13 July 2016

Public statement

Opgenra

Withdrawal of the marketing authorisation in the European Union

On 1 July 2016, the European Commission withdrew the marketing authorisation for Opgenra (eptotermin alfa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Olympus Biotech International Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Opgenra was granted marketing authorisation in the EU on 19 February 2009 for treatment of spondylolisthesis. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2013.

The European Public Assessment Report (EPAR) for Opgenra will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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