



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 May 2013  
EMA/CHMP/320328/2013  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Lucentis

#### ranibizumab

On 30 May 2013, 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 Lucentis. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd. 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:

"The treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM)".

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 indication(s) for Lucentis will be as follows<sup>2</sup>:

Lucentis is indicated in adults for:

- The treatment of neovascular (wet) age-related macular degeneration (AMD)
- The treatment of visual impairment due to diabetic macular oedema (DME)
- The treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)
- **The treatment of visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM)**

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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.

