European Medicines Agency
*Press office*

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**PRESS RELEASE**
**Meeting highlights from the Committee for Medicinal Products for Human Use, 16-19 March 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:

- **Ellaone** (ulipristal acetate), from Laboratoire HRA Pharma, indicated for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. EMEA review began on 25 June 2008, with an active review time of 203 days.
- **Modigraf** (tacrolimus), from Astellas Pharma Europe B.V., indicated for the prophylaxis and treatment of transplant rejection in adult and paediatric kidney, liver or heart allograft recipients. EMEA review began on 26 December 2007, with an active review time of 205 days.
- **Qutenza** (capsaicin), from NeurogesX UK Ltd, indicated for the treatment of peripheral neuropathic pain in non-diabetic adults, either alone or in combination with other medicinal products for pain. EMEA review began on 27 September 2007, with an active review time of 202 days.
- **Renvela (**sevelamer carbonate), from Genzyme Europe B.V., indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis, and for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. EMEA review began on 26 March 2008, with an active review time of 204 days.

*Generic medicinal products*
The Committee adopted a positive opinion for **Nimvastid (**rivastigmine), from Krka, d.d., Novo mesto, intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Nimvastid is a generic of Exelon, which has been authorised in the European Union (EU) since 12 May 1998. EMEA review began on 25 June 2008, with an active review time of 198 days.

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

**Initial evaluation – negative opinions**
The CHMP adopted negative opinions, recommending the refusal of a marketing authorisation, for the following medicines:

- **Cayston** (aztreonam lysine), from Gilead Sciences International Ltd, intended for use in the management of adult cystic fibrosis patients with chronic airway infection caused by pseudomonas aeruginosa bacteria, to improve their pulmonary function and respiratory symptoms. The medicine was designated as an orphan medicine in June 2004. EMEA review began on 26 March 2008, with an active review time of 204 days.
- **Emerflu** (H5N1 split antigen influenza vaccine Alum adjuvanted), from Sanofi Pasteur. The vaccine was intended for use during an influenza pandemic. EMEA review began on 23 May 2007, with an active review time of 204 days.

*Separate question-and-answer documents with more detailed information about the negative opinions for Cayston and for Emerflu are available.*

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**Extension of indication – positive opinions**
The CHMP gave a positive opinion for an application for the extension of indication, adding a new treatment option for **Glivec** (imatinib), from Novartis Europharm Ltd, to extend the indications to include the adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117) positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.
Glivec is currently indicated for the treatment of adult and paediatric patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia, adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), adult patients with myelodysplastic/myeloproliferative diseases (MD/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangements, adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant GIST, and adult patients with dermatofibrosarcoma protuberans (DFSP).

*A summary of opinion for the mentioned product, including its full indication, can be found here.*

**Benefit-risk review for Regranex started**
The CHMP started a review of the benefits and risks of **Regranex** (becaplermin), from Janssen-Cilag International, because of concerns over its efficacy and safety, particularly relating to a possible risk of cancer. Regranex is indicated, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers $\leq 5$ $cm^2$.
The review was initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.

**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:

- **Betavert N and associated names**, 8/16 mg, tablets (betahistine dihydrochloride), from Henning Arzneimittel GmbH&Co. KG, used as an anti-vertigo drug in Menière's disease. The procedure was initiated as a result of disagreements regarding the therapeutic equivalence with the reference medicinal product. The CHMP concluded that the product can be considered as bioequivalent to the originator, and considered that the benefit-risk balance is positive. The CHMP recommended the granting of a marketing authorisation.
- **Gluscan 500,** 500 MBq/ml, solution for injection (fluorodeoxyglucose($^{18}$F)), from Advanced Accelerator Applications SA, used as a medical imaging product. The procedure was initiated because of disagreements regarding one of the proposed indications (infectious or inflammatory diseases). The CHMP concluded that the use of Gluscan in the proposed indication has been well established and that the benefit-risk balance is positive. The CHMP recommended the granting of a marketing authorisation.

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 the product information for medicines authorised at the level of the Member States. The CHMP recommended the amendment of the summary of product characteristics, labelling and package leaflet for the following medicine:

- **Diovan Comp and associated names** (valsartan/hydrochlorothiazide), from Novartis group of companies and associated companies, intended for the treatment of hypertension.

*Question-and-answer documents with more information about these referrals can be found here.*

A more detailed CHMP meeting report will be published shortly.

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