



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends suspension of Avandia, Avandamet and Avaglim

Anti-diabetes medication to be taken off the market

The European Medicines Agency today recommended the suspension of the marketing authorisations for the rosiglitazone-containing anti-diabetes medicines Avandia, Avandamet and Avaglim. These medicines will stop being available in Europe within the next few months.

Patients who are currently taking these medicines should make an appointment with their doctor to discuss suitable alternative treatments. Patients are advised not to stop their treatment without speaking to their doctor.

Doctors should stop prescribing rosiglitazone-containing medicines. Patients taking rosiglitazone-containing medicines should be reviewed in a timely manner to amend their treatment.

The current review of rosiglitazone by the Agency's Committee for Medicinal Products for Human Use (CHMP) was initiated on 9 July 2010 following the availability of new studies questioning the cardiovascular safety of the medicine.

Since its first authorisation, rosiglitazone has been recognised to be associated with fluid retention and increased risk of heart failure and its cardiovascular safety has always been kept under close review. Consequently, the use of rosiglitazone was restricted to a second-line treatment and contra-indicated in patients with heart failure or a history of heart failure when it was first granted a marketing authorisation as Avandia in 2000.

Data from clinical trials, observational studies and meta-analyses of existing studies that have become available over the last three years have suggested a possibly increased risk of ischaemic heart disease associated with the use of rosiglitazone. Further restrictions on the use of these medicines in patients with ischaemic heart disease were introduced.

The availability of recent studies has added to the knowledge about rosiglitazone and overall, the accumulated data support an increased cardiovascular risk of rosiglitazone. In view of the restrictions



already in place on the use of rosiglitazone, the Committee could not identify additional measures that would reduce the cardiovascular risk. The Committee therefore concluded that the benefits of rosiglitazone no longer outweigh its risks and recommended the suspension of the marketing authorisation of the medicines.

The suspension will remain in place unless the marketing authorisation holder can provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks.

The Committee's recommendation has now been forwarded to the European Commission for the adoption of a legally binding decision.

Notes

1. A [question-and-answer document](#) with more information is available on the EMA website.
2. Rosiglitazone was initially authorised as Avandia 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. It was subsequently approved in combination with metformin as Avandamet and with glimepiride as Avaglim.
3. More information about Avandia, Avandamet and Avaglim is available in the European Public Assessment Report (EPAR). For [Avandia](#), for [Avandamet](#) and for [Avaglim](#).
4. 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.
5. 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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