



European Medicines Agency
Press office

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PRESS RELEASE

Bausch & Lomb Ireland withdraws its marketing authorisation application for Retisert

The European Medicines Agency (EMA) has been formally notified by Bausch & Lomb Ireland of its decision to withdraw the application for a centralised marketing authorisation for the medicinal product Retisert (fluocinolone acetonide) 590 microgram Intravitreal Implant.

Retisert was expected to be used for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Retisert was designated as an orphan medicinal product on 7 March 2005.

The application for marketing authorisation for Retisert was submitted to the EMA on 8 September 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Retisert was based on the CHMP's request for additional information, to which the company was unable to respond within the permitted timeframe.

More information about Retisert 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 EMA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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