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Press Office

Press release

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

18-21 January 2010

4th pandemic vaccine recommended for approval

The Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the granting of a conditional marketing authorisation for a fourth pandemic vaccine, **Arepanrix** (split virion, inactivated, AS03 adjuvanted influenza H1N1 pandemic vaccine), from GlaxoSmithKline Biologicals, intended for the prophylaxis of influenza in an officially declared pandemic situation. This recommendation was made using an emergency procedure which fast-tracks evaluation of new vaccines developed during a pandemic.

More information on pandemic medicines is available in a separate press release

Other positive opinions for new medicines adopted

The Committee adopted a positive opinion, recommending the granting of a conditional marketing authorisation, for **Arzerra** (ofatumumab), from Glaxo Group Ltd, intended for the treatment of patients with chronic lymphocytic leukaemia who are refractory to fludarabine and alemtuzumab. The review for Arzerra began on 25 February 2009 with an active review time of 188 days. Arzerra is the 62nd orphan medicinal product to receive a positive opinion by the CHMP.

A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Arzerra this relates to clinical data on the long term use of Arzerra in the double (fludarabine and alemtuzumab) refractory population and comparative clinical data on the use of Arzerra in the fludarabine-refractory, bulky lymphadenopathy population (patients ineligible for alemtuzumab). The European Medicines Agency will review new information within one year and update the product information as necessary.

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Positive opinion for generic medicines adopted

The Committee adopted a positive opinion for **Ribavirin BioPartners** (ribavirin), from BioPartners GmbH, a generic of Rebetol, which is authorised in the European Union for the treatment of hepatitis C as part of a combination treatment with peginterferon alfa-2b or interferon alfa-2b.

The summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Positive opinion for the first 'compassionate use' application adopted

The Committee adopted the first positive opinion on compassionate use under the European rules on compassionate use. This application related to **Tamiflu IV**, a new intravenous formulation of oseltamivir, from F. Hoffmann-La Roche Ltd, to treat critically ill patients having a life-threatening condition due to pandemic or seasonal influenza.

A separate press release with more information about the compassionate use procedure is available here.

Review of Tysabri concluded

Finalising a review of **Tysabri**, from Elan Pharma International Ltd, and the risk of progressive multifocal leukoencephalopathy (PML), a rare brain infection caused by the JC virus, the Committee concluded that the benefits of this medicine continue to outweigh its risks for patients with highly active relapsing-remitting multiple sclerosis, but recommended further measures to manage the risk of PML.

More information about this review is available in a separate press release and a question-and-answer document.

Review of sibutramine concluded

The Committee completed a review of the safety and efficacy of **sibutramine**-containing medicines, recommending the suspension of the marketing authorisation for these medicines because their benefits as a weight-loss aid did not outweigh their cardiovascular risks.

More information about the review is available in a separate press release and a question-and-answer document.

Harmonisation referral on Losec concluded

The Committee recommended harmonisation of the prescribing information for **Losec** and associated names (omeprazole) from AstraZeneca. The medicine is authorised to treat diseases where the stomach produces too much acid. The review was initiated because of differences in the Summaries of Product Characteristics, labelling and package leaflets in the countries where the product is marketed.

A question-and-answer document with more information about this referral can be found here

Review of bufexamac started

The Committee started a safety review of **bufexamac** containing topical medicinal products, because of concerns over allergic contact reactions. Bufexamac is a non-steroidal anti-inflammatory drug (NSAID) used to treat dermatological and proctological diseases.

The review was triggered by Germany under Article 107(2) of Directive 2001/83/EC. As part of this procedure the CHMP will assess the impact of these concerns on the benefit-risk balance of these medicines and make a recommendation whether their marketing authorisations should be maintained, changed, suspended or revoked.

A more detailed CHMP meeting report will be published shortly.

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