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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 22-25 September 2008

Initial evaluation

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions, recommending the granting of a marketing authorisation, for the following new medicines.

- **Azarga** (brinzolamide / timolol), from Alcon Laboratories (UK) Ltd, intended to decrease intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. . EMEA review began on 26 December 2007 with an active review time of 177 days.
- **Kuvan** (sapropterin dihydrochloride), from Merck KGaA, for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients of 4 years of age and over with phenylketonuria (PKU) who have been shown to be responsive to such treatment. Kuvan is also indicated for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment. Kuvan is the 49th orphan medicine to receive a positive opinion by the CHMP. EMEA review began on 23 November 2007 with an active review time of 200 days.
- **Zypadhera** (olanzapine pamoate), from Eli Lilly Nederland B.V., intended for maintenance treatment of adult patients with schizophrenia. EMEA review began on 20 July 2007 with an active review time of 198 days.

Generic medicinal products

The Committee adopted a positive opinion for **Irbesartan krka** (Irbesartan hydrochloride), from Krka d.d. Novo Mesto, for treatment of essential hypertension and treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen. EMEA review began on 26 December 2007 with an active review time of 205 days. The reference product for Irbesartan krka is Aprovel, which is already authorised in the European Union (EU), in the applied indication.

'Informed consent' applications

The Committee adopted four positive opinions for 'informed consent' applications. This type of marketing authorisation application requires that reference is made to an authorised medicine and that the marketing authorisation holder of this reference product has given consent to the use of the dossier in the application procedure. The medicines concerned are:

- **Jalra** (vildagliptin) and **Xiliarx** (vildagliptin), from Novartis Europharm Ltd, for the treatment of type 2 diabetes mellitus. EMEA review began on 27 July 2008 with an active review time of 60 days. Reference product for both medicines is Galvus.
- **Vildagliptin/metformin hydrochloride Novartis** and **Zomarist** (vildagliptin / metformin hydrochloride), from Novartis Europharm Ltd, for the treatment of type 2 diabetes mellitus. EMEA review began on 27 July 2008 with an active review time of 60 days. Reference product for both medicines is Eucreas.

Extension of indication

The CHMP gave a positive opinion to extend the indication of **Cancidas** (caspofungin), from Merck Sharp & Dohme, to paediatric patients (12 months – 17 years of age). Cancidas is currently authorised for the treatment of severe fungal infections in adults.

This is the first recommendation for the use of a medicine in children on the basis of clinical trial data generated in accordance with an agreed paediatric investigation plan (PIP). A separate press release is available: <http://www.emea.europa.eu/humandocs/PDFs/EPAR/cancidas/50283008en.pdf>

Summaries of opinions for all mentioned products, including their full indication, can be found [here](#).

Referral procedure started

The CHMP started a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedures 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. The medicines concerned are:

- Budesonide Sandoz 32/64 µg nasal spray (budesonide), from Sandoz Pharmaceutical GmbH, indicated for the treatment and prevention of signs and symptoms of seasonal and perennial allergic rhinitis. The procedure was initiated because of a disagreement between the Member States whether the paediatric population should be included.
- Loratadine Sandoz 10, 10 mg tablets (loratadine), from Sandoz BV, intended for symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria. The procedure was initiated because of concerns by some Member States over bioequivalence of the medicine with the innovator product.
- Prokanazol 100 mg, hard capsules (itraconazole), from PRO.MED.CS Praha a.s., intended for the treatment of certain fungal infections. The procedure was initiated because of concerns by some Member States over bioequivalence of the medicine with the innovator product.

In addition, the Committee started one ‘harmonisation referral’ for Protium and associated names (pantoprazole) from Nycomed group of companies and associated companies, used in the treatment of gastroesophageal reflux disease. This type of procedure is initiated under Article 30 of Directive 2001/83/EC as amended, with a view to harmonising product information for medicinal products authorised at Member State level.

A more detailed CHMP meeting report will be published shortly.

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