News from the EMEA

Activities of the CHMP

During its meeting from 15-18 November 2010 the Committee for Human Medicinal Products (CHMP) adopted:

- one positive opinion for the granting of a marketing authorisation for:

- **Pumarix** [pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)], from GlaxoSmithKline Biologicals, intended for prophylaxis of influenza in an officially declared pandemic situation. Pumarix is a mock-up vaccine: 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.

- **one positive opinion** for the following generic medicine:

- **Lamivudine/Zidovudine Teva** (lamivudine/zidovudine), from Teva, for the antiretroviral combination therapy of HIV infection (generic of Combivir from Viiv Healthcare).

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

- **Plavix, Iscover** and **Clopidogrel Winthrop** (clopidogrel), from Sanofi Pharma BMS and BMS 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.

Pharmacovigilance:

Review of impact of detection of unexpected viral DNA in live attenuated vaccines concluded: The CHMP finalised the 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 and concluded that the 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. Examples of vaccines of this type that are authorised in the EU include those used to protect against polio, measles, mumps, rubella, or gastroenteritis caused by rotavirus infection.

Re-examination procedure on modafinil-containing medicines concluded: The CHMP 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. 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.

Re-examination procedure on modified-release oral opioids concluded: The CHMP confirmed its initial opinion and recommended the suspension of formulations using polymethacrylate-triethylcitrate controlled release systems because of their interaction with alcohol. It was confirmed that other formulations had a positive benefit-risk balance, but existing warnings regarding concomitant use of all modified-release oral opioid medicines with alcohol should be harmonised.

Review of suppositories containing terpenic derivatives started: The CHMP 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.

Guideline on biosimilars containing monoclonal antibodies released for public consultation: The draft guideline on 'Similar Biological Medicinal Products Containing Monoclonal Antibodies' was released 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.

Date of the next CHMP meeting: 13–16 December 2010.

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