European Medicines Agency

London 4 April 2005
EMEA/41035/2005

PUBLIC STATEMENT ON
VENVIA (rosiglitazone)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 11 July 2000 the European Commission granted a marketing authorisation for the whole European Union to SmithKline Beecham plc, for Venvia (rosiglitazone), indicated as oral monotherapy in type 2 diabetes mellitus patients, particularly overweight patients, inadequately controlled by diet and exercise for whom metformin is inappropriate because of contraindications or intolerance.
Rosiglitazone is also indicated for oral combination treatment in type 2 diabetes mellitus patients with insufficient glycaemic control despite maximal tolerated dose of oral monotherapy with either metformin or a sulphonylurea:

- in combination with metformin particularly in overweight patients.
- in combination with a sulphonylurea only in patients who show intolerance to metformin or for whom metformin is contraindicated.

Venvia was not marketed anywhere in the European Union. On 1 November 2004 the Marketing Authorisation Holder notified the European Commission of its decision to voluntarily withdraw the Marketing Authorisation for Venvia as there were no plans to market this product in the future. It should be noted that there is still one Community Marketing Authorisation valid throughout the European Union for rosiglitazone i.e. Avandia.

On 8 December 2004 the European Commission adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "Venvia". Pursuant to this decision the European Public Assessment Report for Venvia has been removed from the EMEA website.

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