PRESS RELEASE
European Medicines Agency: 
Committee for Medicinal Products for Human Use 
24-27 April 2006

Initial marketing authorisation applications

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

- **Acomplia** and **Zimulti** (rimonabant) from Sanofi-Aventis, for use as adjunct to diet and exercise for the treatment of obese patients or overweight patients with associated risk factors, such as type 2 diabetes or dyslipidaemia. EMEA review for Acomplia began on 18 May 2005 with an active review time of 202 days, EMEA review for Zimulti began on 15 September 2005 with an active review time of 85 days.

- **Avaglim** (rosiglitazone/glimepiride), from SmithKline Beecham plc, for the treatment of type 2 diabetes mellitus. EMEA review began on 15 June 2005 with an active review time of 204 days.

- **Baraclude** (entecavir), from Bristol-Myers Squibb Pharma EEIG, for the treatment of chronic hepatitis B. EMEA review began on 18 October 2004, with an active review time of 210 days.

- **Nexavar** (sorafenib tosylate), from Bayer Healthcare AG, for the treatment of advanced renal cell cancer in patients who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. EMEA review began on 28 September 2005, with an active review time of 177 days. Nexavar is the **twenty-sixth orphan medicinal product** to receive a positive CHMP opinion.

- **RotaTeq** (rotavirus vaccine), from Sanofi Pasteur MSD, for the prevention of rotavirus gastroenteritis in infants from 6 weeks of age. EMEA review began on 18 May 2005, with an active review time of 190 days.

- **Tysabri** (natalizumab), from Elan Pharma International Ltd, for the treatment of multiple sclerosis. EMEA review began on 21 June 2004, with an active review time of 176 days.

The CHMP also adopted the first positive opinion on the granting of a **conditional marketing authorisation** under new EU rules on conditional approvals that came into force at the beginning of April 2006:

- **Sutent** (sunitinib malate), from Pfizer Ltd, for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance, and advanced and/or metastatic renal cell carcinoma (MRCC) after failure of interferon alfa or interleukin-2 therapy. EMEA review began on 28 September 2005, with an active review time of 177 days. Sutent is the **twenty-seventh orphan medicinal product** to receive a positive CHMP opinion.

A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Sutent, this relates to the product’s effect in terms of progression-free survival in patients with MRCC, for which a study is being conducted. The European Medicines Agency will review new information within one year and update the product information as necessary.
Extensions of indications

The Committee adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union:

- **Betaferon** (interferon beta –1b), from Schering AG, to extend its indication to add the early form of multiple sclerosis. Betaferon was first authorised in the European Union on 21 November 1996 and is currently indicated for the treatment of patients with relapsing remitting multiple sclerosis and two or more relapses within the last two years, and the treatment of patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses.

- **Herceptin** (trastuzumab), from Roche Registration Ltd, to extend its indication to include adjuvant treatment of early breast cancer (invasive, non-metastatic) over-expressing HER2 following surgery, chemotherapy (neo-adjuvant or adjuvant) and radiotherapy (if applicable). Herceptin was first authorised in the European Union on 28 August 2000 and is currently authorised for the treatment of patients with metastatic breast cancer, either as monotherapy for patients who have undergone at least two chemotherapy regimens or in combination with paclitaxel or docetaxel for the treatment of patients who have not received chemotherapy for their metastatic disease.

  This is the first accelerated assessment by the European Medicines Agency under new EU legislation introduced in November 2005, with the application submitted in February 2006. A separate question and answer document relating to this extension of indication is available [here](#).

- **Humira** (adalimumab), from Abbott Laboratories, for the extension of indication to include treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. Humira was first authorised in the European Union on 8 September 2003 and is currently indicated for rheumatoid and psoriatic arthritis.

New contraindication

The Committee recommended that the following medicinal products used to treat erectile dysfunction should be contraindicated in patients suffering from vision loss in one eye because of non-arteritic anterior ischemic optic neuropathy (NAION):

- **Cialis** (tadalafil), from Lilly ICOS Limited (first authorised in the EU on 12 November 2002)
- **Levitra and Vivanza** (vardenafil), from Bayer AG (first authorised in the EU on 4 March 2003)
- **Viagra** (sildenafil), from Pfizer Limited (first authorized in the EU on 14 September 1998)

The Committee also recommended that the same contraindication is added for **Revatio** (sildenafil), from Pfizer limited, used for the treatment of patients with pulmonary arterial hypertension classified as WHO functional class III. Revatio was first authorised in the EU on 28 October 2005.

Summaries of opinions for all these products are available and can be found [here](#).

Review procedures started

The Committee started a large number of arbitration and referral procedures for medicinal products authorised through the mutual recognition procedure this month.

Arbitrations under Article 29 of the Community code on human medicinal products (Directive 83/2001/EC as amended) are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure. Procedures were started for the following products:
- **Doxazosin Retard ‘Arrow’ 4 mg prolonged release tablets** (doxazosin as mesylate), from Arrow Generics Ltd
- **Doxazosin Retard ‘Winthrop’ 4 mg prolonged release tablets** (doxazosin as mesylate), from Winthrop Pharmaceuticals UK Ltd
- **Alendros 70** (alendronate sodium trihydricum), from Zentiva a.s.
- **Glucomed 625 mg tablet** (glucosamine hydrochloride), from Navamedic AS.

The Committee started referral procedures for a number of generic medicinal products containing cetirizine dihydrochloride because of concerns over their bioequivalence. The procedures were initiated by the Netherlands under Article 36 of the Community code on human medicinal products (Directive 83/2001/EC as amended) for the following products and associated tradenames: Cetirizine dihydrochloride-APEX 10mg, Cetirizine dihydrochloride Copyfarm 10mg, Cetirizine dihydrochloride Dermapharm 10mg and Cetirizine dihydrochloride Nordic Drugs 10 mg film-coated tablets. Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action.

**Review procedures concluded**

The Committee finalised 4 arbitration procedures for **Seretide Diskus, Viani Diskus, Seretide Evohaler** and **Viani Evohaler** from GlaxoSmithKline. The arbitrations for these fixed dose combinations of the long acting beta agonist salmeterol and the inhaled corticosteroid fluticasone propionate used in the treatment of asthma were made by the marketing authorisation holder in September 2005. The Committee recommended that the products could be tried for a short period of time as initial maintenance therapy in adults and adolescents with moderate asthma for whom rapid control of asthma is essential, after which a decision should be taken whether or not to continue treatment with the product. The arbitration was made under Article 6(13) of Commission Regulation (EC) No 1084/2003. Marketing authorisation holders initiate these types of arbitrations where a type II variation in the mutual recognition procedure is rejected by the Member States.

The Committee also concluded a referral procedure for **Stamaril** and associated tradenames, from Sanofi Pasteur MSD, with a recommendation to harmonise the product information, in particular the sections dealing with indications and safety aspects, across the European Union. Stamaril is a viral vaccine used for active immunisation against yellow fever in persons over 9 months of age. The marketing authorisation holder made the referral in September 2005 under Article 30 of Directive 2001/83/EC as amended.

A more detailed CHMP meeting report will be published shortly.

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