News from the EMA

Activities of the CHMP

During its meeting from 17–20 January 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- five positive opinions for the granting of a marketing authorisation for:

- **Gilenya** (fingolimod), from Novartis, intended for the treatment of adult patients with relapsing remitting multiple sclerosis with high disease activity. The review began on 21 January 2010; active review time: 181 days.
- **Halaven** (eribulin), from Eisai Europe, intended for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. The review began on 26 May 2010; active review time: 180 days.
- **Jevtana** (cabazitaxel), from Sanofi-aventis, intended in combination with prednisone or prednisolone for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. The review began on 26 May 2010; active review time: 208 days.
- **Pravafenix** (fenofibrate/pravastatin), from Laboratoires S.M.B., intended for the treatment of adult patients at high risk of coronary heart disease with mixed dyslipidaemia. The review began on 18 November 2009; active review time: 210 days.
- **Trobalt** (retigabine) from Glaxo, intended as adjunctive treatment of partial onset seizures in adults with epilepsy. The review began on 18 November 2009; active review time: 210 days.

- one negative opinion for the following application:

- **Fampyra** (fampridine), from Biogen Idec Ltd, should not be granted a marketing authorisation. Fampyra was intended to be used to improve the walking ability of adult patients with multiple sclerosis.

- one final negative opinion after re-examination of the previous negative opinion for the following application:

- **Movectro** (cladribine), from Serono, should not be granted a marketing authorisation. Movectro was intended as disease-modifying therapy in relapsing remitting multiple sclerosis.

- one positive opinion for the following informed consent application:

- **Riprazo HCT** (aliskiren/hydrochlorothiazide), from Novartis, intended for the treatment of adult patients with essential hypertension. The review for Riprazo HCT began on 21 November 2010 with an active review time of 60 days. (reference product: Rasilez HCT).

- three positive opinions for the **extension of the indication** for:

- **Baraclude** (entecavir), from BMS Pharma EEIG, to include treatment of adult patients with chronic hepatitis B virus infection and decompensated liver disease.
- **INOmax** (nitric oxide), from INO Therapeutics AB, to include treatment of pulmonary hypertension peri- and post heart surgery.
- **Prezista** (darunavir), from Janssen-Cilag, to include the treatment of HIV infection in adults who have been previously treated with antiretroviral therapy to the 400 mg strength.

Pharmacovigilance:

New recommendations for use of Multaq: Further to the report of two cases of serious liver injury in patients taking the anti-arrhythmic Multaq (dronedarone), from Sanofi-aventis, the Committee recommended, as a precautionary measure, changes to the product information to help manage the possible risk of severe liver complications.

Update on potential presence of endotoxins in Baxter peritoneal dialysis solutions: Since Baxter could not solve the problem of endotoxins **in** peritoneal dialysis solutions and cannot guarantee the production of endotoxin-free solutions from a production line at its Castlebar plant in Ireland the CHMP, at the request of the European Commission, has started a full review of the manufacture of Baxter's dialysis solutions at the affected plant. The recommendations to healthcare professionals and patients were updated.

Review on calcitonin-containing medicines started: The CHMP has begun looking at the increased risk of prostate cancer progression and other types of malignancies in patients taking **calcitonin-containing medicines** for the prevention of acute bone loss. This follows the review of two randomised, double-blind, placebo-controlled clinical trials, suggesting an increased frequency of malignancies.

Date of the next CHMP meeting: 14-17 February 2011.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu