Malta, 23 May 2007

Circular No. P06/2007

Re: Medicines Authority statement on recent publication on cardiac safety of rosiglitazone (Avandia, Avandamet, Avaglim).

On 21 May 2007, an article published in the New England Journal of Medicine (NEJM) "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes"[1] has raised concern about a small increased risk of myocardial infarction and cardiovascular death in patients with type 2 diabetes treated with rosiglitazone. The European Medicines Agency (EMEA) has issued the attached press release on the subject and reviewed the benefit/risk profile of this product. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is of the opinion that the advice provided in the attached press release on rosiglitazone issued by the EMEA is opportune and appropriate, and recommends prescribers to follow this advice when prescribing Avandia® , Avandamet®, Avaglim®. The Medicines Authority will notify health care providers and patients in a timely fashion as new information becomes available. Adverse Drug Reactions (ADRs) associated with this product should be reported to the Medicines Authority by filling an ADR Reporting Form. This can be accessed at:
http://www.medicinesauthority.gov.mt/pub/adr.doc

[1] The article 'Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes' (10.1056/NEJMoa072761) was published on the NEJM website (www.nejm.org) on 21 May 2007.

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