EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Brintellix

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: vortioxetine

Procedure No. EMEA/H/C/002717/PSUV/0003

Period covered by the PSUR: 18 December 2013 – 29 March 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Brintellix, the scientific conclusions of PRAC are as follows:

During the reporting period, 9 cases of serotonin syndrome were received.

An analysis of these cases led to the conclusion that in a number of cases a causal role of vortioxetine could not be excluded (plausible temporal relationship, recovery upon discontinuation of vortioxetine).

Moreover, in a number of reported cases, the diagnosis of serotonin syndrome has been established by a physician and the event has been considered as possibly related by the reporter.

Furthermore, based on a “class effect”, serotonin syndrome is currently considered as a potential risk in the RMP and based on this Serotonin Syndrome is mentioned in section 4.4 of the SmPC.

Considering, the possibly related cases, the pharmacologic properties of vortioxetine and the SmPC guideline that states that any adverse reactions described in section 4.4 or known to result from conditions mentioned here should also be included in section 4.8, it the PRAC concluded that Serotonin Syndrome should be listed in section 4.8 of the SmPC with an unknown frequency.

Therefore, in view of available data regarding serotonin syndrome, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Brintellix, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance vortioxetine is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.