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Press Office

Press release

Pfizer Limited withdraws its application for an extension of the indication for Macugen (pegaptanib sodium)

The European Medicines Agency has been formally notified by Pfizer Limited of its decision to withdraw its application for an extension of the therapeutic indication for the centrally authorised medicine Macugen (pegaptanib sodium), 0.3 mg solution for injection.

On 14 June 2010, Pfizer Limited submitted an application to extend the marketing authorisation for Macugen to include the treatment of visual impairment due to diabetic macular oedema in the indication. At the time of withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Macugen was first authorised in the European Union on 31 January 2006. It is currently authorised for treatment of neovascular (wet) age-related macular degeneration.

In its official letter, the company stated that its decision to withdraw the application was based on the CHMP's view that the data provided so far does not allow the Committee to conclude on a positive benefit-risk balance in the applied for indication.

Macugen continues to be authorised in the currently approved indication.

More information about Macugen and the state of the scientific assessment at the time of 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 Agency's website after the 18-21 July CHMP meeting.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.

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3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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