News from the EMA

Activities of the CHMP

During its meeting from 16-19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:
- five positive opinions for the **granting of a marketing authorisation** for:

- **Benlysta** (belimumab), from Glaxo, 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; active review time: 210 days.
- **Vibativ** (telavancin), from Astellas Pharma, 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; active review time: 210 days.
- **Victrelis** (boceprevir), from MSD, 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 CHMP carried out an accelerated assessment, since boceprevir could answer the unmet medical need to provide improved treatment options for patients infected with hepatitis-C genotype-1. The review for Victrelis began on 15 December 2010; active review time: 120 days.
- **Xgeva** (denosumab), from Amgen, 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; active review time: 210 days.
- **Yervoy** (ipilimumab), from BMS, 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; active review time: 210 days.

- one positive opinion after the re-examination procedure for the application for:

- **Fampyra** (fampridine), from Biogen Idec, intended to improve walking of adult patients suffering from multiple sclerosis with walking disability.

- **one positive opinion** for the application for **the extension of the indications** for:

- **RoActemra** (tocilizumab), from Roche, to include the treatment of systemic juvenile idiopathic arthritis in patients from two years of age and older.

- two positive opinions for the following generic products:

- **Temozolomide Sun** (temozolomide), from Sun Pharmaceutical, intended for the treatment of glioblastoma multiforme and malignant glioma (reference product: Temodal from Schering Plough)
- **Levetiracetam ratiopharm** and **Levetiracetam Teva** intended for the treatment of partial onset seizures (reference product: Keppra from UCB).

Pharmacovigilance:

Review of celecoxib concluded with negative outcome for FAP

The CHMP 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. Pfizer had voluntary withdrawn the

marketing authorisation of its celecoxib-containing orphan medicine, Onsenal, and the CHMP was concerned that other celecoxib-containing products may be used off-label in this indication.

Review on buflomedil-containing medicinal products ongoing, yet the supply of oral products should be suspended

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. 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. This decision was taken, 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.

Review of the safety of somatropin-containing medicines is ongoing; benefit-risk balance still positive

The CHMP agreed on further questions to be sent to the marketing authorisation holders of somatropin-containing medicines. The CHMP confirms that the benefit-risk balance of these medicines continues to be positive in the approved therapeutic indications and doses; prescribers should not to exceed the maximum recommended dose for each approved indication.

Review on trimetazidine-containing medicines started

The CHMP has begun reviewing 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.

Review on cilostazol-containing medicines started

The CHMP has begun reviewing 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.

Harmonisation procedure concluded

The CHMP recommended the harmonisation of the prescribing information for the anti-emetic **Kytril** (granisetron), from Roche. 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.

Date of the next CHMP meeting: 20-23 June 2011.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu