27 September 2010
EMA/CHMP/444944/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Invega

paliperidone

On 27 September 2010, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion via written procedure recommending a variation to the terms of the marketing authorisation for the medicinal product Invega. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"Treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated."

The CHMP concluded that the new therapeutic indication brings significant clinical benefit in the absence of existing therapies. The Committee therefore recommended that one additional year of marketing protection be granted, in accordance with the provisions of Article 14(11) of Regulation (EC) No 726/2004.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), 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 Invega will be as follows[2]:

INVEGA is indicated for the treatment of schizophrenia.

INVEGA is indicated for the treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated.

[1] 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.
[2] The text in bold represents the new or the amended indication.

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