

News from the EMEA

Activities of the CHMP

During its meeting from 21 - 24 June 2010 the Committee for Human Medicinal Products (CHMP) adopted:

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

- **Brinavess** (vernakalant), from MSD, intended for the rapid conversion of recent onset of atrial fibrillation to sinus rhythm in adults. This review began on 19 August 2009 with an active review time of 209 days.
- **Rapiscan** (regadenoson), from Gilead, intended as pharmacological stress agent for radionuclide myocardial perfusion imaging. This review began on 27 May 2009 with an active review time of 209 days.
- **Ruconest** (conestat alfa), previously known as Rhucin, from Pharming, an orphan medicine intended for the treatment of angioedema attacks. The active substance is extracted from the milk of recombinant rabbits. This review began on 23 September 2009 with an active review time of 210 days. This was a resubmission of an application for a marketing authorisation following a negative opinion by the CHMP in December 2007.
- **Sycrest** (asenapine), from Organon, intended for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults. This review began on 27 May 2009 with an active review time of 210 days.
- **Vpriv** (velaglucerase alfa), from Shire, an orphan medicine intended for the treatment of Gaucher disease. This review began on 23 December 2009 with an active review time of 150 days. The Committee carried out an accelerated assessment of this medicine, due to a major public health interest (ongoing shortage of the Genzyme medicine).

- **one positive opinion** for the following **hybrid generic medicine**:

- **PecFent** (fentanyl) nasal spray, from Archimedes for treatment of breakthrough pain in adults

- **positive opinions** for the following **generic medicines**:

- **Ibandronic Acid Teva** 50-mg tablets for the prevention of skeletal events in patients with breast cancer and bone metastases, and 150-mg tablets for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. Ibandronate Teva 50 mg is a generic of Bondronat, and Ibandronate Teva 150 mg is a generic of Bonviva.
- **Telmisartan Actavis** (telmisartan), from Actavis, for the treatment of essential hypertension and reduction of cardiovascular morbidity. Telmisartan Actavis is a generic of Micardis.

- **positive opinions for extensions of indications** for:

- **Byetta** (exenatide), from Lilly, to include treatment of type 2 diabetes mellitus in combination with thiazolidinedione (with or without metformin).
- **Gardasil** and **Silgard** (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)), from Sanofi Pasteur MSD SNC and MSD, to include the prevention of premalignant genital lesions, cervical cancer and external genital warts in mid-adult women, from the age of 26 to 45 years.

Re-examination procedure on Zeftera concluded: The CHMP confirmed its previous negative opinion and adopted a final negative opinion, recommending that **Zeftera** (ceftobiprole medocaryl), from Janssen-Cilag International NV, should not be granted a marketing authorisation. Zeftera is an antibiotic, intended for the treatment of complicated skin and soft-tissue infections.

Arbitration procedures concluded: The CHMP completed arbitration procedures initiated because of disagreement among EU Member States for:

- **Fortipan Combi D** and **Norsed Combi D** (risedronate sodium, calcium carbonate and colecalciferol), from Procter & Gamble and Sanofi-Aventis for the treatment of post-menopausal osteoporosis. The procedures were initiated because of concerns regarding the efficacy of these medicines, in particular regarding claims of improved benefit of the combination pack as compared with the individual active substances and improved compliance compared with the standard treatment. The CHMP concluded that the combination pack will simplify the correct dosage regimen and did not consider the demonstration of improved compliance to be an absolute requirement for the approval of these combination products. Therefore, the Committee concluded that the benefit-risk

profile of these medicines was positive and recommended that marketing authorisations should be granted.

- **Genotropin** (somatropin), from Pfizer for treatment of children with growth disturbances and adults with growth hormone deficiency. This procedure was initiated because of concerns regarding the efficacy of these medicines in children with severe forms of juvenile idiopathic arthritis (JIA) requiring long-term glucocorticoid treatment. The CHMP concluded that the benefit-risk profile of these medicines was negative in children with JIA requiring long term glucocorticoid treatment and recommended that the indications should not be extended.

Harmonisation referral concluded: The CHMP recommended harmonisation of the prescribing information for **Atacand Plus** (candesartan/hydrochlorothiazide), from AstraZeneca. These medicines are authorised to treat essential hypertension in patients whose blood pressure is not optimally controlled with candesartan or hydrochlorothiazide monotherapy.

Review of benefits and risks for Invirase started: The CHMP started a review of the benefits and risks of Invirase (saquinavir), in view of the results of a study by Roche, investigating the proarrhythmic effect of ritonavir-boosted saquinavir in healthy volunteers. The study showed that Invirase had a marked effect on QT interval prolongation and PR prolongation. These findings have been included in the product information of Invirase. The review of the medicine's benefits and risks has been initiated to discuss any additional measures necessary to ensure the safe and effective use of Invirase and to determine how to balance the risks and benefits of the medicine. Ritonavir-boosted Invirase is indicated as combination treatment of HIV-infected adult patients.

Review of angiotensin II receptor inhibitors started: The CHMP has begun looking at the possible risk of cancer in patients taking angiotensin II receptor inhibitors. This follows the publication of a meta-analysis reviewing nine randomised controlled trials involving almost 95,000 patients, which suggests that these medicines may be linked with a modestly increased risk of new diagnoses of cancer when compared with placebo or other heart medicines. The CHMP will review the meta-analysis thoroughly, together with any other available non-clinical and clinical data (including data from clinical trials and epidemiological studies) on angiotensin II receptor inhibitors, to clarify whether there is an increased risk of cancer in patients taking these medicines. The Committee will also issue an opinion on whether a future change to the product information or risk-management plans for these medicines might be necessary.

Date of the next CHMP meeting 19 – 22 July 2010.

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