EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/284732/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Eylea

aflibercept

On 26 June 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 Eylea. The marketing authorisation holder for this medicinal product is Bayer Pharma AG. 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:
"visual impairment due to diabetic macular oedema (DME)".

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 Eylea will be as follows[2]:

Eylea is indicated for adults for the treatment of

- neovascular (wet) age-related macular degeneration (AMD) (see section 5.1).,
- visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO) (see section 5.1).,
- **visual impairment due to diabetic macular oedema (DME) (see section 5.1).**

[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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