European Medicines Agency
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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 21-24 January 2008

Positive opinions
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted 3 positive opinions, recommending the granting of a marketing authorisation, for the following medicines:

- **Effentora** (fentanyl citrate), from Cephalon U.K., for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. EMEA review began on 21 March 2007 with an active review time of 204 days.
- **Pradaxa** (dabigatran etexilate mesilate), from Boehringer Ingelheim International, for the prevention of venous thromboembolic events. EMEA review began on 21 February 2007 with an active review time of 205 days.
- **Thalidomide Pharmion** (thalidomide), from Pharmion Ltd, for the treatment of multiple myeloma. EMEA review began on 21 February 2007 with an active review time of 177 days. Thalidomide is the 45th orphan medicine to receive a positive opinion. A separate press release and a question-and-answer document explaining the grounds for the positive opinion and the risk management plan approved by the CHMP are available.

Negative opinion
The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Lenalidomide-Celgene Europe** (lenalidomide), from Celgene Europe. Lenalidomide-Celgene Europe was intended to be used for the treatment of anaemia due to myelodysplastic syndromes. It was designated as an orphan medicine. EMEA review began on 28 September 2005 with an active review time of 176 days.

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

New contraindication
The CHMP recommended the addition of a new contraindication for rosiglitazone-containing medicines (**Avandia**, **Avandamet**, **Avaglim**), stating that rosiglitazone must not be used in patients with an acute coronary syndrome, such as angina or some types of myocardial infarction. The CHMP also recommended the inclusion of a new warning stating that rosiglitazone is not recommended in patients with ischaemic heart disease and/or peripheral artery disease.
A separate press release on these changes is available here.

In addition the CHMP agreed to change the product information for Avaglim (rosiglitazone maleate/glimepiride) to delete the contraindication for its use in combination with insulin.

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

Re-examination procedures concluded
Following the re-examination of the negative opinion adopted in September 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Mylotarg** (gemtuzumab ozogamicin), from Wyeth Europa Limited. Mylotarg was intended for the re-induction treatment of

CD33-positive acute myeloid leukaemia adult patients in first relapse who are not candidates for other intensive re-induction chemotherapy regimens (e.g. high-dose Ara-C).

A separate question-and-answer document with more detailed information on the grounds for the final negative opinion is available here.

Referral procedures started

The CHMP started a referral procedure for **medicinal products containing a fixed combination of dextropropoxyphene and paracetamol,** intended for the treatment of pain, because of safety concerns related to overdose. The procedure was initiated by the European Commission under Article 31 of Directive 2001/83/EC as amended.

The CHMP started a referral procedure for **Ribavirin iQur**, 200 mg hard capsules, 200 mg, 400 mg, 600 mg film-coated tablets, (ribavirin), from iQur Pharmaceuticals, because of disagreements on the grounds for approval of the medicine in the context of the decentralised procedure. Ribavirin iQur is indicated for the treatment of chronic hepatitis C (HCV) and to be used only in combination with peginterferon-α2a or interferon-α2a. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC) as amended.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended, at the request of the European Commission, in order to harmonise the product information across the EU of the following authorised medicines:

- **Tritace,** 1.25 mg, 2.5 mg, 5 mg and 10 mg capsules and tablets, (ramipril), from Sanofi-Aventis, indicated for the treatment of mild to moderate hypertension in patients of 55 years or more who have clinical evidence of cardiovascular disease, stroke or peripheral vascular disease or in diabetic patients of 55 years or more with cardiovascular risk factors.
- **Tritazide,** 5 mg/ 25 mg and 25 mg/125 mg tablets, (ramipril and hydrochlorothiazide), from Sanofi-Aventis, indicated for the treatment of hypertension in patients (in whom combination therapy is appropriate), who have been stabilised on the individual components given in the same proportion.

The CHMP started a referral procedure for **Menomune**, (Meningococcal Polysaccharide Vaccine**,** Groups A, C, Y and W-135 combined), from Sanofi Pasteur MSD, indicated for prophylaxis of meningitis caused by the meningococcal bacteria groups A, C, Y and W-135. The procedure was initiated by Italy under Article 36 of Directive 2001/83/EC as amended because of manufacturing concerns.

A more detailed CHMP meeting report will be published shortly.

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