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Committee for Medicinal Products for Human Use (CHMP)

Public statement

Avandia

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Avandia (ROSIGLITAZONE) expired on 11 July 2015 following the decision of the marketing authorisation holder, Smithkline Beecham Ltd., not to apply for a renewal of the marketing authorisation. The marketing authorisation for Avandia in the European Union (EU) was suspended at that time.

Avandia was granted marketing authorisation in the European Union (EU) on 11 July 2000 for treatment of type 2 diabetes mellitus treatment of type 2 diabetes mellitus treatment of type 2 diabetes mellitus treatment of type 2 diabetes mellitus.

The marketing authorisation was valid for a 5-year period. It was subsequently renewed for additional 5-year periods on 08 July 2005 and on 26 May 2009.

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Report (EPAR) for Avandia will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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