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PRESS RELEASE
European Medicines Agency:
Committee for Medicinal Products for Human Use
24-27 July 2006

Initial marketing authorisation applications

The Committee for Medicinal Products for Human Use (CHMP) adopted positive opinions on initial marketing authorisation for:

- **Champix** (varenicline), from Pfizer Limited. The approved indication is cessation of smoking in adults. EMEA review began on 23 November 2005 with an active review time of 175 days.
- **Gardasil** (human papillomavirus (types 6, 11, 16 and 18) recombinant vaccine), from Sanofi Pasteur MSD, and **Silgard** (human papillomavirus (types 6, 11, 16 and 18) recombinant vaccine), from Merck Sharpe & Dohme, indicated for prevention of cancer, precancerous or dysplastic lesions and genital warts caused by the human papillomavirus. EMEA review began on 28 December 2005 with an active review time of 177 days.
- **Luminity** (perflutren), from Bristol-Myers Squibb Pharma Belgium Sprl, indicated for use in patients in whom non-contrast echocardiography was suboptimal and who have suspected or established coronary artery disease. EMEA review began on 21 February 2005 with an active review time of 207 days.
- **Suboxone** (buprenorphine and naloxone), from Schering-Plough Europe, indicated for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. EMEA review began on 26 October 2005 with an active review time of 196 days.

The Committee adopted negative opinions for **Valdoxan** (agomelatine) and **Thymanax** (agomelatine), both from Les Laboratoires Servier. Both medicinal products were intended for the treatment of major depressive disorder. EMEA review began on 28 March 2005 with an active review time of 207 days.

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

Extensions of indications

The Committee adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union:

- **Abilify** (aripiprazole), from Otsuka Pharmaceutical Europe Ltd, to extend the indication to add rapid control of agitation and disturbed behaviours in schizophrenic patients when oral therapy is not appropriate. This indication concerns a new route of administration, Abilify 7.5 mg/ml solution for injection. Abilify was first authorised in the European Union on 4 June 2004. It is currently indicated for the treatment of schizophrenia.
- **Glivec** (imatinib), from Novartis Europharm Ltd, to extend its indication to add treatment of dermatofibrosarcoma protuberans (DFSP) and the treatment of adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL). Glivec was first authorised in the European Union on 11 November 2001. It is currently indicated for the treatment of patients with Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) and for the treatment of adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST).
- **Invanz** (ertapenem), from Merck Sharp & Dohme Ltd, to extend its indication to add prophylaxis of surgical site infection following elective colorectal surgery in adults. Invanz was first authorised in the European Union on 18 April 2002. It is currently indicated for the treatment of intra-abdominal infections, community acquired pneumonia, acute gynaecological infections and diabetic foot infections of the skin and soft tissue.

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- **Lyrica** (pregabalin), from Pfizer Limited, to extend its indication to add the treatment of central neuropathic pain in adults. Lyrica was first authorised in the European Union on 6 July 2004. It is currently indicated for the treatment of peripheral neuropathic pain in adults, as adjunctive therapy for the treatment of epilepsy in adults with partial seizures with or without secondary generalisation and for the treatment of General Anxiety Disorder (GAD) in adults.
- **Plavix** (clopidogrel), from Sanofi Pharma Bristol-Myers Squibb SNC, and **Iscover** (clopidogrel), from Bristol-Myers Squibb Pharma EEIG, to extend its indication (in combination with acetylsalicylic acid) in the prevention of atherothrombotic events in patients suffering from acute coronary syndromes, to include patients suffering from ST segment elevation acute myocardial infarction who are eligible for thrombolytic therapy. Plavix was first authorised in the European Union on 15 July 1998 and is currently indicated for prevention of atherothrombotic events in patients suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease and, in combination with acetylsalicylic acid, for the treatment of patients suffering from non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction).
- **Remicade** (infliximab), from Centocor B.V., to change the indication of infliximab from third to second-line therapy in patients with severe, active Crohn's Disease. 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.

The Committee adopted a negative opinion for the extension of indication for **Tarceva** (erlotinib), from Roche Registration Limited. The indication applied for related to the addition of first-line treatment of locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine. Tarceva was first authorised in the European Union on 19 September 2005. It is currently indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer.

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

Summaries of opinions for all products mentioned above are available and can be found here.

Referral procedures started

The Committee started a referral procedure for **bicalutamide 150 mg**-containing medicinal products. The procedure was initiated by Belgium following suspension of Casodex (bicalutamide) 150 mg, from AstraZeneca, due to efficacy and safety concerns, in particular concerns over heart problems, regarding the use of the medicinal product in the treatment of early prostate cancer. The procedure was initiated under Article 31 of the Community code on human medicinal products (Directive 2001/83/EC as amended).

The Committee started a referral procedure for **Ciprofloxacine Hikma 200 mg/100 ml** (ciprofloxacine lactate), from Hikma Farmaceutica, Portugal, because of disagreements among the Member States regarding the dosages used to treat complicated urinary tract infections. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended).

The Committee also started a referral procedure for **Alendronat Hexal 10 mg** (alendronate), from Hexal A/S, Sweden, because of disagreements among the Member States regarding the indication for the treatment of osteoporosis in men. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended).

A more detailed CHMP meeting report will be published shortly.

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