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PRESS RELEASE
**Meeting highlights from the Committee for Medicinal Products for Human Use,
21-24 September 2009**

Two vaccines against Pandemic (H1N1) 2009 recommended for authorisation

The European Medicines Agency has recommended that two pandemic vaccines against influenza A(H1N1)v ('swine flu') be granted a marketing authorisation. The vaccines concerned are:

- **Focetria** from Novartis Vaccines and Diagnostics S.r.l.
- **Pandemrix** from GlaxoSmithKline Biologicals S.A.

More information is available in a separate [press release](#) and a [question-and-answer](#) document published on the Agency's website.

Positive opinions for new medicines

The Committee adopted positive opinions, recommending the granting of a marketing authorisation, for the following new medicines:

- **Multaq** (dronedarone hydrochloride), from Sanofi-Aventis, indicated in adult clinically stable patients with a history of, or current non-permanent atrial fibrillation (AF), to prevent recurrence of AF or to lower ventricular rate. The review of Multaq began on 23 July 2008, with an active review time of 183 days.
- **Onbrez Breezhaler** (indacaterol maleate), **Hirobriz Breezhaler** (indacaterol maleate) and **Oslif Breezhaler** (indacaterol maleate), all from Novartis Europharm Ltd, indicated for the maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). The review of Onbrez Breezhaler began on 28 January 2009, with an active review time of 178 days. The review of Hirobriz Breezhaler and Oslif Breezhaler began on 26 July 2009 with an active review time of 60 days.
- **Prevenar 13** (pneumococcal polysaccharide conjugated vaccine, 13-valent adsorbed), from Wyeth Lederle Vaccines S.A., intended for prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae*. The review of Prevenar 13 began on 24 December 2008 with an active review time of 204 days.
- **Zutectra** (human hepatitis B immunoglobulin), from Biotest Pharma GmbH, intended for the prevention of Hepatitis B virus re-infection in HBV-DNA negative patients \geq 6 months after liver transplantation for Hepatitis B-induced liver failure. The review of Zutectra began on 19 November 2008, with an active review time of 204 days.

Positive opinions for 'informed consent' applications

The Committee adopted positive opinions for **Rivastigmine 1 A Pharma** (rivastigmine), from 1 A Pharma GmbH, **Rivastigmine HEXAL** (rivastigmine), from Hexal AG and **Rivastigmine Sandoz** (rivastigmine), from Sandoz Pharmaceuticals GmbH, for which an 'informed consent' application was submitted. The products are intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and for the treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. 'Informed consent' applications require that reference is made to an authorised medicinal product and that the marketing authorisation holder of the referenced product has given consent to the use of their dossier in the application procedure.

* Correction on page 2 – Extension of indication for Tamiflu: The word *approved* was replaced by *recommended*.

Positive opinions for generic medicines

The Committee adopted positive opinions for the following generic medicines, for which a reference medicine is already authorised in the European Union:

- **Irbesartan Hydrochlorothiazide Teva** (Irbesartan Hydrochlorothiazide), from Teva Pharma B.V., a generic of CoAprovel, indicated for the treatment of hypertension.
- **Lamivudine Teva Pharma BV** (lamivudine), from Teva Pharma B.V. a generic of Epivir, indicated as part of antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infected adults and children.
- **Olanzapine Glenmark Europe** (olanzapine), **Olanzapine Glenmark** (olanzapine), from Glenmark Generics (Europe) Ltd, and **Olazax Desperzi** (olanzapine) and **Olazax** (olanzapine), from Glenmark Pharmaceuticals s.r.o., all generics of Zyprexa, indicated for the treatment of schizophrenia and moderate to severe manic episode.
- **Sildenafil Actavis** (sildenafil citrate), from Actavis Group PTC and **Sildenafil TEVA** (sildenafil citrate) from Teva Pharma B. V., both generics of Viagra, intended to treat erectile dysfunction.
- **Nevirapine Teva** (nevirapine, anhydrous), from Teva Pharma B.V., a generic of Viramune, indicated for treatment of HIV-1 infected adults, adolescents, and children of any age.

Summaries of opinions for all mentioned medicines, including their full indication, can be found [here](#).

Extension of indication for Tamiflu for use in children less than 6 months of age

The Committee has recommended to extend the indication for **Tamiflu** (oseltamivir), from Roche Registration Ltd., to include treatment of children less than 6 months of age during pandemic influenza and post-exposure prophylaxis for children less than 1 year of age. Tamiflu is currently indicated for the treatment of influenza in patients one year of age and older who present with symptoms typical of influenza, when influenza virus is circulating in the community. It is also indicated for the treatment of children 6 to 12 months of age during a pandemic influenza outbreak.

In parallel the Committee has approved instructions to prepare home and pharmacy extemporaneous formulations from Tamiflu 30, 45 and 75mg capsules and dosing recommendations from these extemporaneous formulations for children under 1 year of age.

Additional information including the recommended updated product information in English will be published shortly.

Other extensions of indication – positive opinions

The Committee gave positive opinions for applications for the extension of indication, adding new treatment options, for the following medicines:

- **Effcib, Janumet and Velmetia** (sitagliptin phosphate monohydrate / metformin hydrochloride), and **Januvia, Tesavel and Xelevia** (sitagliptin), from Merck Sharp & Dohme Ltd, to extend the indication of these medicines to include combination therapy with insulin. These medicines are currently authorised for the treatment of type-2 diabetes mellitus, as an adjunct to diet and exercise, in dual combination with metformin or in triple combination with metformin and sulphonylurea or with a PPAR γ agonist and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.
- **Corlontor** (ivabradine) and **Procoralan** (ivabradine), both from Les Laboratoires Servier, to extend the indication to use the medicine in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm. Corlontor and Procoralan are currently indicated for symptomatic treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm, in patients unable to tolerate or with a contra-indication to the use of beta-blockers, or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.
- **Yondelis** (trabectedin), from Pharma Mar S.A., to extend the indication of Yondelis in combination with Caelyx to the treatment of patients with relapsed platinum-sensitive ovarian

cancer. Yondelis is currently indicated for the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.

- **PegIntron** and **ViraferonPeg** (peginterferon alfa-2b), from Schering-Plough Europe, to extend the therapeutic indication of combination therapy with ribavirin to include treatment of the paediatric population and to include the treatment of adult patients with compensated cirrhosis. PegIntron and ViraferonPeg are currently indicated for the treatment of adult patients with chronic hepatitis C who have elevated transaminases without liver decompensation and who are positive for serum HCV-RNA or anti-HCV, including naïve patients with clinically stable HIV co-infection. It is also indicated for the treatment of hepatitis C in adults patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) in combination therapy with ribavirin.

The same extension of indication applies to **Rebetol** (ribavirin) used in combination with peginterferon alfa-2b from Schering-Plough Europe.

Summaries of opinion for all mentioned medicines, including their full indication, can be found [here](#).

Review of bisphosphonates and the risk of osteonecrosis of the jaw

The European Medicines Agency has completed a review on the risk of osteonecrosis of the jaw associated with the use of bisphosphonates. The CHMP was asked to give a scientific opinion on:

- the criteria that define osteonecrosis of the jaw related to bisphosphonates;
- how bisphosphonates may cause osteonecrosis of the jaw;
- whether the risk of osteonecrosis of the jaw is greater with some bisphosphonates or for some groups of patients;
- the measures that could be taken to minimise this risk.

The CHMP has concluded that there is an increased risk of osteonecrosis of the jaw in patients using these medicines. However, further studies should be carried out to better identify the factors that increase the risk and the measures needed to minimise it.

The review was carried out under Article 5(3) of Regulation (EC) 726/2004, opinion on any scientific matter concerning the evaluation of medicinal products for human use. Under this type of procedure the CHMP can give a scientific opinion on any matter concerning the evaluation of medicinal products for human use

More information on the review, including recommendations for patients, dentists and prescribers can be found in a separate question-and-answer document [here](#).

The CHMP initiated two referral procedures under Article 107 for:

- **Propacetamol** (injectable), only approved in France for the symptomatic treatment of pain and fever further to the decision to withdraw the product from the market. The withdrawal was due to risks of serious hypersensitivity reactions, cases of thrombosis and administration site reactions.
- **Antiadiposo** (iodocasein/thiamine), approved only in Italy for treatment of obesity further to the decision to suspend the product from the market due to cases of hyperthyroidism and thyrotoxicosis.

The reviews are carried out under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). These types of procedure are initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally authorised medicine as a result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

A more detailed CHMP meeting report will be published shortly.

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