



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Public statement

Avandamet

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Avandamet (ROSIGLITAZONE / METFORMIN) expired on 20 October 2013 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 Avandamet in the European Union (EU) was suspended at that time.

Avandamet was granted marketing authorisation in the European Union (EU) on 20 October 2003 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 an additional 5-year period on 13 August 2008.

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Report (EPAR) for Avandamet will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

