European Medicines Agency
Press office

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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 19-22 January 2009

Initial evaluation – positive opinions
The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) adopted one positive opinion, recommending the granting of a marketing authorisation for **Synflorix** (pneumococcal polysaccharide conjugate vaccine (adsorbed)), from GlaxoSmithKline Biologicals. Synflorix is indicated for the active immunisation against invasive disease and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age. EMEA review began on 30 January 2008 with an active review time of 209 days.

Generic medicinal products
The Committee adopted a positive opinion for **Ribavirin Teva** (ribavirin), from Teva Pharma B.V., indicated for the treatment of hepatitis C. The reference product for Ribavirin Teva is Rebetol, which is already authorised in the European Union (EU) in the indication applied for. EMEA review began on 28 May 2008 with an active review time of 203 days.

'Informed consent' applications
The Committee adopted one positive opinion for an 'informed consent' application for **Fertavid** (follitropin beta), from Schering-Plough Europe. This type of marketing authorisation application requires that reference is made to an authorised medicine and that the marketing authorisation holder of this reference product has given consent to the use of the dossier in the application procedure. The reference product for Fertavid is Puregon. EMEA review began on 27 July 2008 with an active review time of 89 days.

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

Initial evaluation – negative opinions
The CHMP adopted a negative opinion, recommending the refusal of a marketing authorisation for **Vedrop** (tocofersolan), from Orphan Europe S.A.R.L. Vedrop was intended for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from cystic fibrosis, congenital chronic cholestasis or hereditary chronic cholestasis. EMEA review began on 27 September 2007 with an active review time of 210 days.

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

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

- **Protopic** (tacrolimus), from Astellas Pharma GmbH, to extend the indication 'maintenance treatment'. Protopic is currently indicated for short-term and intermittent long-term treatment of moderate to severe atopic dermatitis in adults.
- **MabThera** (rituximab), from Roche Registration Ltd, to extend the indication to first-line treatment of patients with chronic lymphocytic leukaemia (CLL) in combination with

* corr: Information about a positive opinion to extend the indication for MabThera has been added.

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chemotherapy. MabThera is currently authorised for the treatment of Non-Hodgkins-Lymphoma and severe active rheumatoid arthritis.

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

New contraindication for Fareston recommended

The CHMP recommended that **Fareston** (toremifene), from Orion Pharma, should not be used in patients at risk of prolonged QT intervals or other heart problems. Fareston is currently authorised in the EU as hormone treatment for hormone-dependent metastatic breast cancer in postmenopausal women.

A separate press release and a question-and-answer document with more information on the recommendation are available.

Referrals

Referral procedure for methylphenidate-containing medicines concluded
Finalising a review under Article 31 of Directive 2001/83/EC, as amended, the CHMP concluded that methylphenidate-containing medicines remain suitable for the treatment of children aged six years or older and adolescents with attention deficit/hyperactivity disorder (ADHD). The Committee also recommended that the product information be made consistent across the EU so that all patients, carers and prescribers have the same information for safer and more appropriate use of these medicines.

A separate press release and a question-and-answer-document with more information on the recommendation are available.

Referral procedure for Atifor Chiesi 12 mcg/Atimos/Forair (Formoterol HFA 12mcg) concluded
The CHMP finalised a referral procedure under Article 36 of Directive 2001/83/EC, as amended for **Atifor Chiesi 12 mcg/Atimos/Forair (Formoterol HFA 12mcg)**, intended for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient.
The Committee concluded that these medicines should not be used in children aged from 5 to 12 years because their efficacy could not be demonstrated in this age group. The Committee therefore recommended that the marketing authorisations for these medicines should be changed accordingly.

Article 36 procedures are initiated where one or more Member States consider that there are public health issues relating to a product that may require harmonised regulatory action across the EU.

Referral procedures for Trimetazidine-ratiopharm and Mephatrim concluded
The CHMP finalised two referral procedures under Article 29 of Directive 2001/83/EC, as amended, for **Trimetazidine-ratiopharm**, 35 mg, modified release tablets, (trimetazidine), from ratiopharm GmbH, and for **Mephatrim**, 35 mg, modified release tablets, (trimetazidine), from Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Both medicines are indicated for the treatment of heart disease.
The CHMP concluded that the available data for these two medicines had shown that there is bioequivalence with the reference medicinal product, and that their benefits and risks are taken as being the same as those of the reference product. The CHMP therefore recommended that they should be granted a marketing authorisation in all concerned Member States.
Article 29 procedures are 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.

Separate question-and-answer documents with more information about Trimetazidine-ratiopharm and Mephatrim are available.

A more detailed CHMP meeting report will be published shortly.

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