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Human Medicines Development and Evaluation

Public statement on Sepioglin

Withdrawal of the marketing authorisation in the European Union

On 9 March 2012, the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Sepioglin, (pioglitazone), which had been approved for treatment of type 2 diabetes mellitus.

The marketing authorisation holder (MAH) responsible for Sepioglin was Vaia S.A..

On 6 June 2013, the European Commission issued a decision to withdraw the marketing authorisation for Sepioglin, following its receipt of a letter dated 22 May 2013 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Sepioglin has not been marketed in any European country.

Pursuant to this decision, the European public assessment report for Sepioglin will be updated to reflect that the marketing authorisation is no longer valid.

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