19 September 2013
EMA/489804/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

ABILIFY MAINTENA

aripiprazole

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product ABILIFY MAINTENA, 300 mg and 400 mg, powder and solvent for prolonged-release suspension for injection intended for the maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole. The applicant for this medicinal product is Otsuka Pharmaceutical Europe Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of ABILIFY MAINTENA is aripiprazole (as monohydrate), a psycholeptic antipsychotic, already authorised in the treatment of schizophrenia as oral and rapid intramuscular forms. The pharmacological properties of aripiprazole are mediated through a combination of partial agonism at dopamine D2 and serotonin 5-HT1A receptors and antagonism at serotonin 5-HT2A receptors.

The benefits with ABILIFY MAINTENA are its ability to reduce the proportion of stabilised patients experiencing relapse in long term use and its properties to act as long acting agent, allowing a monthly administration instead of a daily oral intake of aripiprazole. Patients are previously stabilised with oral aripiprazole.

The most common side effects are weight gain, akathisia (restlessness), insomnia (difficulty in sleeping) and injection site pain.

A pharmacovigilance plan for ABILIFY MAINTENA will be implemented as part of the marketing authorisation.

The approved indication is: "maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole."

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for ABILIFY MAINTENA and therefore recommends the granting of the marketing authorisation.