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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 17-19 March 2008

Positive opinion on initial evaluation
The CHMP adopted a positive opinion for **Extavia** (interferon beta-1b), from Novartis Europharm Limited. Extavia is intended for the treatment of patients with multiple sclerosis.

Extavia was assessed 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 this reference product has given consent to the use of the dossier in the application procedure. In the case of Extavia the reference product is Betaferon. EMEA review began on 14 October 2007 with an active review time of 77 days.

Re-examination procedures concluded
Following the re-examination of the negative opinion adopted on 13 December 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Rhucin** (recombinant human C1 inhibitor), from Pharming Group N.V. Rhucin, a designated orphan medicine, was intended to treat sudden attacks of angioedema (swelling of the blood vessels).

A separate question and answer document with more information about the re-examination procedure is available here.

The CHMP concluded the re-examination of the negative opinion adopted on 16 November 2007 for **Cimzia** (certolizumab pegol), from UCB S.A. The CHMP confirmed its previous position and adopted a final negative opinion. Cimzia was intended to be used for reducing signs and symptoms and maintaining clinical response in patients with active Crohn's disease.

A separate question and answer document with more information about the re-examination procedure is available here.

Negative opinion
The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Ceplene** (histamine dihydrochloride), from EpiCept GmbH. Ceplene, a designated orphan medicine, was intended to be used in combination with interleukin-2 for the maintenance of remission in patients with acute myeloid leukaemia in first remission. EMEA review began on 25 October 2006 with an active review time of 202 days.

A separate question-and-answer document with more detailed information about the negative opinion is available here.

Extensions of indication
The Committee gave positive opinions for applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Viread** (tenofovir), from Gilead Science International Limited, to extend the indication to include the treatment of patients with chronic hepatitis B. Viread is currently authorised, in combination with other antiretroviral medicines, for the treatment of HIV-1 infected adults over 18 years of age.

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- **Zevalin** (ibritumomab tiuxetan), from Schering AG, to extend the indication to the consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. Zevalin is currently authorised for the treatment of adult patients with relapsed or refractory follicular B-cell non-Hodgkin's lymphoma, in combination with rituximab.

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

Referral procedures concluded

The CHMP finalised referral procedures under article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) for:

- **Alvesco and associated names,** 40, 80, 160 micrograms, inhaler (ciclesonide), from Altana Pharma AG, for the treatment of obstructive airway disease. The CHMP concluded that the benefits of the medicine outweigh the risks and recommended the granting of a marketing authorisation for Alvesco, subject to certain conditions considered essential for the safe and the effective use of the medicine, including changes in the SPC. The procedure was initiated by United Kingdom due to efficacy and safety concerns on the use of higher doses of the medicine in the treatment of severe asthmatics.
- **Pulairmax,** 100, 200, 400 micrograms/dose, inhalation powder (budesonide), from IVAX Pharmaceuticals UK, for the treatment of asthma. The CHMP concluded that the application does not satisfy the criteria for authorisation in respect of safety and therapeutic equivalence with the reference product, Pulmicort Turbuhaler, and recommended the suspension of the granted marketing authorisation and the refusal of the marketing authorisation, where appropriate. The procedure was initiated by Denmark due to bioequivalence and safety concerns and to the lack of pharmacodynamic and clinical data.

Arbitrations under article 29 of Directive 2001/83/EC are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure.

Finalising a referral procedure under article 6(12) of Regulation (EC) 1084/2003, the CHMP recommended the granting of an extension of indication for **Actira, Avalox, Octegra and associated invented names** (400 mg moxifloxacin as hydrochloride), from Bayer Healthcare AG and Bayer Vital GmbH, to include treatment of mild to moderate pelvic inflammatory disease without an associated tubo-ovarian or pelvic abscess. The data submitted were considered sufficient to demonstrate that the benefits of the medicines outweigh the risks in the indication applied for. Actira, Avalox, Octegra and associated invented names are not recommended for use in monotherapy of mild to moderate pelvic inflammatory disease, unless infection with moxifloxacin-resistant *Neisseria gonorrhoeae* can be excluded. Actira, Avalox, Octegra and associated invented names are currently authorised in a number of Member States as antibiotics.

Procedures under article 6(12) are initiated in cases of disagreement between Member States in the context of the mutual recognition procedure in relation to applications to change the marketing authorisation.

Re-examination of opinion on referral

The CHMP concluded a referral re-examination under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) for **Fentanyl-containing transdermal patches** (Fentastad, Fentador, Fentrans, Matrigesic, Matripain), from STADA Arzneimittel AG, for the treatment of patients with severe chronic pain. The procedure was initiated by a number of Member States in relation to efficacy, safety and bioequivalence concerns. The CHMP confirmed its negative opinion adopted on 16 November 2007 and concluded that the product failed to show adequate characteristics which are key requirements for a product of this type in order to guarantee its safety and efficacy. Therefore the CHMP recommended the refusal of the granting of the marketing authorisations and the suspension of the granted marketing authorisation where appropriate.

Referral procedures started
The CHMP started referral procedures under article 29 of Directive 2001/83/EC for:

- **Sabumalin & Sanohex** 100µg/dose, pressurised inhalation suspension, (salbutamol), from Hexal AG, indicated for the symptomatic treatment of reversible bronchoconstriction due to bronchial asthma and chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema**.**
- **Activelle,** 0.5mg/0.1mg, film-coated tablets, (estradiol/norethisterone acetate), from Novo Nordisk A/S, indicated for Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in women more than one year after menopause and for the prevention of osteoporosis in postmenopausal women at high risk of future fractures**.**
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A more detailed CHMP meeting report will be published shortly.

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