EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)

20-23 June 2011

Positive opinions for new medicines adopted

The Committee adopted positive opinions recommending the granting of marketing authorisations for the following new medicines:

- **Buccolam** (midazolam), from ViroPharma SPRL, intended for the treatment of prolonged, acute, convulsive seizures in paediatric patients from the age of 3 months to 18 years. The review for Buccolam began on 22 September 2010 with an active review time of 210 days. This is the first CHMP recommendation for a paediatric-use marketing authorisation (PUMA).
- **Eurartesim** (dihydroartemisinin/piperaquine phosphate), from Sigma-tau Industrie Farmaceutiche Riunite S.p.A., intended for the treatment of uncomplicated *Plasmodium falciparum* malaria. The review for Eurartesim began on 22 July 2009 with an active review time of 210 days. This is the first CHMP recommendation for an anti-malaria medicine.

More information about these opinions is available in separate press releases on the Agency's website.

- **Trajenta** (linagliptin), from Boehringer Ingelheim International GmbH, intended for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults. The review for Trajenta began on 21 July 2010 with an active review time of 210 days.
- **Votubia** (everolimus), an orphan medicine from Novartis Europharm Ltd, intended for the treatment of patients aged 3 years and older with subependymal giant-cell astrocytoma (SEGA) associated with tuberous sclerosis complex. The review of Votubia began on 18 August 2010 with an active time of 210 days.
  The CHMP recommended the granting of a conditional marketing authorisation for **Votubia**, which means that further evidence on the medicinal product is awaited. In the case of Votubia this relates to the submission of the final results from pivotal phase III study and the long-term follow-up on the efficacy and safety in SEGA patients. The European Medicines Agency will review new information within one year and update the product information as necessary.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Summaries of opinion for these medicines are available on the Agency's website.

Negative opinions for new medicines adopted

The Committee adopted negative opinions recommending that marketing authorisations should not be granted for the following orphan medicines:

- **Bronchitol** (mannitol), from Pharmaxis Pharmaceuticals Ltd, intended for the treatment of adult patients with cystic fibrosis.
- **Luveniq** (voclosporin), from Lux Biosciences GmbH, intended for the treatment of chronic non-infectious uveitis.

More information about these opinions is available in separate question-and-answer documents on the Agency's website.

Negative opinion for advanced therapy medicine adopted

The Committee adopted a negative opinion for the orphan medicine **Glybera** (alipogene tiparvovec), from Amsterdam Molecular Therapeutics B.V. On the basis of the opinion of the Committee for Advanced Therapies (CAT), the CHMP recommended not granting a marketing authorisation for this product. Glybera is a gene-therapy product using an adeno-associated viral vector intended for the treatment of adult patients diagnosed with lipoprotein lipase deficiency demonstrating hyperchylomicronaemia or having a history of acute pancreatitis.

More information about this opinion is available in a separate question-and-answer-document on the Agency's website.

Positive opinions for 'informed consent' applications adopted

The Committee adopted positive opinions for **Entacapone Orion** (entacapone) and **Levodopa/Carbidopa/Entacapone Orion** (levodopa/carbidopa/entacapone), both from Orion Corporation, intended for the treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations.

For both medicines 'informed consent' applications were submitted. This type of application requires reference to be made to an authorised medicine and the marketing authorisation holder of this reference product to give consent to the use of its original dossier in the application procedure. The reference product for Entacapone Orion is Comtess. The reference product for Levodopa/Carbidopa/Entacapone Orion is Stalevo.

Summaries of opinion for these medicines are available on the Agency's website.

Positive opinions for extension of therapeutic indications adopted

The Committee adopted positive opinions for the following applications for extension of the therapeutic indications. This adds new treatment options for the following medicines that are already authorised in the EU:

- **Kiovig** (human normal immunoglobulin), from Baxter AG, to include the treatment of multifocal motor neuropathy.
- **Retacrit** (epoetin zeta), from Hospira UK Ltd, to include the reduction of allogeneic blood transfusions in adult non-iron-deficient patients prior to major elective orthopaedic surgery.

- **Synflorix** (pneumococcal polysaccharide conjugate vaccine (absorbed)), from GlaxoSmithKline Biologicals S.A., to increase the upper age limit for children from 2 to 5 years of age.

Summaries of opinion for these medicines, including their full therapeutic indications, are available on the Agency's website.

Re-examination for Vectibix concluded

Following re-examination of its previous negative opinion, the Committee adopted a final positive opinion, recommending the extension of indication for **Vectibix** (panitumumab), from Amgen Europe B.V., to include the use of panitumumab in combination with specific chemotherapy in patients with wild-type *KRAS* metastatic carcinoma of the colon or rectum.

More information about this re-examination procedure is available in a separate question-and-answer document on the Agency's website.

Review of pioglitazone-containing medicines

The Committee is currently reviewing results from pharmacoepidemiological studies, non-clinical and clinical data and post-marketing reports on **pioglitazone**-containing medicines and the occurrence of bladder cancer to assess their impact on the balance of benefits and risks of these medicines. The CHMP will finalise its review in July 2011 and make recommendations on the future use of these medicines.

More information about this review is available in a separate press release on the Agency's website.

Review of systemic nimesulide-containing medicines concluded

The Committee concluded that the benefits of systemic **nimesulide**-containing medicines continue to outweigh their risks in the treatment of patients with acute pain and primary dysmenorrhoea. However, these medicines should no longer be used for the symptomatic treatment of osteoarthritis.

More information about this review is available in a separate press release and a question-and-answer document on the Agency's website.

Review of dexrazoxane-containing medicines concluded

The Committee recommended restricting the use of **dexrazoxane**-containing medicines to adult patients with advanced or metastatic breast cancer who have already received a certain amount of the anthracyclines doxorubicin and epirubicin to treat their cancer. The Committee also recommended that this medicine should not be used in children.

More information about this review is available in a separate press release and a question-and-answer document on the Agency's website.

Harmonisation referral concluded

The Committee recommended harmonisation of the prescribing information for the antifungal medicine **Diflucan** (fluconazole), from Pfizer group of companies.

This medicine is used to treat various fungal infections, including mucosal and invasive candidiasis, genital candidiasis, cryptococcal meningitis, dermatomycosis, coccidiodomycosis and onychomycosis.

This review was initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the EU Member States where this product is marketed.

More information about this review is available in a separate question-and-answer document on the Agency's website.

Review of Novosis Goserelin, Goserelin Cell Pharm, Novimp and associated names concluded

The Committee completed a review of the clinical studies performed in support of the marketing authorisation applications for the hybrid medicines **Novosis Goserelin**, **Goserelin Cell Pharm, Novimp** and associated names (goserelin, 3.6 mg implant). The Committee concluded that the bioanalytical studies could not be relied upon, because they were not conducted in accordance with good clinical practice (GCP) requirements. Therefore, the therapeutic equivalence of these medicines to the reference medicine, Zoladex, has not been demonstrated. As such the benefit risk balance for these hybrid products was considered to be negative. The marketing authorisations should therefore be suspended in all EU Member States until the companies provide new, GCP-compliant, studies showing therapeutic equivalence.

Goserelin is used to treat patients with advanced prostate cancer where an endocrine treatment is indicated.

More information about this review is available in a separate question-and-answer document on the Agency's website.

Review procedure for anti-tuberculosis medicines in children started

The Committee has begun looking at dosing recommendations of the anti-tuberculosis medicines **isoniazide, rifampicine, pyrazinamide, ethambutol** and **rifabutin** in children.

This review was triggered by France following the publication of pharmacokinetic data on these anti-tuberculosis medicines in children, which showed that the current treatment recommendations across the EU are no longer accurate. This issue had already been recognised by the World Health Organization (WHO) which had recommended changes to the current dosing regimen of first-line anti-tuberculosis medicines and recommended an increase of the dosing of the anti-tuberculosis medicines in children.

The Committee will now review all of the available literature and give an opinion on the optimal dosing regimen for paediatric patients in the EU, taking account of the current WHO recommendation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of pioglitazone-containing medicines is being conducted in the context of a formal review under Article 20 of Regulation (EC) No 726/2004.
3. The review of nimesulide-containing medicines was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC.
4. The review of dexrazoxane-containing medicines was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC.
5. The harmonisation referral on Diflucan was conducted under Article 30 of Directive 2001/83/EC, as amended.
6. The review of Novosis Goserelin, Goserelin Cell Pharm, Novimp and associated names was conducted in the context of a formal review, initiated by Germany on 16 March 2011, under Article 36 of Directive 2001/83/EC, as amended. Novosis Goserelin, Goserelin Cell Pharm, Novimp and

associated names are authorised via the decentralised procedure and are marketed by Acino AG and Cell Pharm GmbH in the Reference Member State, Germany.

7. The review on anti-tuberculosis medicines is being conducted in the context of a formal review under Article 5(3) of Regulation (EC) No 726/2004.

8. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu