



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 April 2020  
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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): vortioxetine

Procedure No. EMEA/H/C/PSUSA/00010052/201909

Period covered by the PSUR: 29 September 2018 to 29 September 2019



## Scientific conclusions

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

In view of available data on **false positive immunoassay results for urine methadone** from the literature and spontaneous reports, the PRAC considers a causal relationship between vortioxetine and false positive results with certain urine enzyme immunoassays for methadone is possible. The PRAC concluded that the product information of products containing vortioxetine should be amended accordingly.

In view of available data on **insomnia** from spontaneous reports including in 99 cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between vortioxetine and insomnia is at least a reasonable possibility. The PRAC concluded that the product information of products containing vortioxetine should be amended accordingly.

In view of available data on **agitation and aggression** from spontaneous reports including in 351 events within the SMQ hostility / aggression 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 vortioxetine and aggression and agitation is at least a reasonable possibility. The PRAC concluded that the product information of products containing vortioxetine should be amended accordingly.

In view of available data on **glaucoma** from clinical trials, spontaneous reports including in 5 cases 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 vortioxetine and glaucoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing vortioxetine should be amended accordingly.

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