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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 22-24 January 2007

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) gave positive opinions recommending the granting of marketing authorisations for **Januvia** (sitagliptin) and **Xelevia** (sitagliptin), from Merck Sharp & Dohme. Both products are intended for the treatment of type-II diabetes mellitus in combination with either metformin or, in certain patients, a PPARγ agonist (i.e. thiazolidinedione) to improve glycaemic control when diet and exercise plus the agent in monotherapy do not provide adequate glycaemic control. EMEA review for Januvia began on 29 March 2006 and for Xelevia on 17 September 2006, with active review times of 202 and 85 days respectively.

Extensions of indication

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

- **Prevenar** (pneumococcal conjugate vaccine), from Wyeth-Lederle Vaccines S.A., to include active immunisation of infants and young children from 2 months to 5 years of age against otitis media (middle ear infection) caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23. Prevenar was first granted a marketing authorisation in the European Union on 2 February 2001 and is currently approved for active immunisation of children from 2 months to 5 years of age against sepsis, meningitis, bacteraemic pneumonia and bacteraemia caused by the same serotypes.
- **Xyrem** (sodium oxybate), from UCB Pharma Ltd, to extend the indication to the treatment of narcolepsy with cataplexy in adult patients. Narcolepsy is the inability to regulate sleep-wake cycles normally. Cataplexy is the sudden loss of voluntary muscle tone and is one of the symptoms of narcolepsy. Xyrem is an orphan medicinal product. It was first granted a marketing authorisation in the European Union on 13 October 2005 and is currently approved for the treatment of cataplexy in adult patients with narcolepsy.

Summaries of all mentioned opinions, including more detailed information on the new indications for all products mentioned above are available and can be found here.

Referral procedures concluded

The Committee concluded two referral procedures:

- For **Ciprofloxacin Nycomed Hikma 200 mg/100 ml solution for infusion** (ciprofloxacine lactate), from Hikma Farmaceutica (Portugal) LDA, 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.
- For **Alendronat Hexal 10 mg tablets** (alendronate), from Hexal A/S, Sweden, the Committee recommended to approve the treatment of osteoporosis in men at increased risk of fracture.

Both procedures were initiated under Article 29 of Directive 2001/83/EC as amended because of disagreements between the Member States in the context of the mutual recognition procedure.

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Referral procedures started

The CHMP started referral procedures for **Fentanyl-ratiopharm 25/50/75/100 µg/h Matrixpflaster** (fentanyl) and **Fentanyl-ratiopharm 25/50/75/100 µg/h TTS** (fentanyl), from ratiopharm GmbH, because of disagreement regarding the scope of the proposed indication, the contraindications and the demonstration of bioequivalence with the originator product. Both products are intended for use in the management of severe chronic pain. The procedures were initiated under Article 29 of Directive 2001/83/EC as amended because of disagreement between the Member States in the context of the mutual recognition procedure.

A more detailed CHMP meeting report will be published shortly.

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