EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2020
EMA/261452/2020
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/00000234/201907

Period covered by the PSUR: 17 July 2018 to 16 July 2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

The cumulative review of post-marketing cases indicates there is an existence of potential association of aripiprazole and photophobia and the comparison of reference safety information documents, showed that photophobia is not a new ADR. Of the 97 post-marketing cases, in 33 cases (34%) a possible role of aripiprazole could not be excluded (this is based on temporal association, and improvement/recovery of symptoms either on discontinuation or dose reduction of aripiprazole), and there were 25 (26%) cases in which there was a positive dechallenge, and 2 cases with a rechallenge positive. Moreover, results of the medical safety review of Abilify and Abilify Maintena cases from the clinical trials indicated that the incidence rate for aripiprazole was 0.2% (52/28729) compared to placebo 0.0% (4/9234).

Of note, the CCDS for the originator product already mentions the ADR photophobia following administration of oral Abilify during clinical trials. Also, the US-SmPC includes photophobia.

The PRAC considers that Photophobia should be listed in SmPC section 4.8 of all aripiprazole containing products, with frequency "Uncommon", under SOC Eye disorders.

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 product(s) containing aripiprazole 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.