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Press Office

Press release

European Medicines Agency starts review of rosiglitazone-containing medicines

New studies question cardiovascular safety of anti-diabetes medicines

The European Medicines Agency has started a review of the rosiglitazone-containing anti-diabetes medicines Avandia, Avandamet and Avaglim, to determine whether new data on the risk of cardiovascular problems have an impact on their benefit-risk profile.

The review by the Agency's Committee for Medicinal Products for Human Use (CHMP) follows the recent publication of further studies on the cardiovascular safety of rosiglitazone.

Rosiglitazone on its own is authorised in the EU as Avandia, in combination with metformin as Avandamet and with glimepiride as Avaglim. At the time of their authorisation, these medicines were contra-indicated in patients with heart failure or a history of heart failure. Since then, the product information has been updated to include warnings and contra-indications on the use of these medicines in patients with heart problems.

In 2008, the CHMP concluded that on the basis of the available evidence and with the restrictions in place, rosiglitazone retained a small, if diminishing, place in diabetes type 2 therapy. The Committee is now assessing the new data and will be discussing the issue at its next plenary meeting of 19-22 July 2010. Once all relevant data on the benefits and the risks of rosiglitazone have been looked at, the CHMP will issue an opinion on whether or not the marketing authorisations for these medicines should be revoked, suspended or changed.

Notes

1. The European Public Assessment Reports (EPARs) with more information are available on the EMA website as follows:
   For Avandia: http://www.ema.europa.eu/humandocs/Humans/EPAR/avandia/avandia.htm
   For Avandamet:
   http://www.ema.europa.eu/humandocs/Humans/EPAR/avandamet/avandamet.htm
   For Avaglim: http://www.ema.europa.eu/humandocs/Humans/EPAR/avaglim/avaglim.htm

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2. A press release on the assessment of the benefits and risks of rosiglitazone and pioglitazone concluded in October 2007 is available on the Agency's website: http://www.ema.europa.eu/pdfs/human/press/pr/48427707en.pdf.
   A question-and-answer document with more information about the outcome of this assessment is also available: http://www.ema.europa.eu/pdfs/human/press/pr/48446407en.pdf.

3. The review of the marketing authorisations of Avandia, Avandamet and Avaglim was initiated on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, following the publication of two studies on 28 June 2010.
   References for the two studies are as follows:
   Graham DJ et al. Risk of acute myocardial infarction, stroke, heart failure, and death in elderly Medicare patients treated with rosiglitazone or pioglitazone. JAMA doi:10.1001/jama.2010.920.
   Nissen SE et al. Rosiglitazone revisited. An updated meta analysis of risk for myocardial infarction and cardiovascular mortality. Arch Intern Med doi:10.1001/archinternmed.2010.207.

4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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