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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 19-22 October 2009

Update on H1N1 pandemic vaccines
The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) reviewed early data from clinical studies for the three authorised pandemic vaccines, Celvapan, Focetria and Pandemrix. The Committee concluded to maintain the recommendation it adopted in September, namely that the three vaccines be preferably given as two doses, at least three weeks apart. The data currently available for Pandemrix and for Focetria indicate that one dose may be sufficient in adults, but are too limited to allow the Committee to recommend the general use of a single-dose vaccination schedule.

More information is available in a question and answer document.
The updated product information showing the changes is also available for Focetria and Pandemrix.
The EPAR Summaries for Focetria and Pandemrix have also been updated and can be found on the Agency's pandemic influenza H1N1 website http://www.emea.europa.eu/influenza/vaccines/home.htm

Positive opinions for new medicines
The Committee adopted positive opinions, recommending the granting of a marketing authorisation, for the following new medicines:

- **Scintimun** (besilesomab), from CIS bio international, a radiopharmaceutical intended for use in scintigraphic imaging, in conjunction with other appropriate imaging modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. The review of Scintimun began on 23 July 2008, with an active review time of 203 days.
- **Zenas** (amifampridine), from EUSA Pharma SAS, intended for the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults, a rare disorder of neuromuscular transmission caused by impaired presynaptic release of acetylcholine (Ach). The review of Zenas began on 25 June 2008, with an active review time of 196 days. Zenas is the **60th orphan medicinal product** to receive a positive opinion by the CHMP. The Committee recommended that it be granted a marketing authorisation under 'exceptional circumstances'.

Positive opinion for generic medicine
The Committee adopted a positive opinion for **Sildenafil ratiopharm** (sildenafil), from ratiopharm GmbH, a generic of Viagra, indicated for the treatment of erectile dysfunction.

Positive opinion for 'informed consent' application
The Committee adopted a positive opinion for **Leflunomide Winthrop** (leflunomide), from Sanofi-Aventis Deutschland GmbH, intended for the treatment of adult patients with active rheumatoid arthritis and with active psoriatic arthritis. The application was made as an 'informed consent' application. This type of application requires that reference is made to an authorised medicinal product and that the marketing authorisation holder of the reference product has given consent to the use of their dossier in the application procedure. The reference medicine for Leflunomide Winthrop is Avara.

Summaries of opinions for all mentioned medicines, including their full indication, can be found here.

* The numbering of the orphan medicine that received a positive opinion from the CHMP has been corrected from 59th to 60th.

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Extensions of indication – positive opinions
The Committee gave positive opinions for applications for the extension of indication, adding new treatment options, for the following medicines:

- **Adcirca** (tadalafil), from Eli Lilly Nederland B.V., to change the indication to pulmonary arterial hypertension. Adcirca was previously authorised as Tadalafil Lilly for the treatment of erectile dysfunction. However, this indication is being withdrawn by the marketing authorisation holder and will be replaced by the new indication related to pulmonary arterial hypertension.
- **Angiox** (bivalirudin), from The Medicines Company UK Ltd, to extend the indication to include patients with ST-segment myocardial infarction undergoing primary percutaneous coronary intervention (PCI). Angiox is currently authorised for treatment of adult patients with acute coronary syndromes (unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI)) planned for urgent or early surgical intervention.
- **Cymbalta** (duloxetine), from Eli Lilly Nederland B. V., and **Xeristar** (duloxetine), from Boehringer Ingelheim International GmbH, to extend the indication of these medicines to include treatment of major depressive disorder. Both products are currently authorised for the treatment of major depressive episodes, of diabetic peripheral neuropathic pain in adults and of generalised anxiety disorder.
- **Micardis** (telmisartan), from Boehringer Ingelheim International GmbH, **Pritor** (telmisartan), from Bayer Schering Pharma AG, and **Kinzalmono** (telmisartan), from Bayer Schering Pharma AG, to extend the indication to include the reduction of cardiovascular morbidity in patients with manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease), or type 2 diabetes mellitus with documented target organ damage. These medicines are currently authorised for the treatment of essential hypertension in adults.

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

Clarification of treatment recommendations for Cerezyme agreed
The CHMP agreed to further update the temporary treatment recommendations for Cerezyme to deal with the supply shortage of the medicine. The new temporary recommendations aim to ensure that patients at greatest need continue to receive Cerezyme. The medicine is used in the treatment of patients with Gaucher disease, a disease in which patients do not have enough of an enzyme called glucocerebrosidase.

The updated recommendations are available here.

Review of benefits and risks for Tysabri started
The Committee started a review of the benefits and risks of Tysabri, in view of reports of 23 cases of progressive multifocal leukoencephalopathy (PML) worldwide since Tysabri has been on the market. This review is initiated to discuss any additional measures necessary to ensure the safe use of Tysabri and how to balance the risks to the patients against the benefits of the treatment. Tysabri is indicated for patients suffering from highly active relapsing remitting multiple sclerosis with high disease activity despite treatment with a beta-interferon and for patients with rapidly evolving severe relapsing-remitting multiple sclerosis.

Review and referral procedures

Referral for Myderison concluded
The CHMP concluded a referral procedure for **Myderison** (tolperison hydrochloride), 50 mg and 150 mg film-coated tablets from Meditop Pharmaceutical Co Ltd, indicated for the spasticity of the skeletal muscles. The procedure was initiated because of concerns by some Member States over efficacy and safety. The CHMP concluded that the benefit/risk ratio of Myderison is not considered to be favourable. The CHMP recommended the refusal of the marketing authorisation for Myderison in the Concerned Member States and the revocation of the marketing authorisation in the Member States where the product is currently authorised.

The procedure was initiated under Article 29 of Directive 2001/83/EC, as amended. This type of procedure is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure.

Re-examination procedure for opinion on dextropropoxyphene-containing medicines concluded
Finalising a re-examination procedure for dextropropoxyphene-containing medicines, the Committee confirmed its previous recommendation to withdraw the marketing authorisation for all non-parenteral formulations of these medicines (tablets, capsules and suppositories), because their risks, particularly the risk of potentially fatal overdose, are greater than their benefits.
However, for the parenteral formulation, the Committee concluded that the marketing authorisations should not be withdrawn but suspended until further clinical data are available which may support the re-introduction of this formulation onto the market.

Dextropropoxyphene is a painkiller used to treat acute and chronic pain. It has been available as a prescription-only medicine for about 40 years, either on its own or in combination primarily with paracetamol, as tablets, capsules, suppositories and solutions for injection.

Re-examination for Teicoplanin concluded
Finalising a re-examination procedure for **Teicoplanin Hospira** and associated names (teicoplanin), 200 mg and 400 mg powder and solvent for injection or infusion, from Hospira UK Limited, the Committee confirmed its previous opinion not to grant a marketing authorisation, because bioequivalence to the reference medicine was not adequately demonstrated.

Question-and-answer documents with more information about these referrals can be found here

The Committee adopted an opinion on regulatory action for iodocasein/thiamine
The Committee concluded a review procedure for **iodocasein/thiamine-containing medicines** approved for the treatment of obesity, recommending the revocation of the marketing authorisations of these medicines because of the risks of hyperthyroidism and thyrotoxicosis.

This procedure was initiated under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a decentralised authorised medicine as a result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

Referral procedure for modified-release oral opioids for management of pain started
The Committee started a referral for modified release oral opioids for management of pain medicinal products (containing morphine, fentanyl, oxycodone and hydromorphone) due to concerns on the dissolution of the prolonged-release oral products and their sensitivity and interaction with alcohol, which may cause dose dumping and potential overdose. The procedure was initiated under Article 31 on the request of the European Commission.

Referral procedure for lipid-lowering fibrate medicines started
The Committee started a referral for fibrate medicines (fenofibrate, bezafibrate, ciprofibrate and gemfibrozil) because of concerns over their long-term clinical benefit in the primary and secondary prevention of cardiovascular disease. The procedure was initiated under Article 31 by the UK.

A more detailed CHMP meeting report will be published shortly.

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