



European Medicines Agency
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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
11-14 December 2005

Initial marketing authorisations

The Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions on initial marketing authorisation applications for

- **Neupro** (rotigotine), Schwarz Pharma Ltd. Neupro is indicated for the treatment of idiopathic Parkinson's disease. EMEA review began on 18 October 2004 with an active review time of 202 days.
- **Rotarix** (human rotavirus, live attenuated), GlaxoSmithKline Biologicals S.A. Rotarix is indicated for active immunisation of infants from the age of 6 weeks for prevention of gastro-enteritis due to rotavirus infection. EMEA review began on 20 December 2004 with an active review time of 175 days.

The CHMP adopted a negative opinion for **Zelnorm**, Novartis Europharm Limited. The indication proposed was: the repeated symptomatic short-term treatment of Irritable Bowel Syndrome in women whose predominant bowel habit is constipation. EMEA review began on 18 October 2004 with an active review time of 204 days. A question and answer document has been published and can be found [here](#):

Extensions of indications and other recommendations

The Committee adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union.

- **Invanz** (ertapenem), Merck Sharp & Dohme, to extend its indication to add diabetic foot infections of the skin and soft tissue. Invanz was first authorised in the European Union on 18 April 2002 and is currently indicated for the treatment of bacterial infections.
- **Tamiflu** (oseltamivir), Roche Registration Ltd, to include children between 1 and 12 years of age in the indication prevention of influenza. Tamiflu was first authorised in the European Union on 20 June 2002 and is currently indicated for the treatment of influenza in adults and children from one year of age and for prevention of influenza in adults and adolescents of 13 years and older.

Summaries of opinions for all these products are available and can be found [here](#):

Safety updates

A review by the European Medicines Agency (EMA) of new safety data for **Tamiflu** has concluded that there is no new safety signal relating to psychiatric disorders while taking Tamiflu and therefore no change to the product safety information of Tamiflu is needed. A separate press release has been issued and can be found [here](#).

Rare cases of macular oedema (swelling of the back of the eye) have been reported with rosiglitazone- (**Avandia/ Avandamet**, from SmithKline Beecham) and pioglitazone- (**Actos/Glustin**, from Takeda Europe) containing medicinal products. Following discussions of these post-marketing findings, the CHMP concluded that a further review should be performed to establish whether there is a possible association between macular oedema and the use of rosiglitazone and pioglitazone.

Referral procedures started

The Committee started a referral procedure for **atorvastatin**-containing medicinal products (Sortis and other associated names) in relation to an application submitted by Parke-Davis GmbH to extend the indication to the prevention of cardiovascular events in patients with multiple risk factors. The procedure was initiated by Spain under Article 6(12) of Commission Regulation EC No 1084/2003 because of differences between Member States with regard to the extent of the patient population likely to benefit from atorvastatin therapy in this clinical setting.

The Committee started a referral procedure for **mifepristone**-containing medicinal products (Mifegyne). France triggered this referral following safety and efficacy concerns with regards to the use of the approved dose of 600 mg mifepristone in the indication of "medical termination of developing intra-uterine pregnancy in sequential use with prostaglandin analogue" as compared to the use of a 200 mg mifepristone dose. The procedure was initiated under Article 31 of Directive 2001/83/EC as amended.

A more detailed CHMP meeting report will be published shortly.

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