EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)

14-17 February 2011

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

The Committee 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 GlaxoSmithKline Biologicals S.A. The Committee 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.

More information about this review is available in a separate press release on the Agency's website.

Positive opinions for new medicines adopted

The Committee adopted positive opinions recommending the granting of marketing authorisations for the following new medicines:

- **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 for Hizentra began on 24 March 2010 with an active review time of 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 for Methylthioninium chloride Proveblue began on 30 December 2009 with an active review time of 210 days. Provepharm S.A.S. has been assigned SME (small and medium-sized enterprise) status by the European Medicines Agency.

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- **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 with an active review time of 208 days.

Positive opinion for informed consent application adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for **Sprimeo HCT** (aliskiren/hydrochlorothiazide), from Novartis Europharm Ltd, 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. This application was an informed consent application referring to the dossier of the authorised medicine Rasilez HCT.

Positive opinion for generic medicines adopted

The Committee adopted positive opinions recommending the granting of a marketing authorisation for the generic medicines **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.

Positive opinion for extension of therapeutic indication adopted

The Committee adopted a positive opinion for an application for extension of the therapeutic indications, adding a new treatment option for a medicine that is already authorised in the European Union (EU), for **Humira** (adalimumab), from Abbott Laboratories Ltd, to include treatment of juvenile idiopathic arthritis in patients aged 4 to 12 years.

The summaries of opinion for all medicines, including their full therapeutic indications, can be found on the Agency's website.

Restrictions on use of Zerit

The Committee recommended that in view of the side effects seen with **Zerit** (stavudine), from Bristol-Myers Squibb Pharma EEIG, the therapeutic indications should be restricted. The Committee recommended that, for both adults and children, the medicine should be used for as short a time as possible and only when there are no appropriate alternatives.

Zerit is used in combination with other antiviral medicines to treat adults and children who are infected with human immunodeficiency virus (HIV).

More information about this review is available in a separate question-and-answer document on the Agency's website.

Restrictions on use of Tygacil

The Committee recommended that the product information for **Tygacil** (tigecycline), from Wyeth Europa Ltd, should be amended 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.

More information about this review is available in a separate question-and-answer document on the Agency's website.

New contraindication for Brinavess

The Committee recommended an update to the contraindications of **Brinavess** (vernakalant), from Merck Sharp & Dohme Ltd, following review of a case of severe hypotension and cardiogenic shock in a patient who was enrolled in an ongoing clinical trial. The new contraindication extends the time during which patients who received Brinavess should not be given any intravenous anti-arrhythmic medicine (class I and III) to 4 hours after administration.

The CHMP agreed a letter to be sent to healthcare professionals reminding them that 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 that 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.

Brinavess is indicated for rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults.

More information including the full contraindication for Brinavess is available in a summary of opinion on the Agency's website.

Supply shortage of Simponi

The Committee 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 European Union (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.

More information about this review is available in a separate question-and-answer document on the Agency's website.

Arbitration concluded

The Committee completed an arbitration procedure initiated by the Netherlands because of disagreement among EU Member States regarding the authorisation of the generic docetaxel-containing 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.

A question-and-answer document with more information about this arbitration procedure is available on the Agency's website.

Review of buflomedil-containing medicines started

The Committee 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 thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and will assess their impact on the balance of the risks and benefits of these medicines.

Review of pholcodine-containing medicines started

The Committee 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 thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and will assess their impact on the balance of risks and benefits of these medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of Pandemrix and the occurrence of cases of narcolepsy is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 27 August 2010.
3. The review of Docetaxel Teva Generics was conducted under Article 29 of Directive 2001/83/EC.
4. The review of buflomedil-containing medicines is being conducted under Article 107 of Directive 2001/83/EC, as amended.
5. The review of pholcodine-containing medicines is being conducted in the context of a formal review, initiated by France on 31 January 2011, under Article 31 of Directive 2001/83/EC, as amended. The Committee will make recommendations on whether the marketing authorisations for pholcodine-containing medicines should be maintained, changed, suspended or revoked.
6. A more detailed CHMP meeting report will be published shortly.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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