European Medicines Agency
*Press office*

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# PRESS RELEASE
## Janssen-Cilag International N.V. withdraws its application for an extension of indication for Invega (paliperidone)

The European Medicines Agency (EMEA) has been formally notified by Janssen-Cilag International N.V. of its decision to withdraw its application for an extension of indication for the centrally authorised medicine Invega (paliperidone) prolonged-release tablets.

Invega was expected to be used for the treatment of acute manic episodes associated with bipolar I disorder.

Invega was first authorised in the European Union on 25 June 2007. It is currently indicated for the treatment of schizophrenia.

The application for the extension of indication for Invega was submitted to the EMEA on 10 September 2008.

In its official letter, the company stated that the withdrawal was based on the feedback from the early evaluation indicating that the data provided were not sufficient to support approval for this indication and the company's view that it was not in a position to adequately address this issue at that time.

Invega continues to be authorised for the currently approved indication.

More information about Invega and the state of the scientific assessment at the time of the withdrawal 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 EMEA 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 Invega is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/humandocs/Humans/EPAR/invega/invega.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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