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): vortioxetine

Procedure No. EMEA/H/C/PSUSA/00010052/201809

Period covered by the PSUR: 29/09/2017 to 29/09/2018

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Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

- The review of a signal for anaphylactic reaction reported a total of 40 post-marketing cases, including seven where causality with vortioxetine treatment was considered possible. Most cases were a combination of airway and skin symptoms. In 1 case, anaphylactic shock was reported.

Based on the above, it was considered that anaphylactic reaction should be included as an adverse drug reaction in the product information of vortioxetine.

- Based upon the role of serotonin on haemostasis, the mechanism of action of vortioxetine and 63 post-marketing cases retrieved from a signal for haemorrhage with possible causality with vortioxetine, it was considered that haemorrhage should be included as an adverse drug reaction in the product information of vortioxetine. Additionally, the class warning on haemorrhage should be updated, to add that haemorrhage has been reported with vortioxetine as well.

- Based upon the review of a signal for rash, a plausible temporal relationship was concluded in several post-marketing cases reported (74% of reported time to onset was within one week and 93% was within one month), including cases with positive de- or re-challenge (respectively 135 and 8 cases). Consequently, it was concluded that rash should be included as an adverse drug reaction in the product information of vortioxetine.

The CHMP agrees with the scientific conclusions made by the PRAC.