News from the EMEA

Activities of the CHMP

During its meeting from 18-21 October 2010 the Committee for Human Medicinal Products (CHMP) adopted:

- one positive opinion for 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..This review began on 23 December 2009 with an active review time of 210 days.

- **three positive opinions** 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. (generic of Bondronat from Roche.
- **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 (generic of Hycamtin from SmithKline Beecham).
- **Docetaxel** Teva Pharma for the treatment of locally advanced or metastatic breast cancer and small cell lung cancer, and of metastatic prostate cancer. (generic of Taxotere from Aventis).

- positive opinions for extensions of indications 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 BMS 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.

Pharmacovigilance:

Review of fibrates concluded: The CHMP 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.

Review of Invirase concluded: The CHMP finalised a review of Invirase (saquinavir), from Roche, 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.

Review of treatment recommendations for Fabrazyme: The CHMP 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 with Fabry disease treated with the lower dose of Fabrazyme that has been

introduced during the shortage. 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.

Harmonisation referrals concluded: The CHMP recommended the EU-wide harmonisation of the prescribing information for the following three medicines:

- **Fortum** (ceftazidime), from GSK. This antibiotic is 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. This antibiotic is 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** (cilazapril/hydochlorothiazide), from Roche. This medicine is authorised for treatment of hypertension in patients whose blood pressure is not adequately controlled with cilazapril alone.

Review of Octagam started: The Committee has begun a review of **Octagam** (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.

Date of the next CHMP meeting: 15–18 November 2010.

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