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Human Medicines Development and Evaluation

Public statement on

Filgrastim ratiopharm (filgrastim)

Withdrawal of the marketing authorisation in the European Union

On 15 September 2009 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Filgrastim ratiopharm (filgrastim) for the treatment of neutropenia. Filgrastim ratiopharm was a biological medicinal product and a biosimilar of the product Neupogen.

The marketing authorisation holder (MAH) for Filgrastim ratiopharm was ratiopharm GmbH. The European Commission was notified by a letter dated 24 March 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for Filgrastim ratiopharm.

Filgrastim ratiopharm was not marketed in any EU country.

On 20 April 2011 the European Commission issued a decision to withdraw the marketing authorisation for Filgrastim ratiopharm.

Pursuant to this decision the European Public Assessment Report for Filgrastim ratiopharm will be updated to reflect that the marketing authorisation is no longer valid.

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