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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): aripiprazole

Procedure No. EMEA/H/C/PSUSA/00000234/201507

Period covered by the PSUR: 17 July 2014 – 16 July 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for aripiprazole, the scientific conclusions of the CHMP are as follows:

From the review of safety databases, clinical database and literature, most of the reports of hiccups were non-serious and resolved spontaneously without any intervention. Considering the number of case reports of hiccups with aripiprazole (primarily oral formulation), the time to onset of hiccups from the start of the aripiprazole therapy, several reports of positive dechallenge and of positive rechallenge, there appears to be some degree of causal association between aripiprazole exposure and hiccups. In addition, the disproportionality analyses scores in Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) and VigiBase databases suggests a potential association between aripiprazole and hiccups. The PRAC considered that the product information of aripiprazole should be updated to include the adverse event 'Hiccups" in section 4.8 of the SmPC, since a contributory role of aripiprazole in the reported cases could not be ruled out. The package leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSURs, the PRAC considered that changes to the product information of medicinal products containing aripiprazole 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 aripiprazole the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing aripiprazole is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.