European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 16-19 February 2009

Initial evaluation – positive opinions
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions, recommending the granting of a marketing authorisation for the following medicines:

- **Conbriza** (bazedoxifene), from Wyeth Europa Ltd. Conbriza is indicated for the treatment of postmenopausal osteoporosis in women at increased risk of fracture. EMEA review began on 27 September 2007 with an active review time of 202 days.
- **Exalief** (eslicarbazepine acetate) and **Zebinix** (eslicarbazepine acetate), from BIAL-Portela & C, S.A. Exalief and Zebinix are indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. EMEA review began on 26 March 2008 with an active review time of 205 days.
- **Pantozol Control** (pantoprazole) from Nycomed GmbH. Pantozol Control is indicated for the short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults. The medicine will be available without prescription. EMEA review began on 28 May 2008 with an active review time of 197 days.
  In addition, positive opinions were adopted for **Controloc Control, Somac Control, Pantecta Control** and **Pantoloc Control** from Nycomed GmbH. These medicines contain the same active substance (pantoprazole) and are intended for the same indication as Pantozol Control. They will also be available without prescription. Start date for these four medicines was 23 November 2008, with an active review time of 80 days.
- **Removab** (catumaxomab), from Fresenius Biotech GmbH. Removab is indicated for the intraperitoneal treatment of malignant ascites in patients with Ep~CAM-positive carcinomas where standard therapy is not available or no longer feasible. EMEA review began on 30 January 2008 with an active review time of 203 days.

Generic medicinal products
The Committee adopted a positive opinion for **Rivastigmine Teva** (rivastigmine), from Teva Pharma B.V., indicated for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Rivastigmine Teva is a generic of Exelon, which has been authorised in the EU since 12 May 1998. EMEA review began on 23 July 2008 with an active review time of 177 days.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

Initial evaluation – negative opinions
The CHMP adopted a negative opinion, recommending the refusal of a marketing authorisation for **Biferonex** (interferon-beta-1a), from BioPartners GmbH. Biferonex was intended for the treatment of adult patients with relapsing remitting multiple sclerosis characterised by two or more exacerbations in the previous two years. EMEA review began on 15 August 2007 with an active review time of 205 days.

A separate question-and-answer document with more detailed information about the negative opinion is available here.

Extension of indication
There were no opinions on extensions of indication in February 2009.

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Removal of contraindication
The CHMP recommended removing a contraindication for **Telzir**, from Glaxo Group Ltd, saying that patients with severe hepatic impairment should not be treated with the medicine. Telzir in combination with low dose ritonavir is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults, adolescents and children of 6 years and above in combination with other antiretroviral medicinal products.

A summary of opinion can be found here.

CHMP recommends suspension of marketing authorisation for Raptiva
The CHMP has recommended the suspension of the marketing authorisation for Raptiva (efalizumab), from Serono Europe Ltd. The CHMP concluded that the benefits of Raptiva do no longer outweigh its risks, because of modest efficacy and increased safety concerns including the occurrence of progressive multifocal leukoencephalopathy (PML) in patients taking the medicine.

A separate press release and question-and-answer document are available.

European Medicines Agency recommends new contraindication and warning for Rasilez and other aliskiren medicines
The CHMP has recommended adding a contra-indication to the Product Information for aliskiren, stating that it must not be used in patients who have experienced angioedema (swelling of the tissues beneath the skin) when taking aliskiren in the past. The Agency also recommended the inclusion of a warning, stating that patients who develop signs of angioedema should stop treatment and seek medical attention.

A separate press release with more information on the recommendation is available.

Referrals

Referral procedures concluded
The CHMP concluded a referral procedure under Article 29 of Directive 2001/83/EC, as amended, for **Budesonide Sandoz and associated names,** 32 or 64 µg, suspension (budesonide), from Sandoz Pharmaceuticals GmbH. The medicine is indicated for the treatment and prevention of signs and symptoms of seasonal and perennial allergic rhino-conjunctivitis as well as the treatment of nasal polyps.
The procedure was initiated because of disagreements between the Member States regarding the inclusion of the indication in paediatric populations. The CHMP concluded that therapeutic equivalence to the originator in adults is proven and that safety in paediatric populations is established. Therefore the CHMP concluded that the benefit-risk balance of these medicines is positive and recommended granting of the marketing authorisations.
Referrals under Article 29 of Directive 2001/83/EC, as amended, are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure.

A question-and-answer document with more information about this referral can be found here

A more detailed CHMP meeting report will be published shortly.

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