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PRESS RELEASE
European Agency for the Evaluation of Medicinal Products: Committee for Proprietary Medicinal Products Meeting of 23 to 25 July 2002

The Agency's scientific committee, the CPMP, adopted 8 opinions on initial marketing authorisation applications at this meeting, including opinions for 2 orphan medicines:

- A positive opinion for **Somavert** (pegvisomant) from Pharmacia Enterprises S.A. intended for the treatment of acromegaly. EMEA review began on 29 March 2001 and the opinion was adopted on 25 July 2002, with an active review time of 195 days.

  Somavert was designated an orphan medicinal product on 14 February 2001 and is the sixth orphan medicinal product to receive a positive opinion for marketing authorisation from the CPMP.

- A positive opinion for **Zavesca** (miglustat) from Oxford GlycoScience (UK) Ltd. intended for the treatment of mild to moderate type 1 Gaucher disease. EMEA review began on 17 July 2001 and the opinion was adopted on 25 July 2002, with an active review time of 198 days.

  Zavesca was designated an orphan medicinal product on 18 October 2000 and is the seventh orphan medicinal product to receive a positive opinion for marketing authorisation from the CPMP.

- A positive opinion for **Cialis** (tadalafil) from Lilly ICOS Limited intended for the treatment of erectile dysfunction. EMEA review began on 17 July 2001 and the opinion was adopted on 25 July 2002, with an active review time of 202 days.

- Positive opinions for multiple applications for the following products containing valdecoxib: **Bextra** (Pharmacia-Pfizer EEIG), **Valdyn** (Pharmacia Europe EEIG), **Valdecoxib Pfizer Ltd** (Pfizer Limited), **Kudeq** (Pfizer Limited) and **Valdecoxib Pharmacia Europe EEIG** (Pharmacia Europe EEIG). The medicinal product is intended for symptomatic relief in the treatment of osteoarthritis or rheumatoid arthritis and treatment of primary dysmenorrhoea. EMEA review began on 17 July 2001 and the opinions were adopted on 25 July 2002, with an active review time of 204 days.

Summaries of these opinions are available on the EMEA web site: http://www.emea.eu.int

The Committee began Community-wide reviews for :

- all medicinal products containing celecoxib, etoricoxib, parecoxib, rofecoxib and valdecoxib following a referral by France under Article 31 of the Community Code on Human medicines (ex-Article 12 of Council Directive 75/319/EEC). The review was initiated because of safety concerns relating to the frequency of gastrointestinal and cardiovascular adverse events.

- lisinopril containing medicinal products (**Cardiostad** and related product names) under Article 7(5) of Commission Regulation 541/95/EEC. The referral relates to a variation application for a generic medicinal product under the mutual recognition procedure for a new indication (treatment of incipient nephropathy in diabetes characterized by microalbuminuria). Furthermore, in parallel to this referral procedure, The Netherlands initiated a Community review under Article 30 of the Community Code on Human medicines (ex-Article 11 of Council Directive 75/319/EEC) for harmonising the product information in all Member States for the original product **Zestril** and associated product names (lisinopril) against which essentially similarity was claimed.

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The Committee also concluded Community-wide reviews for :

- Bupropion containing medicinal products (**Corzen, Quomem, Zyban, Zyntabac**) authorised under the mutual recognition procedure. The Committee considered that the balance of risks and benefits of bupropion remains favourable for the current indication (i.e.: "as an aid to smoking cessation in combination with motivational support in nicotine-dependent patients") and recommended the maintenance of the Marketing Authorisations with amendments to the Summary of Product Characteristics. The Committee recommended also that bupropion should be used in accordance with smoking cessation guidelines. The Member States competent authorities will continue to keep the product under regular review, including follow-up measures to be submitted in the next Periodic Safety Update Report by September 2002. The referral under Article 36 of the Community Code on Human medicines (ex-Article 15a of Council Directive 75/319/EEC) was initiated by Germany in February 2002.

A more detailed CPMP meeting report will be made available next week, including details from the MRFG meeting of 22 July 2002.

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