AWTORITA'
DWAR IL-MEDIĊINI

Malta, 19 October 2007 Circular No. P15/2007

Dear Healthcare Professional,

Re: Benefit-Risk Profile of Avandia (rosiglitazone) and Actos (pioglitazone).

Following a review of the benefits and risks of the thiazolidinediones rosiglitazone (Avandia) and pioglitazone (Actos), as part of the continuous monitoring of the safety of medicines, the Committee for Medicinal Products for Human Use (CHMP) had concluded that the benefit risk balance of these medicinal products is **positive**. However, the CHMP has recommended changing the product information for rosiglitazone with regards to use in patients with ischaemic heart disease and use in combination with insulin. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the **press release** issued by the EMEA, attached here for your perusal.