European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 27 July 2009
EMEA/483040/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
ABILIFY

International Nonproprietary Name (INN): ***aripiprazole***

On 27 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] via written procedure to recommend the variation to the terms of the marketing authorisation for the medicinal product Abilify. The Marketing Authorisation Holder for this medicinal product is Otsuka Pharmaceutical Europe Ltd.

The CHMP adopted a new indication as follows:

Treatment of schizophrenia in adolescents 15 years and older.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication(s) for Abilify will be as follows[***]:

ABILIFY is indicated for the treatment of schizophrenia in adults **and in adolescents 15 years and older.**
ABILIFY is indicated for the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment (see section 5.1).

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu