



European Medicines Agency
Press office

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**Please note that there is a press embargo until Wednesday
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PRESS RELEASE

EMA statement on recent publication on cardiac safety of rosiglitazone (Avandia, Avandamet, Avaglim)

An article published in the New England Journal of Medicine (NEJM) has raised concern about a small increased risk of myocardial infarction and cardiovascular death in patients with type 2 diabetes treated with rosiglitazone. The article, based on an analysis of data retrieved from 42 clinical studies, showed a small increased risk for myocardial infarction and cardiovascular death among approximately 15,500 patients treated with rosiglitazone. However, death from all causes was not significantly increased.

When rosiglitazone was first authorised in the EU in 2000, it was contraindicated in patients with a history of cardiac failure. Since then, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has kept rosiglitazone under close surveillance for cardiovascular effects (cardiac failure and other cardiac disorders including myocardial infarction). The majority of the studies included in the NEJM paper have already been assessed by the CHMP. The EU product information was updated in September 2006 with information about the risk of cardiac ischaemic events.

Some of the studies in the NEJM paper included patients who were not treated in line with the indication approved in the EU. Prescribers are reminded to adhere to the restrictions for use in patients with cardiac disease as set out in the product information.

Patients are advised not to stop treatment with rosiglitazone and to discuss the medication with their doctor at their next regular visit.

--ENDS--

NOTES

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.
2. The rosiglitazone-containing products Avandia (rosiglitazone maleate) Tablets, Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets, and Avaglim (rosiglitazone maleate and glimepiride) Tablets are centrally authorised products and indicated for treatment of type 2 diabetes mellitus as monotherapy or in combination with other oral antidiabetic drugs. Avandia was first authorised in the EU in July 2000; Avandamet in October 2003; Avaglim in June 2006.

3. The European Public Assessment Reports including the up-to-date product information are available on the EMEA website as follows:
Avandia: <http://www.emea.europa.eu/humandocs/Humans/EPAR/avandia/avandia.htm>
Avandamet: <http://www.emea.europa.eu/humandocs/Humans/EPAR/avandamet/avandamet.htm>
Avaglim: <http://www.emea.europa.eu/humandocs/Humans/EPAR/avaglim/avaglim.htm>

4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.europa.eu>

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