European Medicines Agency
Press office

London, 20 November 2009
Doc. Ref. EMEA/CHMP/752431/2009

PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP), 16-19 November 2009

Efficacy and safety of H1N1 pandemic vaccines reaffirmed
The European Medicines Agency has reviewed further data on the centrally authorised pandemic vaccines, Celvapan, Focetria and Pandemrix. The Agency has reaffirmed that they have a positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

A separate press release is available here

Positive opinions for new medicines adopted
The Committee adopted positive opinions, recommending the granting of a marketing authorisation, for the following new medicines:

- **Elonva** (corifollitropin alfa), from N.V. Organon, intended for controlled ovarian stimulation for the development of multiple follicles in women participating in an Assisted Reproductive Technology program. The review of Elonva began on 24 December 2008 with an active review time of 205 days.
- **Urorec** and **Silodyx** (silodosin), from Recordati Ireland Ltd, intended for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). The review for Urorec began on 19 November 2008 with an active review time of 205 days. The review for Silodyx began on 26 July 2009 with an active review time of 85 days and was aligned with that of Urorec.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Negative opinion for two medicines adopted
The Committee adopted two negative opinions, recommending that the following medicines should not be granted a marketing authorisation:

- **Nenad (**lisuride), from Axxonis Pharma AG, intended for the treatment of the signs and symptoms of Restless Legs Syndrome.
- **Oncophage (**vitespen), from Antigenics Therapeutics Ltd. Oncophage is an autologous immunotherapy product, intended for the adjuvant treatment of renal cell carcinoma. Autologous immunotherapy products are produced by isolating tumour cells from an individual and processing these tumour cells into a formulation, which is then administered to the individual from whom the tumour cells were isolated to trigger an immune response against the tumour cells.

Question-and-answer documents with more information on these two medicines are available here:

Positive opinions for generic medicines adopted
The Committee adopted positive opinions for a number of generic medicines:

- **Docetaxel TEVA** (docetaxel), from Teva Pharma 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.
- **Telmisartan Teva** (telmisartan), from Teva Pharma B.V., a generic of Micardis, which is authorised in the EU for the treatment of essential hypertension in adults.
- **Temozolomide Teva** (temozolomide), from Teva Pharma B.V., and **Temomedac** (temozolomide), from Alfred E. Tiefenbacher GmbH & Co. KG, generics of Temodal, which is authorised in the EU for treatment of glioblastoma and malignant glioma.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Extensions of indication – positive opinion adopted

The Committee gave a positive opinion for an application for an extension of indication, adding a new treatment option for **Thyrogen (**thyrotrophin alfa), from Genzyme B.V.. The Committee recommended to extend the indication of the use of Thyrogen for ablation of thyroid remnant tissue to patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. Thyrogen is currently authorised for testing undertaken for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Extension of indication – negative opinion adopted

The Committee adopted a negative opinion for **Avastin** (bevacizumab), from Roche Registration Ltd, recommending that the current indication should not be extended to include the use of the medicine alone or in combination with irinotecan in patients with glioblastoma (WHO Grade IV malignant glioma) after relapse.

More information about the reasons for the negative opinion is available in a question-and-answer document.

Removal of contraindications recommended

The Committee recommended that the contraindication for pregnant and breast-feeding women should be deleted from the product information for **Taxotere** (docetaxel) and **Docetaxel Winthrop** (docetaxel), both from Aventis Pharma S.A.. Both medicines are authorised for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Re-examination procedures concluded

The Committee concluded re-examination of previously adopted opinions for two medicines for which an application for a new marketing authorisation was submitted:

- For **Gemesis (**bercaplermin), from Biomimetic Therapeutics Ltd, the CHMP confirmed its previous negative opinion and adopted a final negative opinion, recommending that the medicine should not be granted a marketing authorisation. The medicine was intended for the treatment of periodontally related defects.
- For **Milnacipran Pierre Fabre Medicament** (milnacipran) and **Impulsor** (milnacipran), from Pierre Fabre Médicament, the CHMP confirmed its previous negative opinion and adopted a final negative opinion, recommending that the medicine should not be granted a marketing authorisation. The medicine was intended for the treatment of fibromyalgia syndrome.

The Committee also concluded a re-examination of its previous negative opinion on an application for an extension of indication for **Erbitux** (cetuximab), from Merck KgaA, confirming its negative opinion that the indication of Erbitux should not be extended to add the first –line treatment of patients with epidermal growth factor receptor (EGFR) – expressing advanced or metastatic non-small cell lung cancer in combination with platinum-based chemotherapy.

More information about these re-examination procedures is available in separate question-and-answer documens here:

Review of gadolinium-containing contrast agents concluded

Finalising a review of gadolinium-containing contrast agents, the Committee made a set of recommendations aimed at minimising the risk of nephrogenic systemic fibrosis (NSF) with these agents in patients at risk of developing the condition.

Gadolinium-containing contrast agents are used in patients undergoing magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA) scans. The CHMP reviewed these agents because of the association between the use of gadolinium-containing contrast agents and NSF, a rare, serious and sometimes life-threatening condition that is characterised by formation of connective tissues in the skin, joints, muscles and internal organs, in patients with severe kidney problems.

More information about the review is available in a separate press release and a question-and-answer document.

Arbitration concluded

The Committee completed arbitration procedures following a disagreement among EU Member States regarding the authorisation of **Pantoprazole Bluefish** 20&40 mg gastro-resistant tablets (pantoprazole sodium sesquihydrate), from Bluefish Pharmaceuticals AB, and **Pantoprazole Olinka** and associated names, 20 and 40 mg, gastro-resistant tablets (pantoprazole sodium sesquihydrate), from Olinka (UK) Ltd. These medicines are indicated for treatment of gastric and duodenal ulcer, reflux oesophagitis (treatment and prevention of relapse), treatment of non-erosive gastroesophageal reflux disease (GERD), prevention of non steroid anti-inflammatory drugs (NSAIDs) related ulcers, Zollinger-Ellison-Syndrome and eradication of H. pylori. The procedure was initiated because of concerns regarding the bioequivalence study comparing these generic medicines to the reference medicine Pantecta. The Committee concluded that the benefits of these medicines outweigh its risks and that a marketing authorisation can be granted in Sweden.
The review was carried out under Article 29 of Directive 2001/83/EC as amended.

Harmonisation referral concluded

The Committee recommended harmonisation of the prescribing information for **Lescol** (fluvastatin) and associated names, from Novartis group of companies and associated companies. Lescol is used to treat adults with primary hypercholesterolaemia or mixed dyslipidaemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments is inadequate and for secondary prevention of major adverse cardiac events in adults with coronary heart disease after percutaneous coronary interventions. The review was initiated because of differences in the Summaries of Product Characteristics (SPCs), labelling and package leaflets in the countries where the product is marketed.
The review was carried out under Article 30 of Directive 2001/83/EC as amended.

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

CHMP started a review of sibutramine-containing medicines (Reductil, Zelium, Reduxade)

The Committee started a safety review of anti-obesity medicines containing sibutramine, because preliminary data suggest a possible increased risk of serious cardiovascular events. The data raising the concern come from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial), which investigates long-term cardiovascular effects of sibutramine treatment in a population with high cardiovascular risk.

The review was triggered by Germany under Article 107 of Directive 2001/83/EC. As part of this procedure the CHMP will assess the impact of the new data on the benefit-risk balance of these medicines and make a recommendation whether their marketing authorisations should be maintained, changed, suspended or revoked.

A more detailed CHMP meeting report will be published shortly.

-- ENDS --

Media enquiries only to:
Monika Benstetter; Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu