European Medicines Agency
Press office

London, 15 December 2006
Doc. Ref. EMEA/506977/2006 - corr

PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 11-14 December 2006

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) gave positive opinions on initial marketing authorisation applications:

- The CHMP recommended the granting of a marketing authorisation for **Cystadane** (betaine anhydrous), from Orphan Europe SARL, intended for the adjunctive treatment of homocystinuria, a rare metabolic disorder caused by an enzyme deficiency. EMEA review began on 17 August 2005 with an active review time of 194 days. Cystadane is the **35th orphan medicinal product** to receive a positive CHMP opinion.

- The CHMP recommended the granting of a conditional marketing authorisation for **Prezista** (Darunavir), from Jansen-Cilag International NV, intended for the treatment of Human Immunodeficiency Virus (HIV-1) infected adult patients with advanced disease and limited treatment options. Conditional marketing authorisations are granted for medicines that are likely to have a significant benefit for patients, before all of the formal studies into its efficacy and safety have been completed. EMEA review began on 1 February 2006 with an active review time of 204 days.

- The CHMP recommended the granting of a marketing authorisation under exceptional circumstances for **Daronrix** (whole virion influenza vaccine of pandemic strain, inactivated), from GlaxoSmithKline Biologicals s.a., intended for the prevention of influenza during an officially declared pandemic situation. Marketing authorisations under exceptional circumstances are granted subject to certain specific obligations to be reviewed annually. Daronrix is the first mock-up pandemic influenza vaccine to receive a positive opinion. A mock-up pandemic influenza vaccine is not intended for use or stockpiling. Based on the mock-up, a final vaccine can be prepared quickly in the event of a pandemic outbreak, once the responsible strain has been identified. EMEA review began on 1 February 2006 with an active review time of 142 days.

  More information is available in a press release and a question and answer document.

Extension of indication

The Committee gave a positive opinion to extend the marketing authorisation for **Actos** (pioglitazone), from Takeda Global R&D Centre (Europe) Ltd. The CHMP recommended to include combination therapy with insulin in type-2 diabetes mellitus patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance. Actos was first granted a marketing authorisation in the European Union on 13 October 2000. It is currently authorised for the treatment of type-2 diabetes mellitus, either as mono, dual or triple oral therapy.

Change to contraindications

The Committee recommended the addition of a contraindication for **Actos**, saying that Actos must not be used in patients with diabetic ketoacidosis, and recommended the removal of the contraindication for use in combination with insulin (see 'Extension of indication' above).

The Committee recommended the removal of a contraindication for **Avandamet** (rosiglitazone/metformin)**,** for use in combination with insulin. Avandamet was first authorised in the European Union on 20 October 2003. It is currently authorised for the treatment of type-2 diabetes mellitus as dual combination therapy and as triple combination therapy with sulphonylurea.

Summaries of opinions, including more detailed information on the new indications or contraindications for all products mentioned above are available and can be found here.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Re-examination procedure concluded
Following a re-examination procedure the Committee adopted a final positive opinion for **Tarceva** (erlotinib), from Roche Registration Limited, recommending the extension of the marketing authorisation to add treatment of metastatic pancreatic cancer, in combination with gemcitabine.

A question and answer document with more detailed information about the re-examination procedure is available here.

Referral procedures concluded
The Committee concluded a referral procedure for **Metoprolol/Felodipine**-containing medicinal products (metoprolol tartrate and felodipine) and associated names, from YES Pharmaceuticals Development Services GmbH*, intended for the treatment of arterial hypertension. The CHMP recommended the refusal of a marketing authorisation in the concerned Member States and a suspension of the marketing authorisation for Metoprolol/Felodipine-containing medicinal products in the reference Member State because equivalence with the reference medicinal product (Mobloc/Logimax) has not been demonstrated. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) because of disagreement among the Member States in the context of the mutual recognition procedure.

The Committee finalised referral procedures for **Gadovist/Gadograf** (gadobutrol) from Schering AG, recommending to extend the marketing authorization to contrast enhanced magnetic resonance imaging (MRI) of liver or kidneys in patients over 18 years of age with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant. The referrals were triggered by Spain in accordance with Article 36(1) of the Community code on human medicinal products (Directive 2001/83/EC as amended), with a view to restrict the indication applied for by the marketing authorization holder in the context of the mutual recognition procedure. The scope of the application for extension of indication originally applied for was contrast enhanced MRI of liver and kidneys. Article 36(1) procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action.

Referral procedures started
The CHMP started a referral procedure for **Lansoprazole 15 & 30mg Gastro-resistant Capsules** (lansoprazole), from Teva UK Ltd, indicated for the treatment of gastro oesophageal reflux disease, ulcers, acid-related dyspepsia and as an adjuvant in the eradication of Helicobacter pylori. The referral was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) because of disagreement among the Member States in the context of the mutual recognition procedure regarding bioequivalence with the originator product.

A more detailed CHMP meeting report will be published shortly.

--ENDS--

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail: press@emea.europa.eu

*Correction: The name of the marketing authorisation holder has been corrected.