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PRESS RELEASE
Meeting highlights from the Committee for Medicinal Products for Human Use, 19-22 March 2007

Positive opinion for Revlimid
The Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for **Revlimid** (lenalidomide), from Celgene Europe, for the treatment of multiple myeloma. EMEA review began on 29 March 2006, with an active review time of 199 days.

The active substance of Revlimid, lenalidomide, has a chemical structure that resembles that of thalidomide. More information about Revlimid and the measures taken to minimise any risk of harmful effects to unborn children of patients taking the medicine is available in a separate question and answer document.

Other initial marketing authorisation applications
The CHMP adopted positive opinions for:

- **Altargo** (retapamulin), from Glaxo Group Ltd, intended for the short-term treatment of the following superficial skin infections: impetigo and infected small lacerations, abrasions or sutured wounds. EMEA review began on 19 July 2006, with an active review time of 191 days.
- **Orencia** (abatacept), from Bristol-Myers Squibb Pharma EEIG, intended for the treatment of moderately to severely active rheumatoid arthritis. EMEA review began on 28 December 2005, with an active review time of 204 days.

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

- **Herceptin** (trastuzumab), from Roche Registration Ltd, to extend the indication to include Herceptin in combination with an aromatase inhibitor in the treatment of HER2+ and ER and/or PgR positive metastatic breast cancer. Herceptin was first granted a marketing authorisation in the European Union on 28 August 2000 and is currently indicated, as monotherapy or in combination with paclitaxel or docetaxel, for the treatment of metastatic breast cancer and for the treatment of early breast cancer.
- **Remicade** (infliximab), from Centocor B.V., to extend the indication to include the treatment of paediatric Crohn's disease in children aged 6 to 17 years who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy or who are intolerant to or have contraindications for such therapies. Remicade was first authorised in the European Union on 13 August 1999. It is currently indicated for the treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, psoriasis and ulcerative colitis.
- **Tracleer** (bosentan), from Actelion Registration Ltd, to extend the indication to include reduction of the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease. Tracleer was first granted a marketing authorisation in the European Union on 15 May 2002. It is currently indicated for the treatment of pulmonary arterial hypertension (PAH) in selected patient populations with grade-III functional status.

Summaries of all mentioned opinions can be found here.

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Re-examination procedure concluded
Following the re-examination of the negative opinion adopted on 16 November 2006, the CHMP confirmed its previous position and adopted a final negative opinion for **Mycograb** (efungumab), from NeuTec Pharma Plc. Mycograb, an orphan medicinal product, was intended to be used for the treatment of invasive candidiasis, in combination with amphotericin B (including lipid-associated formulations).
A separate question and answer document with more information about the re-examination procedure is available here.

Referral procedure concluded
The CHMP finalised a review procedure for mifepristone-containing medicines that started in December 2005. The review was triggered by France, following safety and efficacy concerns regarding the use of the approved dose of 600 mg **mifepristone,** as compared to the use of a 200 mg dose, in the medical termination of developing intra-uterine pregnancy in sequential use with prostaglandin analogue.
The CHMP concluded that the available data support the effectiveness of a 600 mg dose of mifepristone, followed by the use of prostaglandin analogues, for the termination of pregnancy up to 63 days of amenorrhoea (absence of menstrual periods). In pregnancies up to 63 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 1 mg gemeprost delivered vaginally suggest that 200 mg mifepristone may be as effective as 600 mg mifepristone. However, in pregnancies up to 49 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 400 µg misoprostol delivered orally cannot exclude a slightly higher risk of continuing pregnancies with the 200 mg dose. Based on the available published data, the benefit/risk profile of mifepristone in combination with oral misoprostol for pregnancy from 50 to up to 63 days is unfavourable due to poor efficacy.

The CHMP also recommended the addition of new safety information regarding:
- the risk of fatal infections when 200 mg mifepristone is followed by non-authorised vaginal administration of misoprostol tablets for oral use,
- the interactions of mifepristone with other medicines,
- the use of mifepristone and prostaglandin analogues in patients with haemostatic disorders or severe anaemia.

The procedure was carried out in accordance with Article 31 of the Community Code on medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated to review medicinal products authorised at Member State level, because of public health concerns.

Referral procedures started
The CHMP started a large number of referral procedures under Article 29 of the Community Code on medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated because of disagreements between the EU Member States in the context of the mutual-recognition procedure. The medicines concerned are:
- **Simvastatin Krka** (simvastatin), from Krka Sverige AB,
- **Eformax** (formoterol fumarate), inhalation powder from IVAX Pharmaceuticals UK,
- Fentanyl-containing transdermal patches from STADA Arzneimittel AG (**Fentastad, Fentador, Matripain, Matrigesic** and **Fentrans**).

The CHMP also started three harmonisation referrals under Article 30 of the Community Code on medicinal products for human use. This type of procedure is initiated in order to harmonise the product information of a medicinal product across the European Union. The medicines concerned are:
- **Cozaar** (losartan potassium), from Merck Sharp and Dohme BV,
- **Cozaar Comp** and **Cozaar Comp Forte** (losartan potassium/hydrochlorothiazide), from Merck Sharp and Dohme BV,
- **Lamictal** (lamotrigine), from GlaxoSmithKline.

A more detailed CHMP meeting report will be published shortly.

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