European Medicines Agency
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PRESS RELEASE
European Medicines Agency: Committee for Medicinal Products for Human Use 20-23 February 2006

Initial marketing authorisation applications

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

- **Duotrav** (travoprost/timolol maleate), Alcon Laboratories. Duotrav is an eye-drops solution, intended for the decrease of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. EMEA review began on 18 May 2005 with an active review time of 196 days.
- **Evoltra** (clofarabine), Bioenvision Limited. Evoltra is indicated for the treatment of acute lymphoblastic leukaemia in paediatric patients. EMEA review began on 16 August 2004 with an active review time of 209 days. Evoltra is the **twenty-fifth orphan-designated medicinal product** to receive a positive CHMP opinion.
- **M-M-RVAXPRO** (measles, mumps and rubella vaccine (live)), Sanofi Pasteur MSD. M-M-RVAXPRO is a vaccine intended for prophylaxis against measles, mumps and rubella. EMEA review began on 21 June 2004 with an active review time of 193 days.
- **Preotact** (parathyroid hormone), Nycomed Danmark ApS. Preotact is intended for the treatment of osteoporosis in postmenopausal women at high risk of fractures. EMEA review began on 14 March 2005 with an active review time of 224 days.
- **Tygacil** (tigecycline), Wyeth Europa Ltd. Tygacil is intended for complicated skin and soft-tissue infections and complicated intra-abdominal infections. EMEA review began on 24 January 2005 with an active review time of 182 days.

The Committee adopted a negative opinion for **ATryn** (recombinant antithrombin alfa), from Genzyme Europe. ATryn was intended to be used in patients undergoing surgery with congenital antithrombin deficiency for the prophylaxis of deep-vein thrombosis and thromboembolism. EMEA review began on 23 February 2004 with an active review time of 207 days. A question-and-answer document has been published and can be found here.

Similar biological medicinal products

The CHMP adopted a positive opinion for **Valtropin** (somatropin) from BioPartners, a similar biological medicinal product. Valtropin contains somatropin, a growth hormone produced by recombinant DNA technology, and is indicated for the treatment of growth disturbance and growth-hormone deficiency. Valtropin is similar to Humatrope, the reference medicinal product already authorised in the EU. EMEA review began on 19 July 2004 with an active review time of 179 days.

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:

- **Erbitux** (cetuximab) from Merck KGaA, to extend its indication to add the treatment of locally advanced squamous cell cancer of the head and neck in combination with radiation therapy.

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Erbitux was first authorised in the European Union on 29 June 2004 and is currently approved for the treatment of metastatic colorectal cancer.

- **Sifrol** (pramipexole) and **Mirapexin** (pramipexole), from Boehringer Ingelheim International GmbH, to extend their indication to add symptomatic treatment of moderate to severe idiopathic restless legs syndrome. Sifrol was first authorised in the European Union on 14 October 1997 and Mirapexin on 23 February 1998. Both are currently approved for the treatment of signs and symptoms of advanced idiopathic Parkinson's disease.
- **Enbrel** (etanercept), from Wyeth Europe Ltd, to include an alternative dosing regimen of 50 mg once weekly, which will allow treatment of ankylosing spondylitis and psoriatic arthritis to be added as new indications in Enbrel 50 mg. Enbrel was first authorised in the European Union on 3 February 2000 and is currently approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis.

Summaries of opinions for all these products are available and can be found here.

Review procedure started

The Committee started a review for the centrally authorised vaccines **HBVAXPRO** (recombinant Hepatitis B virus small surface antigen (HBsAg)) and **Procomvax** (haemophilus influenzae b conjugate and Hepatitis B (recombinant) vaccine), both from Sanofi Pasteur MSD. The review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, is intended to assess the efficacy of the two products. HBVAXPRO and Procomvax share the same recombinant Hepatitis B component as Hexavac. The marketing authorisation of Hexavac is currently suspended due to concerns about long-term protection against Hepatitis B (for more information on Hexavac see press release and question-and-answer document with advice to patients and healthcare professionals published at the time of the suspension).
The Committee is now reviewing all available data to determine whether similar concerns would also apply to HBVAXPRO and Procomvax.
There is no immediate concern for children or adults vaccinated with these products. Further statements will be made as soon as the information becomes available.

A more detailed CHMP meeting report will be published shortly.

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