European Medicines Agency
Press office

London, 15 September 2005
Doc. Ref. EMEA/303099/2005

PRESS RELEASE
European Medicines Agency: Committee for Medicinal Products for Human Use 12-15 September 2005

Initial marketing authorisations

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

- **Macugen** (pegaptanib sodium), from Pfizer Ltd, for the treatment of the wet form of age-related macular degeneration (AMD), a condition that leads to vision loss resulting from damage to the central part of the retina. EMEA review began on 20 September 2004 with an active review time of 216 days.
- **Naglazyme** (galsulfase (recombinant human N-acetylgalactosamine-4-sulfatase)), from BioMarin Europe Ltd, for long-term enzyme replacement therapy in Mucopolysaccharidosis VI, an inherited enzyme deficiency resulting in greater than normal levels of mucopolysaccharides in body tissues. EMEA review began on 20 December 2004 with an active review time of 213 days. **Naglazyme is the twenty-third orphan medicinal product to receive a positive CHMP opinion**.
- **Proquad** (combined measles, mumps, rubella and varicella virus vaccine), from Sanofi Pasteur MSD, for simultaneous vaccination against measles, mumps, rubella and varicella in individuals from 12 months of age. EMEA review began on 18 October 2004 with an active review time of 209 days.
- **Yttriga** (yttrium), from AEA Technology OSA GmbH, for radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide. EMEA review began on 17 May 2004 with an active review time of 209 days.

Extensions of indications

The Committee adopted a positive opinion for the extension of indication for **Busilvex** (busulfan), from Pierre Fabre Médicament, to include the conditioning treatment of children prior to conventional haematopoietic progenitor cell transplantation. Busilvex is an orphan medicinal product and was first authorised in the European Union on 9 July 2003.

Summaries of opinion for initial marketing authorisation applications and applications for extensions of indication are available and can be found here.

Review of NSAIDs

The Committee continued its assessment of the available data on the cardiovascular, gastro-intestinal and skin safety of non-selective non-steroidal anti-inflammatory drugs (NSAIDs). It is expected that an overall view on the different safety aspects considered in this review will be reached during the Committee's October 2005 meeting.

Finalised referral procedures

The CHMP finalised a referral procedure for **Adartrel** (ropinirole), from Laboratoires GlaxoSmithKline, with the recommendation to approve the medicinal product for the treatment of

moderate to severe idiopathic restless legs syndrome. The referral was initiated because of concerns regarding efficacy and long-term safety by Spain and The Netherlands under Article 29(2) of Directive 2001/83/EC as amended. After reviewing all available evidence the Committee concluded that the benefit-risk balance for Adartel is positive and that a marketing authorisation should be granted.

The CHMP recommended the harmonisation of the summaries of product characteristics (SPCs) of three generic medicinal products containing lanzoprazol. **Lanzoprazol AbZ** and **Lanzoprazol-CT** were reviewed because of differences in the posology section between the SPCs of the reference product and the SPCs of the generic products. The procedure was initiated by Germany under Article 29(2) of Directive 2001/83/EC as amended. The procedure for **Lanzoprazol-ratiopharm** was initiated on the same legal basis by Germany and Portugal because of differences in the posology and indication section of the SPCs.

Start of referral procedures

The CHMP began a referral procedure for the generic product **Ceftriaxone Tyrol 1g and 2g** (ceftriaxone) from Sandoz Ltd, because of differences between the SPC of the reference product and the SPC of the generic product, concerning the dosing of newborn infants. The procedure was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC as amended.

The CHMP began a referral procedure for the generic product **Nifedipine Pharmamatch retard 30 and 60 mg (nifedipine),** from Pharmamatch BV. The procedure concerns differences between the SPC of the reference product and the SPC of the generic product relating to contraindications during pregnancy and lactation. It was initiated by the United Kingdom under Article 29 (2) of Directive 2001/83/EC as amended.

The CHMP began a referral procedure for **Stamaril** and associated tradenames, from Sanofi Pasteur MSD, in order to harmonise the national SPCs, in particular the sections dealing with indications and safety aspects, across the European Union. The referral was made by the marketing authorisation holder under Article 30 of Directive 2001/83/EC as amended.

The Committee began referral procedures for **Seretide Diskus, Viani Diskus, Seretide Evohaler and Viani Evohaler** from GlaxoSmithKline. These products are used in the treatment of asthma. The matter was referred to the CHMP by the marketing authorisation holder under Article 6(13) of Commission Regulation (EC) No 1084/2003. The Committee is requested to consider whether or not the proposed extension of indication should be granted.

A more detailed CHMP meeting report will be published shortly.

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