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PRESS RELEASE

Meeting highlights from the Committee for Medicinal Products for Human Use, 27-30 May 2008

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

- **Bridion** (sugammadex), from N.V. Organon, for the reversal of neuromuscular block induced by rocuronium or vecuronium. EMEA review began on 20 July 2007 with an active review time of 203 days.
- **Doribax** (doripenem), from Janssen-Cilag International NV, for the treatment of adult patients with nosocomial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections. EMEA review began on 20 July 2007 with an active review time of 202 days.

Negative opinion
The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Ramelteon** (ramelteon), from Takeda Global Research & Development Centre (Europe) LTD. Ramelteon was intended to be used for the treatment of primary insomnia in patients aged 18 years or older. EMEA review began on 21 March 2007 with an active review time of 210 days.

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

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

- **Erbitux** (cetuximab), from Merck KGaA, to update the current indication for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in combination with chemotherapy and to add an indication for the use as a single agent in KRAS wild-type metastatic colorectal cancer patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. Erbitux is currently indicated in combination therapy for the treatment of patients with metastatic colorectal cancer expressing EGFR after failure of irinotecan, and in combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck.
- **Gardasil** (human papilloma virus vaccine), from Sanofi Pasteur MSD, and **Silgard** (human papilloma virus recombinant vaccine), from Merck Sharp & Dohme to extend the indication to include the prevention of high-grade vaginal dysplastic lesions. Gardasil and Silgard are currently indicated for the prevention of high-grade cervical dysplasia, cervical carcinoma, high-grade vulvar dysplastic lesions and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18.

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

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Re-examination procedure concluded
Following the re-examination of the negative opinion adopted in January 2008, the CHMP confirmed its previous position and adopted a final negative opinion for **Lenalidomide Celgene Europe** (lenalidomide), from Celgene Europe. Lenalidomide Celgene Europe was intended for the treatment of anaemia due to myelodysplastic syndromes. It was designated orphan medicine.

A separate question-and-answer document with more detailed information on the grounds for the final negative opinion is available here.

Referral procedures concluded
The CHMP concluded a re-examination procedure for a referral under Article 29(2) of the Community code on human medicinal products (Directive 2001/83/EC, as amended) for **Coxtral gel**, 3% gel, (nimesulide) from Zentiva A.S., indicated for the symptomatic relief of pain associated with sprains and acute traumatic tendinitis. The procedure was initiated because of disagreement in relation to efficacy concerns. The CHMP confirmed the negative opinion adopted in February 2008 and recommended the refusal of the granting of marketing authorisations and the suspension of the granted marketing authorisations, where appropriate.

Arbitrations under Article 29 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.

The CHMP finalised a harmonisation referral under Article 30 of the Community code on human medicinal products (Directive 83/2001/EC as amended) for **Zyrtec/Reactine and associated names** (cetirizine), from UCB, used as antiallergic and antihistaminic agent. The CHMP recommended the harmonisation of the product information across the European Union (EU). The procedures were initiated by the European Commission.

Article 30 referrals are initiated with a view to harmonising the product information across the EU for medicinal products authorised at Member State level.

Referral procedures started
The CHMP started a referral procedure under Article 29(2) of Directive 2001/83/EC as amended for **Salbutamol Easyhaler "Orion" inhalation powder 100 mcg/ dose and 200 mcg/dose** (salbutamol), from Orion Corporation, intended for the treatment of asthma. The procedure was initiated because of disagreement in relation to therapeutic equivalence with the reference medicine.

The CHMP started a referral procedure under Article 36 for **Forair/Atimos modulite 12 microgram** (formoterol) and associated medicinal products, from Chiesi Farmaceutici SPA, intended for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient. The procedure was initiated by the United Kingdom and the Netherlands because of concerns that therapeutic equivalence of these medicines with the reference medicine is not established for children aged 5 years of older.

Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended for **Topamax** (topiramate), from Janssen-Cilag, used as an anticonvulsant, at the request of the European Commission, with a view to harmonising the product information for this medicine across the EU.

A more detailed CHMP meeting report will be published shortly.

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