EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement on

Duloxetine Boehringer Ingelheim (duloxetine)

Withdrawal of the marketing authorisation in the European Union

On the 8th October 2008 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Duloxetine Boehringer Ingelheim, duloxetine, which had been approved for the treatment of diabetic peripheral neuropathic pain in adults.

The marketing authorisation holder (MAH) responsible for Duloxetine Boehringer Ingelheim was Boehringer Ingelheim International GmbH. The European Commission was notified by a letter dated 12 April 2010 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Duloxetine Boehringer Ingelheim for commercial reasons. Duloxetine Boehringer Ingelheim was not marketed in any European country.

On 26th May 2010 the European Commission issued a decision to withdraw the marketing authorisation for Duloxetine Boehringer Ingelheim. Pursuant to this decision the European Public Assessment Report for Duloxetine Boehringer Ingelheim will be updated to reflect that the marketing authorisation is no longer valid.

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