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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 20-23 July 2009

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

- **Arcalyst** (rilonacept), from Regeneron UK Limited, indicated for the treatment of adults and children aged 12 years and older with severe symptoms of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). CAPS is a rare, inherited condition causing recurrent fever, rash and joint pain. Arcalyst is the **58th orphan medicine** to receive a positive opinion from the CHMP. The review began on 23 July 2008, with an active review time of 197 days**.**
- **Exforge HCT** (amlodipine besylate/valsartan/hydrochlorothiazide), **Copalia HCT** (amlodipine besylate/valsartan/hydrochlorothiazide), **Imprida HCT** (amlodipine besylate/valsartan/hydrochlorothiazide) and **Dafiro HCT** (amlodipine besylate/valsartan/hydrochlorothiazide), all from Novartis Europharm Limited, indicated for the treatment of essential hypertension, as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide. The review for Exforge HCT began on 24 September 2008, with an active review time of 206 days. The review for the three other products began on 29 March 2009, with an active review time of 89 days and was aligned with that of Exforge HCT**.**
- **Ilaris** (canakinumab), from Novartis Europharm Ltd., indicated for the treatment of adults, adolescents and children aged 4 years and older with Cryopyrin-Associated Periodic Syndromes (CAPS), including Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), and severe forms of Familial Cold Autoinflammatory Syndrome (FCAS). CAPS is a rare, inherited condition causing recurrent fever, rash and joint pain. Ilaris is the **59th orphan medicine** to receive a positive opinion from the CHMP. The review began on 24 December 2008, with an active review time of 176 days.
- **Ratioepo (**epoetin theta), **Eporatio** (epoetin theta), both from Ratiopharm GmbH, and **Biopoin** (epoetin theta), from CT Arzneimittel GmbH, indicated for the treatment of symptomatic anaemia associated with chronic renal failure in adult patients and for the treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy. Reviews began on 25 June 2008, with an active review time of 205 days**.**
- **Resolor** (prucalopride), from Movetis NV, indicated for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. The review began on 28 May 2008, with an active review time of 206 days**.**

Positive opinions for 'informed consent' duplicate applications
The Committee adopted positive opinions for duplicate applications for three pandemic influenza mock-up vaccines.
Positive opinions were adopted for duplicate applications of the following mock-up vaccines:

- **Pandemic Influenza Vaccine H5N1 Baxter AG** (whole virion, Vero cell derived, inactivated), from Baxter AG, a duplicate of **Celvapan**, from Baxter AG.

* The numbering of the orphan medicines that received a positive opinion from the CHMP has been corrected from 57th and 58th to **58th and 59th.**

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- **Foclivia** (H5N1 virus surface antigens), from Novartis Vaccines and Diagnostics S.r.L., a duplicate of **Focetria**, from Novartis Vaccines and Diagnostics S.r.L.
- **Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals** (H5N1 split virion, inactivated, adjuvanted with AS03), from GSK Biologicals, a duplicate of **Pandemrix**, from GSK Biologicals.

A separate press release and a question-and-answer document with an update on the Agency's pandemic vaccines activities are available.

The Committee also adopted a positive opinion for **Alendronate sodium and colecalciferol, MSD**, from Merck Sharp & Dohme Ltd, a duplicate application to Fosavance, which is already authorised in the EU for the treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency.

When submitting 'informed consent' duplicate applications, applicants can make reference to a medicine that is already authorised in the EU, provided they have obtained consent from the marketing authorisation holder of the reference medicine to do so.

Positive opinions for generic medicines

The Committee adopted positive opinions for the following generic medicines, for which a reference medicine is already authorised in the European Union:

- **Enyglid (**repaglinide), and **Repaglinide Krka** (repaglinide), both from Krka, d.d., Novo mesto, generics of Novonorm, intended to treat patients with type-2 diabetes.
- **Irbesartan Teva (**irbesartan), from Teva Pharma B.V., a generic of Aprovel, intended for the treatment of essential hypertension.
- **Lamivudine Teva** (lamivudine), from Teva Pharma B.V., a generic of Zeffix, intended for the treatment of chronic hepatitis B in adults.
- **Clopidogrel MYLAN Pharma** (clopidogrel, as besilate), from Mylan S.A.S., a generic of Plavix, intended for the prevention of atherothrombotic events in patients suffering from myocardial infarction or established peripheral arterial disease.

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

Negative opinions for new medicines

The Committee adopted two negative opinions, recommending that marketing authorisations for the following two medicines should be refused:

- **Gemesis** (bercaplermin), from Biomimetic Therapeutics Ltd, intended for the treatment of periodontally related defects.
- **Milnacipran Pierre Fabre Médicament** (milnacipran) and **Impulsor** (milnacipran), both from Pierre Fabre Médicament, intended for the treatment of fibromyalgia syndrome.

Question and-answer documents with more information about the reasons for the refusals can be found here.

Extension of indication – positive opinions

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

- **Isentress** (raltegravir), from Merck Sharp & Dohme Ltd, to extend the indication to include antiretroviral-treatment naïve adult patients. Isentress is currently authorised as combination-therapy with other anti-retroviral medicines for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-experienced adult patients.
- **Keppra** (levetiracetam), from UCB S.A., to extend the age range for use of the medicine to children and infants from 1 month of age in the indication of adjunctive treatment of partial

seizures (fits) with or without secondary generalisation. Keppra is currently authorised in this indication in patients from 4 years of age. It is also currently authorised as monotherapy to treat partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is also authorised as combination therapy to treat myoclonic seizures in patients from 12 years of age with juvenile myoclonic epilepsy and primary generalised tonic-clonic seizures in patients from 12 years of age with idiopathic generalised epilepsy.

- **Mabthera** (rituximab), from Roche Registration Ltd, to extend the indication to include the treatment of relapsed/refractory chronic lymphocytic leukaemia. Mabthera is currently authorised for the treatment of Non-Hodgkin's Lymphoma, first-line treatment of patients with chronic lymphocytic leukaemia (CLL) and second-line treatment of adult patients with severe active rheumatoid arthritis.
- **Torisel** (temsirolismus), from Wyeth Europa Ltd., to extend the indication to include the treatment of adult patients with relapsed and/or refractory mantle cell lymphoma. Torisel is currently authorised for the first-line treatment of patients with advanced renal cell carcinoma.

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

Negative opinions adopted for extensions of indication
The Committee adopted a negative opinion, recommending the refusal of an extension of indication for **Erbitux** (cetuximab), from Merck KGaA. The indication applied for was first-line treatment of patients with epidermal growth factor receptor (EGFR)-expressing advanced or metastatic non-small cell lung cancer in combination with platinum-based chemotherapy. Erbitux is currently authorised for single and combination treatment of patients with EGFR-expressing metatstatic colorectal cancer and as combination therapy for the treatment of patients with squamous cell cancer of the head and neck.

A question-and-answer document with more information about the reasons for the refusals can be found here.

Re-examination procedure concluded
Finalising a re-examination procedure for **Lyrica** (pregabalin), from Pfizer Limited, the Committee adopted a final negative opinion, recommending that the indication should not be extended to the treatment of fibromyalgia in adults.

More information on the re-examination procedure is available in a separate question-and-answer document.

Update on safety of insulin glargine
Following review of all available information on a possible relationship between insulin analogues, in particular insulin glargine, and the risk of cancer, the Committee concluded that the available data does not provide a cause for concern and that changes to the prescribing advice are therefore not necessary.
Insulin glargine is a long-acting insulin analogue, authorised in the European Union (EU) as Lantus and Optisulin, for the treatment of adults, adolescents and children aged six years or above with diabetes, when treatment with insulin is required.

More information is available in a separate press release.

Opinion on paediatric extension for Arimidex adopted
The CHMP adopted an opinion for Arimidex (anastrozole), from AstraZeneca AB, to reflect new clinical data on the use of anastrozole in the treatment of short stature in pubertal boys with growth hormone deficiency in association with exogenous growth hormone, and in the treatment of

testotoxicosis. These data were generated in accordance with an agreed paediatric investigation plan (PIP).
AstraZeneca AB had applied for an extension of indication to include treatment of short stature in pubertal boys with growth hormone deficiency in association with exogenous growth hormone. The Committee's opinion was that the data do not support the authorisation of the medicine for children. However the information on the paediatric studies will be included in the product information. This opinion will be transformed into a decision by the European Commission, after which the Member States must implement the changes adopted.
The opinion was adopted in accordance with Article 29 of the Paediatric Regulation (1901/2006).

Re-examination of referral procedure for Ciclosporin IDL concluded
The Committee finalised a re-examination procedure for a referral under Article 29 of Directive 2001/83/EC, as amended, for **Ciclosporin IDL** and associated names (ciclosporin), 25 mg, 50 mg and 100 mg, capsules from International Drug Licensing (IDL), indicated in transplantation and auto-immune diseases. The Committee concluded that Ciclosporin IDL is not bioequivalent to the reference product and recommended the refusal of the Marketing Authorisation in the Concerned Member States and the suspension of the Marketing Authorisation for Ciclosporin IDL in the Member States where the product is currently authorised.

Referrals under Article 29 of Directive 2001/83/EC, as amended are 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.

A question-and-answer document with more information about this procedure can be found here.

Referral procedure for Meronem and associated names concluded
The CHMP concluded a referral procedure under Article 30 of Directive 2001/83/EC, as amended, for **Meronem** and associated names (meropenem), from AstraZeneca group of companies and associated companies, used as an anti-infective. The CHMP adopted a harmonised product information.
This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level. The CHMP recommended the amendment of the Summary of Product Characteristics, labelling and package leaflet for the following medicinal products:

A question-and-answer document with more information about this referral can be found here.

A more detailed CHMP meeting report will be published shortly.

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