News from the EMA

Activities of the CHMP

During its meeting from 14-17 February 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:
- three positive opinions for the granting of a marketing authorisation for:

- **Hizentra** (human normal immunoglobulin), from CSL Behring GmbH, intended for replacement therapy in adults and children in primary immunodeficiency syndromes, and in myeloma or chronic lymphatic leukaemia patients with severe secondary hypogammaglobulinaemia and recurrent infections. The review began on 24 March 2010; active review time: 210 days
- **Methylthioninium chloride Proveblue** (methylthioninium chloride), from Provepharm S.A.S., intended for acute symptomatic treatment of methaemoglobinaemia induced by medicinal and chemical products. The review began on 30 December 2009; active review time: 210 days. Provepharm S.A.S. has been assigned SME (small and medium-sized enterprise) status by the European Medicines Agency.
- **Rasilamlo** (aliskiren/amlodipine), from Novartis Europharm Ltd, intended for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone. The review for Rasilamlo began on 23 December 2009; active review time: 208 days.

- one positive opinion for the following informed consent application:

- **Sprimeo HCT** (aliskiren/hydrochlorothiazide), from Novartis, intended for the treatment of adult patients with essential hypertension. The review for Sprimeo HCT began on 19 December 2010 with an active review time of 60 days. (reference product: Rasilez HCT).

- one positive opinion for the **extension of the indication** for:

- **Humira** (adalimumab), from Abbott Laboratories Ltd, to include treatment of juvenile idiopathic arthritis in patients aged 4 to 12 years

- two positive opinions for the following generic products:

- **Ibandronic Acid Sandoz** (ibandronic acid), from Sandoz Pharmaceuticals GmbH, and for **Ibandronic Acid HEXAL** (ibandronic acid), from Hexal AG, intended for the prevention of skeletal events in patients with breast cancer and bone metastases. Ibandronic Acid Sandoz and Ibandronic Acid HEXAL are generics of Bondronat from Roche.

Supply shortage of Simponi: The CHMP has been informed of a manufacturing problem with **Simponi** (golimumab) pre-filled pens, from Janssen Biologics B.V, which will lead to a temporary shortage of this presentation of the medicine in some EU Member States. To deal with the shortage, the Committee is recommending that affected patients should be switched to the other presentation of Simponi, the pre-filled syringe, or to alternative treatments as advised by their doctors. Simponi is a medicine for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

Pharmacovigilance:

Restrictions on use of Zerit (stavudine), from BMS Pharma EEIG**:** The CHMP recommended that in view of the side effects, for both HIV-infected adults and children,

the medicine should be used for as short a time as possible and only when there are no appropriate alternatives.

Restrictions on use of Tygacil (tigecycline), from Wyeth Europa Ltd: The CHMP recommended to ensure that the medicine is used appropriately, by making prescribers aware that the medicine has been associated with an increased mortality in clinical studies.

The medicine should only be used in its approved therapeutic indications, namely in the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections, and only when other antibiotics are not suitable.

New contraindication for Brinavess (vernakalant), from MSD: The CHMP recommended an update to the contraindications of **Brinavess**, following review of a case of severe hypotension and cardiogenic shock in a patient who was enrolled in an ongoing clinical trial. A letter was agreed which would alert healthcare professionals of the new contraindication: Any patient receiving Brinavess should be frequently monitored during administration of the medicine and up to two hours after the start of infusion until clinical and ECG parameters have stabilised, and patients must not be given any i.v. anti-arrhythmic medicines (class I or class III) within 4 hours prior to and up to 4 hours after vernakalant administration.

Arbitration concluded: The CHMP completed an arbitration procedure initiated by the Netherlands because of disagreement among EU Member States regarding the authorisation of the generic medicine **Docetaxel Teva Generics**, from Teva Generics B.V. This medicine is intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. This procedure was initiated because of concerns that bioequivalence studies with Docetaxel Teva Generics had not been performed. The Committee concluded that additional data was not needed and that the benefit-risk balance of this medicine is positive. The CHMP therefore recommended that marketing authorisations should be granted in the Netherlands as well as in all the concerned Member States.

Review of buflomedil-containing medicines started: The CHMP has begun looking at the high risk of cardiac and nervous toxicity, especially following accidental or voluntary overdose, in patients taking **buflomedil-containing medicines** for the treatment of symptoms of peripheral arterial occlusive disease. This follows the suspension of the marketing authorisation of these medicines in France, based on the review of all available safety information. The CHMP will now review all available data and will assess their impact on the balance of the risks and benefits of these medicines.

Review of pholcodine-containing medicines started: The CHMP has begun looking at the potential link between the use of **pholcodine-containing medicines** and anaphylactic reactions in patients subsequently exposed to neuromuscular blocking agents (NMBA) used in anaesthesia. This follows the publication of studies suggesting that pholcodine induces immunologic stimulation in exposed individuals, and that in some Member States where pholcodine is no longer marketed, a decrease in reports of NMBA-related anaphylaxis has been observed. Pholcodine-containing medicines are used to treat cough in children and adults. The CHMP will now review all available data and will assess their impact on the balance of risks and benefits of these medicines

Update on the review on narcolepsy and the possible association with Pandemrix

The CHMP reviewed further data from Finland on the suspected link between narcolepsy in children and adolescents and Pandemrix (influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted)), from GSK Biologicals S.A. The CHMP concluded that the new

evidence added to the concern arising from case reports in Finland and Sweden, but that the data were still insufficient to establish a causal relationship between Pandemrix and narcolepsy. Further analyses and study results are awaited to clarify the observations in Finland.

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

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