News from the EMA

Activities of the CHMP

During its meeting from 12-15 December 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- three positive opinions for the **granting of a marketing authorisation** for:

- **Esmya** (ulipristal acetate) 5 mg, tablet, from PregLem France SAS, intended for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.
- **Vepacel (**A/H5N1 pre-pandemic influenza vaccine, whole virion, vero cell derived, inactivated) 7.5 µg Haemagglutinin (HA) antigen per 0.5 ml dose, suspension for injection) from Baxter Innovations GmbH intended for the prophylaxis of H5N1 subtype of influenza A in either a pre-pandemic or pandemic situation in adults aged 18 years and older.
- **Zelboraf (vemurafenib)**, 240mg, film-coated tablet from Roche intended for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

- one positive vote for granting approval for:

- 10-mg/ml syrup of the anti-epilepsy medicine Vimpat to replace the 15-mg/ml syrup recalled earlier in the year

- five positive opinions for the following extensions of indications:

- **Galvus, Jalra, Xiliarx** (vildagliptin), from Novartis, to include treatment of patients as monotherapy who inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance".
- **Procorolan, Corlentor** (Ivabradin), from Servier, to include treatment of certain patients with chronic heart failure.

Pharmacovigilance:
Review of Norditropin: The CHMP concluded that the requested change to the marketing authorisation for Norditropin to include a new indication for use in children with Prader-Willi syndrome cannot be granted.
Review of somatotropin-containing medicines: Following the results of a French study which suggested an increased risk of mortality in patients treated with somatropin compared with the general population a review was made. The CHMP concluded that the benefits of somatropin continue to outweigh its risks, but recommended changes to the product information to ensure that somatropin-containing medicines are used appropriately.

Start of safety reviews:
For the following medicines a safety review was started:
Mabthera (rituximab): due to a the unexpected detection of a contaminant (only found at an early stage of the manufacturing at a site in the US)
Alli, Mircera, Pegasys, Tamiflu, Xeloda, Xenical: European Commission asking for a review of these products manufactured using active substances or other materials produced at a US site (due to concerns with the quality management system at this site).
Iron containing parenteral medicines: France asking for reviewing the benefit-risk-balance due to safety concerns of allergic reactions.
Metoclopramide containing medicines: France asking for a review of the benefit-risk-balance due to efficacy and safety concerns (neurological and cardiological events).
Preflucel (influenza vaccine): Austria asking for reviewing the benefit-risk-balance due to concerns of an increase in reports on hypersensitivity reactions, flu-like symptoms and

ocular reactions in particular with one batch; Baxter has voluntarily withdrawn all batches from the European market.

Date of the next CHMP meeting: 16-19 January 2012.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu