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Public statement

Insulin Human Winthrop

Withdrawal of the marketing authorisation in the European Union

On 11 January the European Commission withdrew the marketing authorisation for Insulin Human Winthrop (insulin human) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sanofi-Aventis Deutschland GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Insulin Human Winthrop was granted marketing authorisation in the EU on 17 January 2007 for treatment of diabetes mellitus. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2011.

Insulin Human Winthrop is an identical product to Insuman, which is authorised in the EU to treat diabetes mellitus. Insulin Human Winthrop was a duplicate application to Insuman, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Insuman.

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(EPAR) for Insulin Human Winthrop will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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