



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)

15-18 February 2010

5th pandemic vaccine recommended for approval

The Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the granting of a conditional marketing authorisation for a fifth pandemic vaccine, **Humenza** (split virion, inactivated, AF03 adjuvanted influenza H1N1 pandemic vaccine), from Sanofi Pasteur SA, intended for the prophylaxis of influenza in an officially declared pandemic situation. This recommendation was made using an emergency procedure which fast-tracks evaluation of new vaccines developed during a pandemic.

More information on pandemic medicines is available in a separate [press release](#).

Other positive opinions for new medicines adopted

The Committee adopted a positive opinion, recommending the granting of a conditional marketing authorisation, for **Votrient** (pazopanib), from Glaxo Group Ltd, intended for the treatment of patients with advanced renal cell carcinoma. The review for **Votrient** began on 25 March 2009 with an active review time of 210 days. **Votrient** is the **63rd orphan medicinal product** to receive a positive opinion by the CHMP.

A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of **Votrient** this relates to clinical data of pazopanib in comparison with sunitinib in the treatment of patients with advanced renal cell carcinoma. The European Medicines Agency will review new information within one year and update the product information as necessary.

The summaries of opinion for this medicine, including the full indication, can be found [here](#).



Negative Opinion for Zeftera adopted

The Committee adopted a negative opinion, recommending that **Zeftera** (ceftobiprole medocartil), from Janssen-Cilag International NV, should not be granted a marketing authorisation. Zeftera is an antibiotic, intended for the treatment of patients with complicated skin and soft tissue infections.

More information about Zeftera is available in a [question-and answer-document](#).

Positive opinion for generic medicines adopted

The Committee adopted a positive opinion for **Docefrez** (docetaxel), from Sun Pharmaceutical Industries Europe B.V., a generic of Taxotere, which is authorised in the European Union for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

The Committee adopted a positive opinion for **Raloxifene Teva** (raloxifene hydrochloride), from Teva Pharma B.V., a generic of Evista, which is authorised in the European Union for treatment and prevention of osteoporosis in postmenopausal women.

The summaries of opinion for all mentioned medicines, including their full indication, can be found [here](#).

Positive opinion for the second 'compassionate use' application adopted

The Committee adopted the second positive opinion on compassionate use. This application related to **IV Zanamivir**, a new intravenous formulation of zanamivir, from GlaxoSmithKline Research & Development, to treat critically ill patients having a life-threatening condition due to pandemic or seasonal influenza.

More information about this compassionate use procedure is available [here](#)

Extensions of indication – positive opinion adopted

The Committee gave positive opinions for applications for an extension of the therapeutic indication, adding new treatment options for medicines that are already authorised in the European Union:

- **Cholestagel** (colesevelam), from Genzyme Europe B.V., to extend the therapeutic indication, to include combination treatment of colesevelam with ezetimibe, with or without a statin, in adult patients with primary hypercholesterolaemia, including patients with familial hypercholesterolaemia.
- **Tyverb** (lapatinib), from Glaxo Group Ltd, to extend the therapeutic indication to include the treatment of patients with breast cancer whose tumours overexpress HER2 (ErbB2), in combination with an aromatase inhibitor in postmenopausal women with hormone receptor-positive metastatic disease, not currently intended for chemotherapy. The patients in the registration study were not previously treated with trastuzumab or an aromatase inhibitor.

Summaries of opinion for all mentioned medicines, including their full indication, can be found [here](#).

Review of Regranex concluded

Finalising a review of **Regranex** (bercaplermin), from Janssen-Cilag International NV, and the possible risk of cancer, the Committee concluded that the benefits of this medicine continue to outweigh its risks for diabetic patients with long-term skin ulcers, but recommended to contraindicate Regranex, as a precautionary measure, in patients who have any pre-existing cancer.

More information about this review is available in a separate [press release](#) and [a question-and-answer document](#).

Arbitrations concluded

The Committee completed arbitration procedures initiated because of disagreement among EU Member States regarding the authorisation of **Clopidogrel Teva 75 mg Film coated Tablets** (clopidogrel), from Teva Pharma, and **Clopidogrel Orion 75 mg Film coated Tablets** (clopidogrel), from Orion Corporation. These medicines are generics of Plavix and are indicated for patients suffering from myocardial infarction, ischaemic stroke, established peripheral arterial disease or acute coronary syndrome. The procedures were initiated because of concerns regarding the use of a clopidogrel base as the active substance, which had to be stabilised using the antioxidant butylated hydroxyanisole. The Committee concluded that the antioxidant in the medicine did not pose a serious risk to patients and that the benefit-risk profile of these medicines was positive and recommended that marketing authorisations should be granted.

Referral on escitalopram concluded

The Committee recommended that the marketing authorisations of generic **escitalopram**-containing medicinal products from Alfred E. Tiefenbacher GmbH & Co KG and associated companies should be suspended in Member States where these medicines are currently authorised. These medicines are used to treat major depressive episodes. The review was initiated because of disagreements on whether to maintain or suspend the marketing authorisations in the countries where they were authorised. The Committee noted that some of the data to support the applications for the generic medicines were still protected under the data exclusivity rules and could not be used in the assessment of the application. The CHMP was of the opinion that the rest of the submitted data provided insufficient evidence to show that the generic medicines were comparable to the reference medicine and recommended that marketing authorisations should be suspended.

Question-and-answer documents with more information about these referrals can be found [here](#)

Review of nimesulide started

The Committee started a full assessment of the benefits and risks of nimesulide-containing medicinal products for systemic use, because of ongoing concerns over their gastrointestinal and hepatic safety. Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) used to treat acute pain, the symptoms of painful osteoarthritis and primary dysmenorrhoea.

The review was started at the request of the European Commission under Article 31 of Directive 2001/83/EC. The CHMP will make a recommendation on whether marketing authorisations of nimesulide-containing medicinal products should be maintained, changed, suspended or revoked.

Update on supply shortage for Cerezyme and Fabrazyme

The Committee was informed that the supply shortages for Cerezyme and Fabrazyme are continuing for longer than expected and that Genzyme has not resumed full production.

Therefore, patients and prescribers of Cerezyme and Fabrazyme are advised to continue to follow the interim recommendations made by the Committee on [22 October 2009](#) for Cerezyme and [25 September 2009](#) for Fabrazyme.

All patients, especially those with adjusted dose regimens, should be closely monitored by their doctor.

These recommendations remain valid until further notice.

Because the manufacturing difficulties have been on-going since June 2009, the CHMP is closely monitoring the GMP compliance status of the manufacturing site and has requested a further inspection.

A more detailed CHMP meeting report will be published shortly.

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu