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Public statement

Ristempa

Withdrawal of the marketing authorisation in the European Union

On 28 September 2017 the European Commission withdrew the marketing authorisation for Ristempa (pegfilgrastim) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Amgen Europe B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Ristempa was granted marketing authorisation in the EU on 13 April 2015 for the treatment of neutropenia.

Ristempa was a duplicate application to Neulasta, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Neulasta.

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Report (EPAR) for Ristempa will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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