European Medicines Agency
*Press office*

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# PRESS RELEASE
## Otsuka Pharmaceutical Europe Ltd withdraws its application for an extension of indication for Abilify (aripiprazole)

The European Medicines Agency has been formally notified by Otsuka Pharmaceutical Europe Ltd of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Abilify (aripiprazole) tablets, orodispersible tablets and oral solution.

Abilify was expected to be used in the treatment of major depressive episodes, as adjunctive therapy, in patients who have had an inadequate response to previous treatment with antidepressants.

Abilify was first authorised in the European Union on 4 June 2004. It is currently indicated for the treatment of schizophrenia and for the treatment and prevention of manic episodes in bipolar I disorder.

The application for the extension of indication for Abilify was submitted to the Agency on 11 December 2008.

The company stated in its official letter that the withdrawal was based on the CHMP's consideration that the long-term data provided in support of the proposed indication were insufficient, as long-term randomised controlled data are needed before this indication can be licensed.

Abilify continues to be authorised for the currently approved indications.

More information about the withdrawal of Abilify will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website in due course.

--ENDS--

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about Abilify is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/abilify/abilify.htm
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu.

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