EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: aripiprazole

Procedure No. EMEA/H/C/PSUSA/00000234/201407

Period covered by the PSUR: 17 July 2013 – 16 July 2014

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Scientific conclusions

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

A cumulative search of the MAH safety database up to 16 Jul 2014 was performed for all cases where aripiprazole was considered a suspect or interacting drug and at least one adverse event mapped the MedDRA Preferred Term 'Hypersexuality'. Eighty-five (85) cases were retrieved. In 25 cases, based on factors of temporality, dechallenge, and lack of confounders, the event of hypersexuality was likely due to aripiprazole therapy. Therefore based on the review of the cases, a contributory role of aripiprazole could not be ruled out. The product information for Abilify Maintena already reflects this risk, however the product information for Abilify does not and therefore needs to be updated to include 'hypersexuality' with a frequency ' uncommon'. The package leaflet for both products needs to be updated accordingly.

Therefore, in view of available data regarding aripiprazole, 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 aripiprazole the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing aripiprazole is favourable subject to the proposed changes to the product information

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