European Medicines Agency
Post authorisation Evaluation of Medicines for Human Use

London, 24 January 2008
Doc.Ref. EMEA/CHMP/42712/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
AVANDIA

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

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 Avandia. 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)"

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 Avandia will be as follows***:
- known hypersensitivity to rosiglitazone 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
- diabetic ketoacidosis or diabetic pre-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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu