European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency confirms positive benefit-risk balance for rosiglitazone and pioglitazone

Finalising a review of the benefits and risks of the thiazolidinediones rosiglitazone (Avandia) and pioglitazone (Actos), the European Medicines Agency has concluded that the benefits of these antidiabetic medicines continue to outweigh their risks in the approved indications. However, the Agency recommended changing the product information for rosiglitazone and agreed further initiatives to increase scientific knowledge on the safety of both medicines.

The Agency's Committee for Medicinal Products for Human Use (CHMP) carried out this review as part of its continuous monitoring of the safety of medicines, because of new information on these medicines' side effects. This included information on the risk of bone fractures in women, and, in patients taking rosiglitazone, a possible risk of ischaemic heart disease (reduced blood supply to the heart muscle). This raised concerns over the benefit-risk balance of both rosiglitazone and pioglitazone.

Having assessed all available data, the CHMP concluded that the benefits of both rosiglitazone and pioglitazone in the treatment of type 2 diabetes continue to outweigh their risks. However, the prescribing information should be updated to include a warning that, in patients with ischaemic heart disease, rosiglitazone should only be used after careful evaluation of each patient's individual risk. In addition, the combination of rosiglitazone and insulin should only be used in exceptional cases and under close supervision.

These changes will be introduced in forthcoming regulatory procedures for rosiglitazone-containing medicines. No changes to the prescribing information for medicines containing pioglitazone were considered necessary.

The Committee will review the results of currently ongoing studies. It also recommended that further studies be performed in order to increase the level of scientific knowledge on the two medicines.

-- ENDS --

Notes:

1. More information is available in a question-and-answer document.
2. Rosiglitazone is available as Avandia (rosiglitazone maleate), Avandamet (rosiglitazone/metformin) and Avaglim (rosiglitazone maleate/glimepiride). Pioglitazone is available as Actos/Glustin (pioglitazone), Competact (pioglitazone/metformin hydrochloride) and Tandemact (pioglitazone/glimepiride). These are centrally authorised products, indicated for the treatment of type 2 diabetes mellitus as monotherapy or in combination with other oral antidiabetic medicines. 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;
   Actos: http://www.emea.europa.eu/humandocs/Humans/EPAR/actos/actos.htm;
   Glustin: http://www.emea.europa.eu/humandocs/Humans/EPAR/glustin/glustin.htm;

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Tandemact: http://www.emea.europa.eu/humandocs/Humans/EPAR/tandemact/tandemact.htm

3. A statement on the cardiovascular safety of Avandia was published in May 2007: http://www.emea.europa.eu/pdfs/general/direct/pr/23005707en.pdf
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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