News from the EMA

Activities of the CHMP

During its meeting from 20-23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- four positive opinions for the **granting of a marketing authorisation** for:

- **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; active review time: 210 days. This is the first CHMP recommendation for a paediatric-use marketing authorisation (PUMA).
- **Eurartesim** (dihydroartemisinin/piperaquine phosphate), an orphan medicine from Sigma-tau Industrie, intended for the treatment of uncomplicated *Plasmodium falciparum* malaria. The review for Eurartesim began on 22 July 2009; active review time: 210 days. This is the first CHMP recommendation for an anti-malaria medicine.
- **Trajenta** (linagliptin), from Boehringer Ingelheim, intended for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults. The review for Trajenta began on 21 July 2010: 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: active time: 210 days.

- two positive opinions for the following 'informed consent' applications:

- **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; reference products: Comtess and Stalevo

- three positive opinions for extension of indications:

- **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.

- a final positive opinion for extension of indications after re-examination of the previous negative opinion 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.

- three negative opinions 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.
- **Glybera** (alipogene tiparvovec), from Amsterdam Molecular Therapeutics B.V. this negative opinion was based on the basis of the opinion of the Committee for Advanced Therapies (CAT). 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.

Pharmacovigilance:

Review of pioglitazone-containing medicines: The current review of the results from pharmacoepidemiological studies, non-clinical and clinical data and post-marketing reports on pioglitazone**-**containing medicines and the occurrence of bladder cancer will be finalised in July 2011; then the CHMP will make recommendations on the future use of these medicines.

Review of systemic nimesulide-containing medicines concluded: The CHMP 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.

Review of dexrazoxane-containing medicines concluded: The CHMP 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. Tis medicine should not be used in children.

Harmonisation referral for Diflucan (fluconazole) concluded: The CHMP recommended harmonisation of the prescribing information for this antifungal medicine from Pfizer.

Review of Novosis Goserelin, Goserelin Cell Pharm, Novimp implants concluded: The CHMP concluded that the bioanalytical studies for theses medicines 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 and the marketing authorisations should be suspended in all EU Member States. Goserelin is used to treat patients with advanced prostate cancer where an endocrine treatment is indicated.

Review procedure for anti-tuberculosis medicines in children started: The CHMP has begun reviewing the dosing recommendations of **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. The World Health Organization (WHO) had already recommended an increase of the dosing of these anti-tuberculosis medicines in children.

Date of the next CHMP meeting: 18–21 July 2011.

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: s.throm@vfa.de)
for:

Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu