



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 April 2014  
EMA/243851/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Invega paliperidone

On 25 April 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion 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:

INVEGA is indicated for the treatment of schizophrenia in adolescents 15 years and older.

For information, the full indication(s) for Invega will be as follows<sup>2</sup>:

INVEGA is indicated for the treatment of schizophrenia in adults **and in adolescents 15 years and older**.

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

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.

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<sup>1</sup> 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.

<sup>2</sup> The text in bold represents the new or the amended indication.

