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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 18-21 February 2008

First pre-pandemic influenza vaccine receives positive opinion
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the granting of a marketing authorisation for the first pre-pandemic influenza vaccine, **Prepandrix** (split inactivated, adjuvanted, H5N1 influenza vaccine containing antigens from A/VietNam/1194/2004 NIBRG-14), from GlaxoSmithKline Biologicals S.A.

Pre-pandemic vaccines are vaccines prepared from influenza viruses with a pandemic potential that are intended for use before a pandemic is declared or during an officially declared influenza pandemic. EMEA review began on 24 January 2007 with an active review time of 189 days. A separate press release is available here.

In addition, the CHMP has adopted a positive opinion recommending the granting of a marketing authorisation for **Pandemrix (**split inactivated, adjuvanted, H5N1 influenza vaccine containing antigens from A/VietNam/1194/2004 NIBRG-14), from GlaxoSmithKline Biologicals S.A. Pandemrix is a mock-up pandemic influenza vaccine, intended for the prevention of influenza during an officially declared pandemic influenza situation, once the pandemic viral strain has been included. It is the third mock-up pandemic influenza vaccine to receive a positive opinion from the Committee. EMEA review began on 21 February 2007 with an active review time of 161 days.

A question-and-answer document on mock-up pandemic influenza vaccines is available here.

Other positive opinions for initial marketing authorisation
The CHMP adopted positive opinions for:

- **Adenuric** (febuxostat), from Ipsen Manufacturing Ireland, for the management of chronic hyperuricaemia in conditions where urate/uric acid deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). EMEA review began on 27 September 2006 with an active review time of 188 days.
- **Mycamine** (micafungin sodium), from Astellas Pharma GmbH, for the the treatment of invasive candidiasis; prophylaxis of candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia, and in adolescents aged 16 years or older and adults for the treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate. EMEA review began on 24 May 2006 with an active review time of 203 days.
- **Privigen** (Human Normal Immunoglobulin), from ZLB Behring AG, for use as replacement therapy in immunodeficiency and for immunomodulation in immune-mediated diseases. EMEA review began on 21 February 2007 with an active review time of 188 days.
- **Volibris** (ambrisentan), from Glaxo Group Limited, for the treatment of pulmonary arterial hypertension. Volibris is the **46th orphan medicine** to receive a positive opinion. EMEA review began on 21 March 2007 with an active review time of 205 days.

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Positive opinions for four biosimilars
The CHMP adopted positive opinions for four biosimilar medicinal products. **Ratiograstim** (filgrastim), from ratiopharm GmbH**, Biograstim** (filgrastim), from CT Arzneimittel GmbH, **Tevagrastim** (filgrastim), from Teva Generics GmbH, and **Filgrastim ratiopharm** (filgrastim), from ratiopharm GmbH, are intended for the treatment of neutropenia. All four medicines have been shown to be similar to Neupogen, the reference medicinal product already authorised in the European Union (EU), in the applied indication. EMEA review began on 21 February 2007 with an active review time of 209 days.

Extensions of indication
The Committee gave positive opinions for applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Abilify** (aripiprazole), from Otsuka Pharmaceutical Europe Ltd, to extend the indication to add the treatment of moderate to severe manic episodes in bipolar-I disorder and the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment. Abilify is currently authorised for the treatment of schizophrenia.
- **Alimta** (pemetrexed), from Eli Lilly Nederland B.V., to extend the indication to include first line treatment in combination with cisplatin of patients with locally advanced or metastatic non small cell lung cancer other than predominantly squamous cell histology. In addition, the existing second line monotherapy indication has been amended to exclude treatment of patients with predominantly squamous cell histology. Alimta is currently authorised in combination therapy for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma and as monotherapy for the treatment of patients with locally advanced or metastatic non small cell lung cancer after prior chemotherapy.
- **Forsteo** (teriparatide), from Eli Lilly Nederland B.V., to extend the indication to add the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk of fracture. Forsteo is currently indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.
- **Azomyr, Aerius and Neoclarityn** (desloratadine), from SP Europe, to extend the indication from chronic idiopathic urticaria to urticaria. Azomyr, Aerius and Neoclarityn are currently indicated for relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

Referral procedures concluded
The CHMP concluded a referral procedure for **Coxtral gel**, 3% gel, (nimesulide) from Zentiva A.S., recommending the refusal of the granting of marketing authorisations and the suspension of the granted marketing authorisations, where appropriate. Coxtral gel is indicated for the symptomatic relief of pain associated with sprains and acute traumatic tendinitis. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) because of disagreement between Member States relating to the efficacy of the medicine. In its scientific assessment, the CHMP concluded that the therapeutic equivalence has not been adequately demonstrated and that therefore the benefit-risk profile of Coxtral gel is considered unfavourable.

Concluding the re-examination of a referral procedure for **Eformax**, inhalation powder, (formoterol fumarate), from IVAX Pharmaceuticals UK, the CHMP confirmed its previous recommendation to refuse the granting of the marketing authorisations and the suspension of the granted marketing authorisation where appropriate. Eformax is indicated for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) because of disagreement between Member States relating to the safety and efficacy of the medicine. The CHMP concluded that equivalent safety and efficacy to the reference medicinal product could not be demonstrated and that therefore the benefit-risk profile of Eformax is considered unfavourable.

Review procedure under Article 107
The European Commission has referred the positive opinion for **nimesulide-containing medicines** back to the CHMP. This opinion, which was issued by the CHMP on 20 September 2007 under Article 107, recommended the maintenance of the marketing authorisations for these medicines, subject to restricted use. It followed the suspension of the marketing authorisation for nimesulide in Ireland, due to concerns over serious liver problems.

The Commission has requested that the CHMP reconsider its position in the light of further cases of suspected liver injury and re-evaluate the recommended risk minimisation measures. The outcome is expected in the coming months and will be published on the Agency's website.

Referral procedures started
The CHMP started a referral procedure for **Lisonorm,** 5mg amlodipine/ 10 mg lisinopril tablets, (amlodipine/lisinopril), from Gedeon Richter, because of disagreement between the Member States on the grounds for approval of this medicine. Lisonorm is indicated as substitution therapy for patients with blood pressure adequately controlled with lisinopril and amlodipine given concurrently at the same dose level. The referral was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended).

The CHMP started a referral procedure for **Augmentin** (amoxicillin/clavulanic acid), from GSK, because of divergence in the product information. Augmentin is indicated for the treatment of bacterial infections. The procedure was initiated under Article 30 of the Community code on human medicinal products (Directive 2001/83/EC, as amended).

A more detailed CHMP meeting report will be published shortly.

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