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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/00010052/201603

Period covered by the PSUR: 30 September 2015 to 29 March 2016

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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:

Based on an evaluation of causality from Individual Case Safety Reports (ICSRs) and on the plausible mechanism, the PRAC considered that a causal relationship between vortioxetine and hyponatremia is at least a reasonable possibility. In addition, hyponatraemia is a known risk for the majority of antidepressants (selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs)) and not mentioning hyponatraemia in the product information could give the erroneous impression that vortioxetine is a safer treatment than older antidepressants for patients at risk of hyponatraemia.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing vortioxetine were warranted.

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.