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)

15 - 18 November 2010

Positive opinion for a new medicine adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for a new medicine, **Pumarix** [pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)], from GlaxoSmithKline Biologicals S.A., intended for prophylaxis of influenza in an officially declared pandemic situation. Pumarix is a mock-up vaccine. This means that the current strain can be changed to the pandemic strain once identified. The review for Pumarix began on 6 August 2009 with an active review time of 104 days.

Positive opinion for a generic medicine adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for the generic medicine Lamivudine/Zidovudine Teva (lamivudine/zidovudine), from Teva, for the antiretroviral combination therapy of Human Immunodeficiency Virus infection. Lamivudine/Zidovudine Teva is a generic of Combivir.

Positive opinions for extensions of therapeutic indications adopted

The Committee adopted positive opinions for applications for extensions of the therapeutic indications, adding new treatment options for medicines that are already authorised in the European Union (EU), for **Plavix, Iscover** and **Clopidogrel Winthrop** (clopidogrel), from Sanofi Pharma Bristol-Myers Squibb SNC and Bristol-Myers Squibb Pharma EEIG, to include the prevention of atherothrombotic and thromboembolic events, including stroke, in adult patients with atrial fibrillation who have at least one risk factor for vascular events and who cannot take vitamin K antagonist therapy.

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

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Review of impact of detection of unexpected viral DNA in live attenuated vaccines concluded

The Committee finalised a review of the impact of the detection of unexpected viral DNA fragments from porcine circovirus in some **live attenuated vaccines** using a new testing method. The Committee concluded that the presence of unexpected viral DNA in these vaccines does not pose a risk to public health, because the type of virus found does not cause disease in humans.

Live attenuated vaccines are vaccines that contain viruses that have been 'attenuated' (weakened) so that they trigger an immune response but do not cause disease. Examples of vaccines of this type that are authorised in the European Union include those used to protect against polio, measles, mumps, rubella, or gastroenteritis caused by rotavirus infection.

More information about the review of live attenuated vaccines is available in a separate press release and a question-and-answer document on the Agency's website.

Re-examination procedure on modafinil-containing medicines concluded

Finalising a re-examination procedure on **modafinil-containing medicines**, the Committee confirmed its initial opinion and recommended restricting the use of these medicines to the treatment of sleepiness associated with narcolepsy. Doctors and patients should no longer use these medicines for the treatment of idiopathic hypersomnia, excessive sleepiness associated with obstructive sleep apnoea or chronic shift work sleep disorder.

Modafinil is a wakefulness-promoting agent. The review had been initiated because of a number of safety concerns relating to neuropsychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and the potential for abuse.

A question-and-answer document with more information about this procedure can be found on the Agency's website.

Re-examination procedure on modified-release oral opioids concluded

Finalising a re-examination procedure on **modified-release oral opioid products** in level III of the World Health Organization (WHO) scale for the management of pain, the Committee confirmed its initial opinion and recommended the suspension of formulations using polymethacrylate-triethylcitrate controlled release systems because of their interaction with alcohol. The Committee concluded that other formulations had a positive benefit-risk balance, but recommended harmonising existing warnings regarding concomitant use of all modified-release oral opioid medicines with alcohol.

Modified-release oral opioids of the WHO level III scale for the management of pain are strong painkillers used to treat pain that has not been controlled with other medicines.

A question-and-answer document with more information about this procedure can be found on the Agency's website.

Review of suppositories containing terpenic derivatives started

The Committee has started reviewing a potential increased risk of neurological disorders such as convulsions in children under three years of age receiving suppositories containing terpenic derivatives as adjunctive treatment during benign acute bronchial disorders or oropharyngeal congestive states.

This procedure follows reviews for appropriate use of cough and cold medicines carried out at the level of the Member States throughout Europe.

The CHMP will review all available data to clarify the impact of the potential increased risk of neurological disorders, coupled with limited data on efficacy, on the balance of risks and benefits of these medicines.

Guideline on biosimilars adopted for release for public consultation

The Committee adopted the guideline on 'Similar Biological Medicinal Products Containing Monoclonal Antibodies' for release for a five-month public consultation period. This guideline lays down the non-clinical and clinical requirements for monoclonal antibody-containing medicines claiming to be similar to another one already marketed.

The guideline will be published on the Agency's website shortly.

Notes

1. This press release, together with all relevant documents, is available on the European Medicines Agency's website here.
2. The review of live attenuated vaccines was conducted under Article 5(3) of Regulation (EC) No 726/2004, at the request of the Agency's Executive Director, following the detection, using new testing methods, of endogenous and adventitious viral fragments in manufactured vaccines.
3. The review of modafinil-containing medicines was conducted under Article 31 of Directive 2001/83/EC, as amended.
4. The review of modified-release oral opioids was conducted under Article 31 of Directive 2001/83/EC, as amended.
5. The review of suppositories containing terpenic derivatives is being conducted in the context of a formal review, initiated by France under Article 31 of Directive 2001/83/EC, as amended. Terpenic derivatives include camphor, cineole, pine oil, eucalyptus, terpine, niaouli, turpentine, terpineol and wild thyme. The Committee will make recommendations on whether the marketing authorisations for suppositories containing terpenic derivatives 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 the Agency's website: www.ema.europa.eu

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