUR: 01 April 2016 to 31 March 2019

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Scientific conclusions

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

Following the review of case reports in the UK Sentinel database, the EudraVigilance database, and the literature, a signal for salivary hypersecretion with olanzapine was identified on 14 February 2019 by the Medicines and Healthcare products Regulatory Agency (MHRA) and validated by the PRAC.

Based on signal analysis presented by the MAH including mechanistic plausibility, number of dechallenge/rechallenge cases and strong temporal relationship, the PRAC agrees that salivary hypersecretion may be associated with olanzapine and the adverse reaction salivary hypersecretion should be added to the product information.

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