20 May 2011
EMA/CHMP/306703/2011
Press Office

Press release

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

16-19 May 2011

Positive opinions for new medicines adopted

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

- **Benlysta** (belimumab), from Glaxo Group Ltd, intended as add-on therapy in adult patients with active autoantibody-positive systemic lupus erythematosus with a high degree of disease activity. The review for Benlysta began on 23 June 2010 with an active review time of 210 days.
- **Vibativ** (telavancin), from Astellas Pharma Europe B.V., intended for the treatment of adults with nosocomial pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA). The review for Vibativ began on 18 November 2009 with an active review time of 210 days. This is the first antibacterial medicine to receive a positive CHMP opinion in two years, albeit in a restricted indication, addressing an increased need for new antibiotics.
- **Victrelis** (boceprevir), Merck Sharp & Dohme Ltd, intended for the treatment of chronic hepatitis-C genotype-1 infection, in combination with peginterferon alpha and ribavirin, in adult patients with compensated liver disease who are previously untreated or for whom previous therapy has failed. The review for Victrelis began on 15 December 2010 with an active review time of 120 days. The Committee carried out an accelerated assessment of this medicine, because it found that boceprevir could answer the unmet medical need to provide improved treatment options for chronic hepatitis-C genotype-1 naïve as well as pretreated patients. Boceprevir is the first of a new class of medicines for the treatment of chronic hepatitis that directly inhibit the replication of the hepatitis-C virus in hepatitis-C-virus-infected host cells.
- **Xgeva** (denosumab), from Amgen Europe B.V., intended for the prevention of skeletal-related events in adults with bone metastases from solid tumours. The review for Xgeva began on 23 June 2010 with an active review time of 210 days.

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- **Yervoy** (ipilimumab), from Bristol-Myers Squibb Pharma EEIG, intended for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. The review for Yervoy began on 26 May 2010 with an active review time of 210 days.

Re-examination for Fampyra concluded

Following re-examination of its previous negative opinion, the Committee adopted a final positive opinion, recommending the granting of a conditional marketing authorisation for **Fampyra** (fampridine), from Biogen Idec Ltd. Fampyra is intended to improve walking of adult patients suffering from multiple sclerosis with walking disability.

A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Fampyra this relates to a long-term efficacy and safety study to investigate a broader primary endpoint that is clinically meaningful in terms of walking ability and to further evaluate the early identification of responders in order to guide further treatment. The European Medicines Agency will review new information within one year and update the product information as necessary.

More information about this re-examination procedure is available in a separate question-and-answer document on the Agency's website.

Positive opinions for generic medicines adopted

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

- **Temozolomide SUN** (temozolomide), from Sun Pharmaceutical Industries Europe B.V., intended for the treatment of glioblastoma multiforme and malignant glioma. Temozolomide SUN is a generic of Temodal.
- **Levetiracetam ratiopharm** (levetiracetam), from ratiopharm GmbH, and **Levetiracetam Teva** (levetiracetam), from Teva Pharma B.V., intended for the treatment of partial onset seizures. Both medicines are generics of Keppra.

Positive opinion for extension of therapeutic indications adopted

The Committee adopted a positive opinion for an application for extension of the therapeutic indications, adding a new treatment option for a medicine that is already authorised in the European Union (EU), for **RoActemra** (tocilizumab), from Roche Registration Ltd, to include the treatment of systemic juvenile idiopathic arthritis in patients from two years of age and older.

The summaries of opinion for all medicines, including their full therapeutic indications, can be found on the Agency's website.

Review of celecoxib concluded

The Committee finalised its review on the use of the COX-2 inhibitor **celecoxib** in the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis (FAP). The CHMP concluded that existing evidence of safety and efficacy does not support the use of celecoxib in FAP patients.

More information about this review is available in a separate press release and a question-and-answer document on the Agency's website.

Review on buflomedil-containing medicinal products ongoing

The Committee recommended that the supply of oral **buflomedil-containing medicines** be suspended in all EU Member States where it is currently authorised. A review of buflomedil solution for injection is still ongoing. The CHMP will adopt a full opinion once this review is finalised.

Buflomedil, a vasoactive agent, is used to treat peripheral arterial occlusive disease.

The review of buflomedil was initiated following the decision of the French regulatory authority in February 2011 to suspend the marketing authorisation, because serious and sometimes fatal neurological and cardiac side effects continued to occur, mainly related to accidental or intentional overdose, despite risk minimisation measures being put in place by regulatory authorities previously.

More information about this review is available in a separate press release and a question-and-answer document on the Agency's website.

Update on the review of the safety of somatropin-containing medicines

The Committee finalised the first round of its review of the safety of somatropin-containing medicines and agreed on further questions to be sent to the marketing authorisation holders.

While this review is ongoing, the CHMP confirms that the benefit-risk balance of these medicines continues to be positive in the approved therapeutic indications and doses. Prescribers are reminded not to exceed the maximum recommended dose for each approved indication.

The Agency will provide updates as new information becomes available.

Review on trimetazidine-containing medicines started

The Committee has begun looking at the benefit-risk balance of **trimetazidine-containing medicines**, currently used for the prophylactic treatment of angina pectoris crisis, the ancillary symptomatic treatment of vertigo and tinnitus and the ancillary treatment of visual acuity decrease and visual field disturbances due to vascular reasons.

The review was initiated by France following concerns over the benefit-risk balance of trimetazidine-containing medicines in all authorised indications due to the insufficient demonstration of efficacy and the risk of serious adverse events, in particular the occurrence and worsening of Parkinson syndrome.

The Committee will now review all available data to assess the balance of benefits and risks of these medicines.

Review on cilostazol-containing medicines started

The Committee has begun looking at the benefit-risk balance of **cilostazol-containing medicines**, currently used to improve the maximal walking distance and maximal pain-free walking distances in patients with intermittent claudication.

This review was triggered by Spain following the review of all safety reports during the first 18 months of marketing of these medicines. The safety review showed an increased risk of cardiovascular and haemorrhagic reactions. This increased risk has to be assessed in the light of a modest clinical efficacy mainly shown in a population younger than the population receiving these medicines in daily practice.

The Committee will now review all available data to assess the balance of benefits and risks of these medicines.

Harmonisation procedure concluded

The Committee recommended the harmonisation of the prescribing information for the anti-emetic **Kytril** (granisetron), from Roche group of companies. This medicine is used to prevent nausea and vomiting in patients who receive treatments for cancer such as chemotherapy and radiotherapy.

This review was initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where this product is marketed.

A question-and-answer document with more information about this procedure is available on the Agency's website.

Notes

- This press release, together with all related documents, is available on the Agency's website.
- The review on celecoxib was conducted in the context of a formal review under Article 5(3) of Regulation (EC) No 726/2004.
- The review on buflomedil-containing medicines is being conducted in the context of a formal review under Article 107 of Directive 2001/83/EC.
- The reviews of the centrally authorised somatropin-containing medicines NutropinAq, Omnitrope and Valtropin are being conducted in the context of formal reviews under Article 20 of Regulation (EC) No 726/2004.
- The review of nationally authorised somatropin-containing medicines is being conducted in the context of a formal review under Article 107 of Directive 2001/83/EC.
- The review on trimetazidine-containing medicines is being conducted in the context of a formal review under Article 31 of Directive 2001/83/EC.
- Review on cilostazol-containing medicines is being conducted in the context of a formal review under Article 31 of Directive 2001/83/EC.
- The harmonisation procedure for Kytril was conducted in the context of a formal review under Article 30 of Directive 2001/83/EC.
- More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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