News from the EMA

Activities of the CHMP

During its meeting from 13-16 February 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted:

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

- **Nimenrix** (meningitis vaccine) powder and solvent for solution for injection, from GlaxoSmithKline Biologicals, intended for active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y.
- **Pixuvri** (pixantrone), from CTI Life Sciences, intended for patients with non-Hodgkin's B-cell lymphoma whose cancer is aggressive and has come back after multiple rounds of previous chemotherapy or is not responding to other treatments (conditional approval).
- **Sancuso** (granisetron) 3.1 mg/24 h transdermal patch, from ProStrakan Ltd., intended for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy.

- a positive scientific opinion according to Article 58 of Regulation (EC) No 726/2004, in cooperation with the World Health Organization (WHO), on the following medicine intended exclusively for markets outside the European Union (EU):

- **Pyramax** (pyronaridine plus artesunate), from Shin Poong Pharmaceutical Co. Ltd, for the treatment of acute, uncomplicated malaria infection caused by *Plasmodium falciparum* or by *Plasmodium vivax* in adults and children weighing 20 kg or more, in areas of low transmission with evidence of artemisinin resistance.

- five positive opinions for the following generics:

- **Capecitabine Accord** and **Capecitabine Krka** 150 mg, 300 mg, 500 mg film coated tablet, from Accord Healthcare Ltd, resp. Krka, d.d., Novo mesto, intended for the treatment of colon, colorectal, gastric and breast cancer.
- **Capecitabine Teva,** 150 mg and 500 mg film-coated tablet, from Teva Pharma B.V., intended for the treatment of colon, colorectal, gastric and breast cancer.
- **Sabervel (irbesartan)** 75mg, 150 mg and 300mg film-coated tablets, from Pharmathen S.A., intended for the treatment of essential hypertension, and the treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen.
- **Zoledronic acid Actavis** 4mg/5ml concentrate for solution for infusion, from Actavis Group, intended for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone, and the treatment of tumour-induced hypercalcaemia (TIH).

a positive opinion for the following informed consent application:

- **Riluzole Zentiva** 50 mg film-coated tablet, from Aventis Pharma S.A., intended to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).

- five positive opinions for the following extensions of indications:

- **BYETTA (exenatide),** from Eli Lilly, is also indicated as adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents".

- **Humira (adalimumab),** from Abbott Lab. Ltd, is also indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies."
- **Pegintron (peginterferon alfa-2b),** from Schering-Plough, is also indicated for the tritherapy in combination with ribavirin and boceprevir for adults with chronic hepatitis C (CHC) genotype 1 infection with compensated liver disease who are previously untreated or who have failed previous therapy.
- **Rebetol (ribavirin),** from Schering-Plough, is also indicated for the tritherapy in combination with boceprevir and peginterferon alfa-2b of adults with chronic hepatitis C (CHC) genotype 1 infection with compensated liver disease who are previously untreated or who have failed previous therapy.
- **ViraferonPeg (peginterferon alfa 2b),** from Schering Plough, is also indicated for the tritherapy in combination with ribavirin and boceprevir for adults with chronic hepatitis C (CHC) genotype 1 infection with compensated liver disease who are previously untreated or who have failed previous therapy.

Pharmacovigilance:

Finalisation of reviews:

For the following medicines reviews were finalised:

Aliskiren-containing medicines: The CHMP has recommended that these medicines from Novartis Europharm should be contraindicated in patients with diabetes or moderate to severe renal impairment who take angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). In addition a warning should be included that the combination of aliskiren and ACE inhibitor or ARB is not recommended in all other patients because adverse outcomes cannot be excluded.

Anti-tuberculosis medicines: dose recommendations for used in children: The CHMP has concluded its review of dosing recommendations from the World Health Organization (WHO) for first-line anti-tuberculosis medicines in children. While acknowledging that the dosing regimen of these therapies is difficult to define in children due to the limited data available and several other influencing factors, it agreed with the WHO dosing recommendations for ethambutol, isoniazid, pyrazinamide and rifampicin for children above three months.

Aprotinin-containing medicines: The CHMP has recommended that the suspension of the marketing authorisations for aprotinin-containing medicines in the European Union (EU) be lifted. This follows a full review of the benefits and risks of all antifibrinolytic medicines, which found that the results of the BART study on which the suspension was based are unreliable.

Vivaglobin (human normal immunoglobulin for s.c. injection): The CHMP has recommended changes to the manufacturing process to prevent the presence of impurities and thus reduce the risk of thromboembolic events.

Orlistat-containing medicines: The CHMP has concluded that the benefit of these medicines continue to outweigh their risks in the treatment of obese or overweight patients with a body mass index of 28 kg/m^2 or above. The product information for these products should be harmonised to ensure that the information on possible very rare liver-related side effects is the same for all orlistat-containing medicines.

Victrelis (boceprevir): The CHMP has recommended updating the prescribing information with information about drug interactions between this hepatitis C medicine and the ritonavir-boosted HIV protease inhibitors atazanavir, darunavir and lopinavir.

Halaven (eribulin): The CHMP has agreed that a letter should be sent to healthcare professionals in the EU to clarify the way the strength of this medicine is expressed in the product information. This is expected to avoid misunderstanding and ensure that patients are given the correct dose. Halaven contains eribulin mesilate, which releases the active substance, eribulin. The strength of Halaven is expressed in the product information in terms of the active substance, eribulin, in line with EU guidelines. However, the strength of Halaven is often expressed in terms of the salt in the scientific literature as well as in

the prescribing information used in some countries, including the United States of America (USA).

Start of reviews:
For the following medicines reviews were started:
Rocephin (ceftriaxon): triggered by the European Commission to harmonise the product information across the member states.
Levothyroxine Alapsis: due to disagreements regarding the benefit-risk ratio in the paediatric population.

GMP matters:
Continuing its review on the shortcomings in quality assurance identified at Ben Venue Laboratories, Ohio, United States, the CHMP has confirmed its initial advice and given final recommendations for 12 out of 14 centrally authorised medicines manufactured at this site (Angiox, Busilvex, Vidaza, Vistide, Velcade, Ecalta diluent, Soliris, Cayston, Luminity, Mepact, Torisel and Vibativ). These medicines can continue to be prescribed as previously.

Date of the next CHMP meeting: 12-15 March 2012.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu