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Press Office

Press release

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

15-18 March 2010

Update on pandemic medicines

The Committee reviewed further results from clinical studies and post-marketing experience for all three centrally authorised pandemic influenza vaccines, **Celvapan**, **Focetria** and **Pandemrix**. The data confirm the expected immunogenicity and safety profile for the vaccines. For Celvapan, the Committee recommended changes to the product information to include additional information on the vaccine's immunogenicity and safety. The latest data on the safety of Celvapan show no unexpected serious safety issue. The most frequent adverse reactions that have been reported are non-serious and as expected.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary. The most recent pandemic influenza pharmacovigilance update report was published on 10 March 2010 and can be found here.

Positive opinion for a biosimilar medicine adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for **Nivestim** (filgrastim), from Hospira UK Ltd, intended for the treatment of neutropenia. This medicine has shown to be similar to the reference medicinal product Neupogen, already authorised in the European Union, in the indication applied for. The review for Nivestim began on 25 March 2009 with an active review time of 210 days.

The summary of opinion for this medicine, including the full indication, can be found here.

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Positive opinions for generic medicines adopted

The Committee adopted positive opinions recommending the granting of marketing authorisations for the following generic medicines:

- **Olanzapine Apotex** (olanzapine), from Apotex Europe BV, a generic of Zyprexa, which is authorised in the European Union for the treatment of schizophrenia.
- **Ribavirin Three Rivers** (ribavirin), from Three Rivers Global Pharma Ltd, a generic of Rebetol, which is authorised in the European Union for the treatment of chronic hepatitis C.
- **Tolura** (telmisartan), from Krka, d.d., Novo mesto, a generic of Micardis, which is authorised in the European Union for the treatment of hypertension.
- **Topotecan Hospira** (topotecan), from Hospira UK Ltd, a generic of Hycamtin, which is authorised in the European Union for the treatment of carcinoma of the ovary and cervix and of small cell lung cancer.

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

Positive opinion for an extension of indication adopted

The Committee gave a positive opinion for an application for an extension of the therapeutic indication, adding a new treatment option for **Tarceva** (erlotinib), from Roche Registration Ltd. The Committee recommended to extend the therapeutic indication to include maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after four cycles of standard platinum-based first-line chemotherapy.

The summary of opinion for this medicine, including the full indication, can be found here.

Restriction of indication for Kepivance adopted

The Committee recommended to restrict the therapeutic indication of **Kepivance** (palifermin), from Biovitrum AB (publ), to patients with haematological malignancies receiving myeloablative radiochemotherapy associated with a high incidence of severe mucositis and requiring autologous haemopoietic stem cell support, further to the results of a clinical study.

The summary of opinion for this medicine, including the full indication, can be found here.

Re-examination procedure on gadolinium containing contrast agents concluded

The Committee concluded a re-examination of **gadolinium-containing contrast agents**, confirming its previous opinion and the set of recommendations aimed at minimising the risk of nephrogenic systemic fibrosis (NSF) associated with the use of these agents.

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 the formation of connective tissues in the skin, joints, muscles and internal organs, in patients with severe kidney problems.

Arbitration on Levact concluded

The Committee completed an arbitration procedure initiated because of disagreement among EU Member States regarding the authorisation of **Levact** powder for concentrate for solution for infusion (bendamustine hydrochloride) and associated names, from Astellas Pharma GmbH. These medicines are indicated for the treatment of chronic lymphocytic leukaemia in patients for whom treatment with fludarabine is not appropriate, of non-Hodgkin's lymphoma in patients who have had a relapse following treatment containing rituximab, and of multiple myeloma in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and cannot be treated with thalidomide or bortezomib. This procedure was initiated because of concerns regarding the efficacy of the medicinal product in non-Hodgkin's lymphoma and in multiple myeloma. The Committee concluded that the benefit-risk profile of these medicines was positive in non-Hodgkin's lymphoma and in multiple myeloma and recommended that marketing authorisations should be granted in all indications applied for.

Harmonisation referral on candesartan concluded

The Committee recommended harmonisation of the prescribing information for **Atacand** (candesartan cilexetil) and associated names, from AstraZeneca and associated companies. These medicines are authorised to treat patients with essential hypertension and patients with heart failure and impaired left ventricular systolic function. The review was initiated because of differences in the Summaries of Product Characteristics, labelling and package leaflets in the countries where these products are marketed.

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

New paediatric indication for Sortis

The CHMP recommended a line extension for **Sortis** (atorvastatin calcium), from Pfizer Ltd, to add chewable tablets, a pharmaceutical formulation suitable for the paediatric population. The paediatric formulation has been developed for the treatment of hypercholesterolaemia in adolescents and children aged 10 years or older. The CHMP also recommended that this indication be approved for the currently available presentations of Sortis (film-coated tablets).

The Committee's recommendation was made on the basis of data generated in accordance with an agreed paediatric investigation plan (PIP).

The changes to the marketing authorisation for Sortis were recommended under Article 29 of Regulation 1901/2006, the Paediatric Regulation. This allows companies to submit to the European Medicines Agency an application for a new indication, a new pharmaceutical form or a new route of administration for medicines that are already authorised at the level of the Member States. Once the CHMP opinion has been transformed into a decision by the European Commission, the company will be able to market Sortis with the new formulation and indication in all EU Member States where the medicine is authorised.

Review of antifibrinolytics started

The Committee has started an assessment of the benefits and risks of **antifibrinolytics** containing **aprotinin, aminocaproic acid** and **tranexamic acid**. Antifibrinolytics are used to prevent the loss of blood or reduce the number of transfusions needed during surgery.

This follows an earlier review of aprotinin-containing medicines, which led to the suspension of their marketing authorisations on 15 February 2008 due to concerns over an increased risk of mortality observed in a clinical study. Germany has now requested a review under Article 31 of Directive 2001/83/EC to compare the benefits and risks of the above mentioned antifibrinolytics. The CHMP is asked to make a recommendation on whether the suspension of the marketing authorisations of aprotinin-containing medicinal products should be maintained or lifted, or whether their marketing authorisations should be revoked. The Committee will also make a recommendation on whether the marketing authorisations of aminocaproic acid and tranexamic acid containing medicinal products should be maintained, changed, suspended or revoked.

A more detailed CHMP meeting report will be published shortly.

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