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Press Office

Press release

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

18-21 October 2010

Positive opinion for a new medicine adopted

The Committee adopted a positive opinion, recommending the granting of a marketing authorisation for **Fluenz** (influenza vaccine (live attenuated, nasal)), from MedImmune LLC, intended for the prophylaxis of influenza in children from 24 months to less than 18 years of age. The review for Fluenz began on 17 December 2008 with an active review time of 210 days.

Positive opinions for generic medicines adopted

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

- **Iasibon** (ibandronic acid), from Pharmathen S.A., for the prevention of skeletal events in patients with breast cancer and bone metastases, and for the treatment of tumour-induced hypercalcaemia with or without metastases. Iasibon is a generic of Bondronat.
- **Potactasol** (topotecan), from Actavis Group PTC ehf, for the treatment of metastatic carcinoma of the ovary, small cell lung cancer and carcinoma of the cervix. Potactasol is a generic of Hycamtin.
- **Docetaxel** Teva Pharma (docetaxel), from Teva Pharma B.V., for the treatment of locally advanced or metastatic breast cancer and small cell lung cancer, and of metastatic prostate cancer. Docetaxel Teva Pharma is a generic of Taxotere.

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Positive opinions for extensions of therapeutic indications adopted

The Committee gave positive opinions for applications for extensions of the therapeutic indications, adding new treatment options for medicines that are already authorised in the European Union, for:

- **Lucentis** (ranibizumab), from Novartis Europharm Ltd, to include the treatment of visual impairment due to diabetic macular oedema.
- **Sprycel** (dasatinib), an orphan medicine from Bristol-Myers Squibb Pharma EEIG, to include the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukaemia in the chronic phase.
- **Sutent** (sunitinib), from Pfizer Ltd, to include the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.

More information about all above mentioned medicines, including their full indication, can be found on the Agency's website.

Review of treatment recommendations for Fabrazyme

The Committee has reviewed its previous recommendations on the use of Fabrazyme (agalsidase beta) during the ongoing supply shortage. This was triggered by an increase in reported adverse events in patients treated with the lower dose of Fabrazyme that has been introduced during the shortage.

Fabrazyme is used to treat the rare, inherited enzyme-deficiency disorder, Fabry disease. Temporary treatment recommendations to manage patients relying on this medicine have been in place since the start of the supply shortage and have been regularly updated.

The CHMP is now recommending that physicians switch back to prescribing the full dose of Fabrazyme according to the authorised product information, depending on the availability of enzyme replacement therapy and the severity of the disease.

More information about the review of the treatment recommendations for Fabrazyme is available in a separate press release on the Agency's website.

Review of Invirase concluded

The Committee finalised a review of Invirase (saquinavir), from Roche Registration Ltd, following the detection of QT and PR interval prolongation in healthy volunteers. The Committee concluded that ritonavir-boosted Invirase combination treatment for HIV-1 infected adult patients continues to have a positive benefit-risk balance. However, the Committee recommended that treatment-naïve patients should take a reduced dose of Invirase during the first week of treatment, as a precautionary measure. Also, the CHMP asked Roche to investigate the potential risk of arrhythmia in treatment-naïve patients receiving the reduced dose of Invirase in combination with other antiretroviral medicines in a new study.

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

Review of fibrates concluded

The Committee finalised a review of the four **fibrates** bezafibrate, ciprofibrate, fenofibrate and gemfibrozil, and concluded that their benefits continue to outweigh their risks in the treatment of patients with blood lipid disorders. However, doctors should not prescribe them to newly diagnosed patients with blood lipid disorders as first-line treatment, except for patients with severe hypertriglyceridaemia or patients who cannot take statins. For fenofibrate, the Committee noted additional new data and recommended that it can also be used together with a statin in some circumstances when a statin on its own has not been enough to completely control blood lipid levels.

Fibrates are a class of medicines that have been in use for many years to control levels of lipids such as cholesterol and triglycerides in the blood.

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

Harmonisation referrals concluded

The Committee recommended harmonisation of the prescribing information for three medicines. The reviews were initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where the products are marketed. The medicines reviewed are:

- **Fortum** (ceftazidime), from GSK and associated companies. The medicine is an antibiotic authorised for treatment of infections such as hospital acquired pneumonia, complicated skin and soft tissue infections, bone and joint infections, chronic otitis media, complicated intra-abdominal infections, meningitis and complicated urinary tract infections, and bacteraemia that is associated with these infections.
- **Tazocin** (piperacillin/tazobactam), from Pfizer and associated companies. The medicine is an antibiotic authorised for treatment of infections such as severe pneumonia, complicated urinary tract infections, complicated intra-abdominal infections, complicated skin and soft tissue infections and bacteraemia that is associated with these infections.
- **Vascace Plus** and associated names (cilazapril/hydochlorothiazide), from Roche and associated companies. The medicine is authorised for treatment of hypertension in patients whose blood pressure is not adequately controlled with cilazapril alone.

Question-and-answer documents with more information about these referrals can be found on the Agency's website.

Review of Octagam started

The Committee has begun a review of **Octagam** and associated names (human normal immunoglobulin). This follows the recommendation for the suspension of the marketing authorisations of Octagam at the September 2010 CHMP meeting, due to an increased risk of thromboembolic events in patients receiving this medicine.

Octagam is an intravenous solution used to strengthen the body's immune system to lower the risk of infection in patients with a weakened immune system.

This review will allow for a scientific assessment of all available data on the safety and quality issues identified previously. This includes the manufacturing process and the identification of appropriate corrective measures, and will allow for a coordinated approach on the resulting actions.

Notes

1. This press release together with all relevant documents is available on the European Medicines Agency's web site.
2. The review of Invirase was conducted under Article 20 of Regulation (EC) No 726/2004.
3. The review of fibrates was conducted under Article 31 of Directive 2001/83/EC, as amended.
4. The harmonisation referral of Fortum was conducted under Article 30 of Directive 2001/83/EC, as amended.
5. The harmonisation referral of Tazocin was conducted under Article 30 of Directive 2001/83/EC, as amended.
6. The harmonisation referral of Vascace plus was conducted under Article 30 of Directive 2001/83/EC, as amended.
7. The review of Octagam is being conducted in the context of a formal review, initiated by Germany under Article 31 of Directive 2001/83/EC, as amended. The Committee will make recommendations on whether the marketing authorisations for Octagam should be maintained, changed, suspended or revoked.
8. A more detailed CHMP meeting report will be published shortly.
9. More information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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