



European Medicines Agency  
Press office

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**PRESS RELEASE**  
**Meeting highlights from the Committee for Medicinal Products for Human Use,  
15-18 December 2008**

**Initial evaluation**

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

- **Efient** (prasugrel), from Eli Lilly and Company Limited, for the prevention of atherothrombotic cardiovascular events in patients who are to undergo percutaneous coronary intervention for acute coronary syndrome. EMA review began on 27 February 2008 with an active review time of 204 days;
- **Fablyn** (lasofoxifene), from Pfizer Ltd, for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. EMA review began on 30 January 2008 with an active review time of 203 days;
- **Firmagon** (degarelix), from Ferring Pharmaceuticals A/S, for the treatment of advanced prostate cancer. EMA review began on 26 March 2008 with an active review time of 195 days;
- **Intanza** (influenza vaccine, split virion inactivated), from Sanofi Pasteur MSD SNC, and **IDflu** (influenza vaccine, split virion inactivated), from Sanofi Pasteur S.A., for the prophylaxis of influenza. EMA review began on 26 December 2007 with an active review time of 205 days;
- **Ixiaro** (Japanese encephalitis vaccine, inactivated, adsorbed), from Intercell AG, for the active immunisation against Japanese encephalitis in adults. Ixiaro is the 52nd orphan medicine to receive a positive opinion from the CHMP. EMA review began on 30 January 2008 with an active review time of 204 days;
- **Mepact** (mifamurtide), from IDM Pharma S.A., for the treatment of non-metastatic osteosarcoma. Mepact is the 53rd orphan medicine to receive a positive opinion from the CHMP. EMA review began on 22 November 2006 with an active review time of 205 days.

*Pandemic influenza vaccine*

The CHMP adopted a positive opinion recommending the granting of a marketing authorisation under exceptional circumstances and subject to specific obligations that will be reviewed annually for the pandemic influenza vaccine **Celvapan** (pandemic influenza vaccine (H5N1 whole virion, vero cell derived, inactivated)), from Baxter AG. Pandemic vaccines are vaccines prepared from influenza viruses with a pandemic potential that are intended for use during an officially declared influenza pandemic. EMA review began on 27 February 2008 with an active review time of 205 days.

Further information on pandemic influenza vaccines can be found in a question-and-answer document [here](#).

**Extensions of indication**

The CHMP gave positive opinions for applications for extension of indication, adding new treatment options for the following previously approved medicines:

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\* The information concerning the use of pandemic vaccines has been changed.

- **TachoSil** (human fibrinogen and human thrombin), from Nycomed Austria GmbH, to extend the indication to promote tissue sealing and for suture support in vascular surgery. TachoSil is currently indicated for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient;
- **Zavesca** (miglustat), from Actelion Registration Ltd, to extend the indication to the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease. Zavesca is currently indicated for the oral treatment of mild to moderate type 1 Gaucher disease in patients for whom enzyme replacement therapy is unsuitable. Zavesca is an orphan-designated medicine.

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

### **Update of product information recommended for anti-epileptic medicines**

The CHMP recommended updating the product information of the centrally authorised antiepileptic medicines Keppra (levetiracetam), Lyrica (pregabalin), Vimpat (lacosamide) and Zonegran (zonisamide) with information on available evidence on the risk of suicidal thought and behaviour and the advice to monitor patients for suicidal ideation or behaviour during treatment.

The CHMP recommendation follows a review of the Pharmacovigilance Working Party (PhVWP) of all antiepileptic medicines available in the European Union. Having reviewed the available evidence, the PhVWP concluded that the benefits of these medicines continue to outweigh their risks and that patients should continue to take antiepileptic medicines as prescribed. However, treatment with antiepileptic medicines is associated with a small risk of suicidal thoughts and behaviour, and therefore the product information of all antiepileptic medicines in the EU should be updated with appropriate information.

### **Referral procedures concluded**

The CHMP concluded a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedure is 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. The medicines concerned are:

- **Bleomycin Pharmachemie and associated names**, 15 U, powder for solution for injection (bleomycin), from Pharmachemie BV, used as an anti-cancer agent. The procedure was initiated due to disagreements regarding the safety of the medicine. The CHMP concluded that the benefits of the medicines outweigh the risks. Therefore, the CHMP recommended granting the marketing authorisations. A separate question-and-answer document with more information about the procedure is available [here](#);
- **Sabumalin and associated names**, 100 µg/dose, suspension for pressurised inhalation (salbutamol), from Hexal AG, indicated for treatment of asthma or chronic obstructive pulmonary disease and to prevent asthma symptoms. The procedure was initiated due to disagreements regarding bioequivalence. The CHMP concluded that the medicine is bioequivalent to the reference product and that the benefits of the medicine outweigh the risks. Therefore, the CHMP recommended granting the marketing authorisations. A separate question-and-answer document with more information about the procedure is available [here](#);
- **Sanohex and associated names**, 100 µg/dose, suspension for pressurised inhalation (salbutamol), from Hexal AG, indicated for treatment of asthma or chronic obstructive pulmonary disease and to prevent asthma symptoms. The procedure was initiated due to disagreements regarding bioequivalence. The CHMP concluded that the medicine is bioequivalent to the reference product and that the benefits of the medicine outweigh the risks. Therefore, the CHMP recommended granting the marketing authorisations. A separate question-and-answer document with more information about the procedure is available [here](#);
- **Uman Big**, 180 IU/ml, solution for injection (human hepatitis B immunoglobulin), from Kedrion S.p.A., indicated for the immunoprophylaxis of hepatitis B in specific circumstances. The procedure was initiated due to disagreements regarding safety and efficacy. The CHMP concluded that the benefits of the medicine outweigh the risks. Therefore, the CHMP

recommended granting the marketing authorisations. A separate question-and-answer document with more information about the procedure is available [here](#).

The CHMP concluded referral procedures under Article 30 of Directive 2001/83/EC, as amended. This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level. The CHMP recommended harmonising the product information for the following medicines:

- **Tritace and associated names** (ramipril), from Sanofi-Aventis group of companies and associated companies, indicated for the treatment of hypertension, cardiovascular preventions, myocardial infarction, treatment of renal disease and heart failure. A separate question-and-answer document with more information about the procedure is available [here](#);
- **Tritazide and associated names** (ramipril and hydrochlorothiazide), from Sanofi-Aventis group of companies and associated companies, indicated for the treatment of hypertension. A separate question-and-answer document with more information about the procedure is available [here](#);
- **Zoloft and associated names** (sertraline), from Pfizer group of companies and associated companies, indicated for the treatment of depression, obsessive-compulsive disorder, panic disorder, social anxiety disorder and post-traumatic stress disorder. A separate question-and-answer document with more information about the procedure is available [here](#).

A more detailed CHMP meeting report will be published shortly.

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