European Medicines Agency
Post authorisation Evaluation of Medicines for Human Use

London, 24 January 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
AVAGLIM

International Nonproprietary Name (INN): ***rosiglitazone / glimepiride***

On 24 January 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Avaglim. The Marketing Authorisation Holder for this medicinal product is SmithKline Beecham Plc.

The CHMP adopted a new contraindication as follows:
"an Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI) (see section 4.4))"

The CHMP adopted the removal of a contraindication as follows:
"Avaglim is also contraindicated for use in combination with insulin (see section 4.4)."

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for AVAGLIM will be as follows[***]:
- hypersensitivity to rosiglitazone, glimepiride, other sulphonylureas or sulphonamides or to any of the excipients
- cardiac failure or history of cardiac failure (NYHA class I to IV)
- **an Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI) (see section 4.4)**
- hepatic impairment
- severe renal impairment i.e. creatinine clearance less than 30 ml/min (including renal dialysis).
- insulin dependant diabetes
- diabetic ketoacidosis or diabetic coma.

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

[***] The text in bold represents the new or the amended contraindication.

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