



European Medicines Agency
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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 13-16 November 2006

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) gave positive opinions on initial marketing authorisation applications, including one opinion for a medicinal product that is intended for the treatment of patients suffering from rare diseases:

- **Exforge, Dafiro, Copalia and Imprida** (amlodipin besylate/valsartan), from Novartis Europharm Ltd, are intended for the treatment of essential hypertension. EMEA review time for Exforge was 173 days and 80 days for Dafiro, Copalia and Imprida.
- **Inovelon** (rufinamide), from Eisai Ltd, is intended for the treatment of seizures associated with Lennox-Gastaut syndrome, one of the most severe forms of childhood epilepsy. EMEA review time was 208 days. Inovelon is the **34th orphan medicinal product** to receive a positive CHMP opinion.
- **Lucentis** (ranibizumab), from Novartis Europharm Ltd, for the treatment of neovascular (wet) age-related macular degeneration (AMD), which causes damage to the retina by abnormal blood vessels growing and leaking into the eye. EMEA review time was 195 days.

The Committee adopted a negative opinion for **Mycograb** (efungumab), from NeuTec Pharma Plc. Mycograb, an orphan medicinal product, was intended to be used for the treatment of invasive candidiasis, in combination with amphotericin B (including lipid-associated formulations). EMEA review time was 207 days.

A separate question and answer document explaining the grounds for the negative opinion can be found [here](#).

Extensions of indication

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

- **Keppra** (levetiracetam), from UCB S.A., to include the treatment of primary generalised tonic-clonic seizures as adjunctive therapy in adults and adolescents from 12 years of age with idiopathic generalised epilepsy. Keppra was first granted a marketing authorisation in the European Union on 29 September 2000 and is currently indicated to treat partial onset seizures and myoclonic seizures in patients with epilepsy.
- **Neupro** (rotigotine), from Schwarz BioSciences GmbH, to include the treatment of the signs and symptoms of advanced-stage idiopathic Parkinson's disease in combination with levodopa. Neupro was first granted a marketing authorisation in the European Union on 15 February 2006 and is currently indicated to treat signs and symptoms of early stage idiopathic Parkinson's disease.

'Informed consent' applications

The Agency adopted positive opinions for a number of medicinal products for which 'informed consent' applications were submitted. This type of application requires that reference is made to an authorised medicinal product and that the marketing authorisation holder of this reference product has given consent to the use of the dossier in the application procedure.

- **Insulin Human Winthrop** (insulin human), from Sanofi-Aventis Deutschland GmbH, is recommended for the treatment of diabetes mellitus where treatment with insulin is required. The

reference product for this application is Insuman, also from Sanofi-Aventis Deutschland GmbH. EMEA review time was 110 days.

- **Irbesartan Hydrochlorothiazide BMS** (irbesartan/hydrochlorothiazide*), from Bristol-Myers Squibb Pharma EEIG, is intended for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on Irbesartan or Hydrochlorothiazide alone. The reference product for this application is Karvezide, also from Bristol-Myers Squibb Pharma EEIG. EMEA review time was 50 days.
- **Irbesartan Hydrochlorothiazide Winthrop** (irbesartan/hydrochlorothiazide*), from Sanofi Pharma Bristol-Myers Squibb SNC, is recommended for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on Irbesartan or Hydrochlorothiazide alone. The reference product for this application is CoAprovel, also from Sanofi Pharma Bristol-Myers Squibb SNC. EMEA review time was 50 days.
- **Irbesartan BMS** (irbesartan), from Bristol-Myers Squibb Pharma EEIG, is recommended for treatment of essential hypertension and treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an anti-hypertensive regimen. The reference product for this application is Karvea, also from Bristol-Myers Squibb Pharma EEIG. EMEA review time was 50 days.
- **Irbesartan Winthrop** (irbesartan), from Sanofi Pharma Bristol-Myers Squibb SNC, is recommended for the treatment of essential hypertension and treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an anti-hypertensive regimen. The reference product for this application is Aprovel, also from Sanofi Pharma Bristol-Myers Squibb SNC. EMEA review time was 50 days.

New contraindications

The Committee recommended to add a contraindication for **Ketek and Levviax** (telithromycin), from Aventis Pharma S.A., saying that Ketek or Levviax must not be used in patients with previous history of hepatitis and/or jaundice associated with the use of telithromycin. Ketek and Levviax were first granted marketing authorisation on 9 July 2001 and are currently authorised for a number of respiratory-tract infections.

Summaries of opinions, including more detailed information on the new indications or contraindications for all products mentioned above are available and can be found [here](#).

Referral procedures concluded

The Committee concluded two referral procedures, one for **Ciprofloxacin Nycomed** 2mg/ml solution for infusion (ciprofloxacin), from Nycomed Danmark APS, and one for **Ciprofloxacin Kabi** (ciprofloxacin hydrogen sulphate), from Fresenius Kabi Nederland B.V. The Committee recommended the harmonisation of the dosing recommendation for the treatment of complicated urinary tract infections, and of the maximum daily dose for adults in approved indications, across the European Union. The procedures were initiated under Article 29 of Directive 2001/83/EC as amended because of disagreement in the context of the mutual recognition procedure.

Re-examination application withdrawn

The Committee was informed by Les Laboratoires Servier of their decision to withdraw the application for re-examination of the negative opinion for **Valdoxan** and **Thymanax** (agomelatine), adopted by the Committee on 27 July 2006.

A question and answer document explaining the grounds for the negative opinion and the next steps in the procedure can be found [here](#).

*Correction: The version of the press release published on 17 November 2006 stated irbesartan/hydrochloride instead of irbesartan/hydrochlorothiazide as active substance for these two medicinal products.

Update on Tamiflu

Following recent media interest, the CHMP reaffirmed its position of [15 December 2005](#) that there is no new safety signal relating to psychiatric disorders while taking Tamiflu and therefore no need to change the current prescribing advice to doctors in the EU.

The Agency has been aware of incidents of psychiatric disorders associated with the use of Tamiflu since its approval. No causal relationship has been identified between use of Tamiflu and these incidents. The Agency has required Roche to follow closely all reports of such behaviour since the launch of Tamiflu in Europe in February 2003.

Tamiflu, from Roche, was approved in the European Union in June 2002 and is currently indicated for prevention and treatment of influenza in adults and children aged one year or above.

A more detailed CHMP meeting report will be published shortly.

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