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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
10-13 October 2005

Initial marketing authorisations

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

- **Exubera** (insulin human), Aventis/Pfizer EEIG. Exubera is human insulin that is administered through inhalation. It is indicated for the treatment of adult patients with Type 2 diabetes mellitus who are not adequately controlled with oral antidiabetic agents and require insulin therapy. Exubera is also indicated for the treatment of adult patients with Type 1 diabetes mellitus, in addition to long- or intermediate-acting subcutaneous insulin, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns. EMEA review began on 23 February 2004 with an active review time of 208 days.
- **Ionsys** (fentanyl hydrochloride iontophoretic (HCI) transdermal patch), Janssen-Cilag International N.V. Ionsys is a transdermal patch indicated for the management of acute, moderate to severe post-operative pain, for use in a hospital setting only. EMEA review began on 19 July 2004 with an active review time of 199 days.

Extensions of indications

The Committee adopted positive opinions on extension of indication for the following products that are already authorised in the EU:

- **Avandamet** (rosiglitazone/metformin), from SmithKline Beecham plc, to extend the indication to triple oral combination treatment with sulphonylurea. Avandamet was first authorised in the EU on 20 October 2003 and is indicated in the treatment of Type 2 diabetes.
- **Axura** (memantine), from Merz Pharmaceuticals, and **Ebixa** (memantine), from Lundbeck A/S, to extend the indication to the treatment of patients with moderate to severe Alzheimer's disease. Axura and Ebixa were previously only indicated for patients with moderately severe to severe Alzheimer's disease*. Axura was first authorised in the EU on 17 May 2002 and Ebixa on 15 May 2002.

The Committee recommended that the indication of **Exelon** and **Prometax** (rivastigmine), from Novartis Europharm Ltd, should not be extended to add dementia associated with Parkinson's disease. Exelon was first authorised in the EU on 12 May 1998 and Prometax on 4 December 1998. Both products are indicated for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

Summaries of opinion for initial marketing authorisation applications and applications for extensions of indication are available here.

* Correction of previous indication for Axura and Ebixa.

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Pandemic influenza preparedness

In the context of the EMEA's preparedness for pandemic influenza, the CHMP made a commitment to accelerate the scientific evaluation of applications for scientific advice and marketing authorisation for pandemic influenza vaccines 'core dossiers', thus increasing pandemic influenza preparedness and helping to ensure that such vaccines are available to EU citizens as soon as possible in the event of an outbreak.

The EMEA has developed the concept of 'core dossiers' to facilitate the submission and review of applications for pandemic influenza vaccines. This concept allows the CHMP to review the bulk of an application prior to the actual outbreak of a pandemic. Once the specific strain of the influenza virus is known, the Committee could approve a variation to this core dossier, following a 'rolling review', within a few days. More information on the core dossier concept can be found in the CHMP 'Guideline on dossier structure and content for pandemic influenza vaccine marketing authorisation application', available here.

New Chair of the Pharmacovigilance Working Party

The CHMP elected Dr June Raine as the new Chair of the Pharmacovigilance Working Party. Dr Raine is a member of the Executive Board of the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).

A more detailed CHMP meeting report will be published shortly.

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