European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 April 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
ABILIFY

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

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Abilify 7.5 mg/ml solution for injection. The Marketing Authorisation Holder for this medicinal product is Otsuka Pharmaceutical Europe Ltd.

The CHMP adopted a new indication as follows:

"rapid control of agitation and disturbed behaviours in patients with manic episodes in Bipolar I Disorder, when oral therapy is not appropriate."

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 indications for Abilify 7.5 mg/ml solution for injection will be as follows***:
"ABILIFY solution for injection is indicated for the rapid control of agitation and disturbed behaviours in patients with schizophrenia **or in patients with manic episodes in Bipolar I Disorder**, when oral therapy is not appropriate."

* 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.

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