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Press Office

Press release

European Medicines Agency update on ongoing benefit-risk review of Avandia, Avandamet and Avaglim

Doctors reminded to follow current restrictions for rosiglitazone-containing anti-diabetes medicines until further notice

The European Medicines Agency is currently reviewing rosiglitazone to determine the impact of new data from recent publications on the risk of cardiovascular problems on the benefit- risk profile of these medicines. Prescribers in the European Union are reminded to strictly follow the current restrictions in the product information.

Avandia (rosiglitazone) was initially authorised in the European Union in July 2000 as second-line diabetes type-2 treatment to be used when other treatments have either failed or are unsuitable for a patient. Avandia has been contra-indicated in patients with heart failure or a history of heart failure since its first authorisation. It was subsequently approved in combination with metformin as Avandamet and with glimepiride as Avaglim. Since then, the use of these medicines has been further restricted several times by new warnings and contra-indications on their use in patients with heart problems.

The current review of rosiglitazone was initiated on 9 July 2010 on the request of the European Commission following publication of studies questioning the cardiovascular safety of the medicine. At its 19-22 July meeting the Agency's Committee for Medicinal Products for Human Use (CHMP) held preliminary discussions, including with experts in diabetes, cardiovascular diseases and pharmacovigilance and with patients.

The Committee noted that additional new data sets have become available very recently. It will assess these data in depth together with all other available data on the benefits and risks of rosiglitazone to allow the finalisation of the current review by September 2010.

While the CHMP is reviewing all available evidence on rosiglitazone, prescribers in Europe are reminded to strictly follow the recommendations in the product information with respect to patients indicated for treatment, defined contraindications and warnings.

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Prior to initiation of new treatment and in the ongoing monitoring of patients, doctors should pay particular attention to the following:

- rosiglitazone must not be used in patients with current or previous heart failure and in patients with acute coronary syndrome;
- rosiglitazone and insulin should only be used together in exceptional cases and under close supervision.
- the use of rosiglitazone is not recommended in patients with ischaemic heart disease or peripheral arterial disease;

Patients who wish to have more information on the potential risks and benefits associated with their treatment may contact their doctor and should consult the package leaflet. Patients are advised not to stop their medication without consulting their doctor.

Notes

1. Avandia was first authorised in 2000, Avandamet in 2003 and Avaglim in 2006. A European Public Assessment Reports (EPARs) with more information is available on the EMA website: for Avandia; for Avandamet; for Avaglim.
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. A question-and-answer document with more information about the outcome of this assessment is also available.
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.
4. 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.
5. A press release published on the initiation of the review is available.
6. 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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