European Medicines Agency
Press office

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PRESS RELEASE
EMEA recommends new warnings and contraindications for rosiglitazone

The European Medicines Agency (EMEA) has recommended updating the product information for rosiglitazone-containing antidiabetic medicines. Rosiglitazone is available in the European Union as Avandia (rosiglitazone maleate), Avandamet (rosiglitazone maleate/metformin) and Avaglim (rosiglitazone maleate/glimepiride).

During its January 2008 meeting, the Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a scientific opinion recommending the inclusion of a new warning stating that the use of rosiglitazone in patients with ischemic heart disease and/or peripheral arterial disease is not recommended.

The CHMP also adopted an opinion recommending the addition of a new contraindication stating that rosiglitazone must not be used in patients with an acute coronary syndrome, such as angina or some types of myocardial infarction, because the medicine has not been studied in controlled trials in this specific patient group.

The recommended changes to the product information have been made as a follow-up measure to the re-assessment of the benefits and risks of rosiglitazone and pioglitazone, another antidiabetic medicine. This re-assessment was finalised by the CHMP in October 2007, concluding that the benefits of both medicines continued to outweigh their risks in their approved indications, but that the product information for rosiglitazone should be changed.

Looking more globally at antidiabetic medicines and the cardiovascular risk associated with their use, the CHMP and its Efficacy Working Party are currently re-examining their existing 'Note for guidance on clinical investigation of medicinal products in the treatment of diabetes mellitus' to decide whether changes are needed. A concept paper, setting out the main points for revision, is expected to be released in February.

-- ENDS --

Notes:

1. Avandia, Avandamet and Avaglim 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 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;
2. A statement on the assessment of benefits and risks of rosiglitazone and pioglitazone concluded in October 2007 is available here:
   http://www.emea.europa.eu/pdfs/human/press/pr/48427707en.pdf
   A question-and-answer document with more information about the outcome of this assessment is available here:
   http://www.emea.europa.eu/pdfs/human/press/pr/48446407en.pdf

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3. A summary of opinion with the exact wording of the new contraindication is available here: http://www.emea.europa.eu/htms/human/opinion/opinion.htm
4. The 'Note for guidance on clinical investigation of medicinal products in the treatment of diabetes mellitus'is available here: http://www.emea.europa.eu/pdfs/human/ewp/108000en.pdf
5. 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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