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Press Office

**Press release**

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

14-17 December 2009

## Update on pandemic medicines

The Committee has reviewed further data on the centrally authorised pandemic medicines, the pandemic influenza vaccines Celvapan, Focetria and Pandemrix, and the antiviral Tamiflu. In the European Union at least 26 million people have been vaccinated so far and worldwide 13 million patients have taken Tamiflu from 1 May 2009 to 31 October 2009. The Agency has reaffirmed their positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

*More information is available in a separate press release*

## Positive opinions for new medicines adopted

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

- **DuoCover** (Clopidogrel/acetylsalicylic acid), from Bristol-Myers Squibb Pharma EEIG, and **DuoPlavin** (Clopidogrel/acetylsalicylic acid), from Sanofi Pharma Bristol-Myers Squibb SNC; both are fixed combination medicinal products intended for the prevention of atherothrombotic events. The review for DuoCover and DuoPlavin began on 25 March 2009 with an active review time of 172 days.
- **ImmunoGam** (human hepatitis B immunoglobulin), from Cangene Europe Ltd, intended for the immunoprophylaxis against Hepatitis B. The review for ImmunoGam began on 20 August 2008 with an active review time of 205 days.
- **Menveo** (MenACWY), from Novartis Vaccines and Diagnostics S.r.l., intended for the active immunisation of adolescents (from 11 years of age) and adults at risk of exposure to *Neisseria*

* corr. 1: A referenced to orphan drug status for Revolade (page 2) has been added.
* corr. 2: A reference to orphan drug status for Tepadina (page 2) has been added.

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*meningitidis* groups A, C, W-135 and Y, to prevent invasive disease. The review for Menveo began on 19 November 2008 with an active review time of 205 days.

- **Prolia** (denosumab), from Amgen Europe B.V., intended for the treatment of osteoporosis in postmenopausal women at increased risk of fractures and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. The review for Prolia began on 28 January 2009 with an active review time of 212 days.
- **Revolade** (eltrombopag olamine), from GlaxoSmithKline Trading Services Ltd, intended for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP). The review of Revolade began on 24 December 2008 with an active review time of 201 days. Revolade is the **61st orphan medicinal product** to receive a positive opinion by the CHMP.
- **Tepadina** (thiotepa), from ADIENNE S.r.l., intended for the conditioning treatment prior to conventional haematopoietic progenitor cell transplantation. The review for Tepadina began on 23 July 2008 with an active review time of 206 days. Tepadina is the **62nd orphan medicinal product** to receive a positive opinion by the CHMP.

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

## Negative opinion for Cerepro adopted

The Committee adopted a negative opinion, recommending that Cerepro (sitimagene ceradenovec - adenoviral vector-mediated Herpes Simplex Virus-thymidine kinase gene used with subsequent administration of ganciclovir), from Ark Therapeutics Ltd, should not be granted a marketing authorisation. Cerepro is a gene therapy medicinal product, intended for the treatment of high-grade glioma (a type of brain tumour).

Because Cerepro is an advanced therapy medicine, it was assessed by the Committee for Advanced Therapies (CAT). Taking into account the assessment performed by the CAT, the CHMP concluded that the benefits of Cerepro did not outweigh its risks and recommended that it be refused marketing authorisation.

*More information about Cerepro is available in a question-and-answer document.*

## Positive opinions for generic medicines adopted

The Committee adopted positive opinions for **Temozolomide Hexal** (temozolomide), from Hexal AG, **Temozolomide Sandoz** (temozolomide), from Sandoz Pharmaceuticals GmbH and **Temozolomide Hospira** (temozolomide), from Hospira UK Ltd, generics of Temodal, which is authorised in the EU for the treatment of glioblastoma and malignant glioma.

## Positive opinions for 'informed consent' applications adopted

The Committee adopted two positive opinions for marketing authorisations that were submitted as 'informed consent' applications. 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 medicines concerned are:

- **Ristaben** (sitagliptin), from Merck Sharp & Dohme Ltd, intended for the treatment of type 2 diabetes mellitus. The reference medicine for Ristaben is Januvia.

- **Ristfor** (sitagliptin / metformin hydrochloride), from Merck Sharp & Dohme Ltd, intended for the treatment of type 2 diabetes mellitus. The reference medicine for Ristfor is Janumet.

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

## Extensions of indication – positive opinion adopted

The Committee gave a positive opinion for applications for an extension of indication, adding new treatment options for medicines that are already authorised in the European Union:

- **Herceptin** (trastuzumab), from Roche Registration Ltd, to extend the indication to include the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease in combination with capecitabine or 5-fluorouracil and cisplatin. Herceptin is currently authorised as mono-therapy or in combination with other medicines for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2. It is also authorised for the treatment of patients with HER2-positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy.
- **Orencia** (abatacept), from Bristol-Myers Squibb Pharma EEIG, to extend the indication to include treatment of moderate to severe active polyarticular juvenile idiopathic arthritis in paediatric patients from 6 years of age who have had an insufficient response to other disease-modifying anti-arthritic drugs including at least one tumour necrosis factor inhibitor. Orencia is currently authorised as combination therapy for the treatment of moderate to severe active rheumatoid arthritis in adult patients.

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

## Review of benfluorex-containing medicines concluded

Finalising a review of the safety and efficacy of **benfluorex**, the Committee concluded that the benefits of benfluorex no longer outweigh its risks, and that all marketing authorisations for medicines containing benfluorex should be revoked throughout the European Union.

Benfluorex is used as an add-on treatment in patients with diabetes who are overweight. It is used in combination with an appropriate diet.

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

## Review of valproate concluded

The Committee completed a review of the safety and efficacy of **valproate** in the treatment of manic episodes in bipolar disorder, concluding that the benefits of valproate in this condition outweigh its risks, and that marketing authorisations for all solid formulations (e.g. tablets, capsules or granules) of medicines containing valproate throughout Europe should be amended to include the treatment of manic episodes in bipolar disorders when lithium is contraindicated or not tolerated.

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

## Update on the review of sibutramine

The Committee is reviewing data from the Sibutramine Cardiovascular OUTcomes (SCOUT) trial that indicate an increased risk of serious cardiovascular events, such as stroke or heart attack, with medicines containing **sibutramine**. These weight-loss medicines are used to treat obese patients and overweight patients who also have other risk factors such as type-2 diabetes or dyslipidaemia (abnormal levels of fat in the blood).

*More information about the ongoing review of sibutramine is available in a separate press release.*

## Harmonisation referrals concluded

The Committee recommended harmonisation of the prescribing information for **Protium** and associated names (pantoprazole) from Nycomed. 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 (SPCs), labelling and package leaflets in the countries where the product is marketed.

A q*uestion-and-answer document with more information about this referral can be found here*

## Review of topical formulations of ketoprofen started

The Committee started a safety review of topical formulations of **ketoprofen**, an anti-inflammatory treatment, because of concerns over serious photosensitivity reactions.

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

## New paediatric indication for Diovan

The CHMP recommended a line extension for Diovan (valsartan), from Novartis Pharma AG, to add an oral solution, a pharmaceutical formulation suitable for the paediatric population. The paediatric formulation has been developed for the treatment of children and adolescents between 6 and 18 years with hypertension. The CHMP also recommended that this indication be approved for the currently available presentations of Diovan (film-coated tablets).

The Committee's recommendation was made on the basis of data generated in accordance with an agreed paediatric investigation plan (PIP).

The changes to the marketing authorisation for Diovan were recommended under Article 29 of Regulation 1901/2006, the Paediatric Regulation. This allows companies to submit to the European Medicines Agency an application for a new indication, a new pharmaceutical form or a new route of administration for medicines that are already authorised at the level of the Member States. Once the CHMP opinion has been transformed into a decision by the European Commission, the company will be able to obtain approval for the new formulation and indication in all EU Member States where the medicine is authorised.

A more detailed CHMP meeting report will be published shortly.

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