European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency
Committee for Medicinal Products for Human Use
27-29 July 2004

The Committee adopted three positive opinions on the initial marketing authorisation applications for:

- **Emselex** (darifenacin), from Novartis Europharm Limited, for the symptomatic treatment of patients with overactive bladder syndrome. EMEA review began on 23 June 2003 and the opinion was adopted on 29 July 2004, with an active review time of 181 days.
- **Mimpara** and **Parareg** (cinacalect), from Amgen Europe B.V., for the treatment of secondary hyperparathyroidism in patients with chronic renal disease, and for reduction of hypercalcaemia in patients with parathyroid carcinoma. EMEA review began on 27 October 2003 and the opinion was adopted on 29 July 2004, with an active review time of 196 days.

Summaries of these opinions, including the full indications for each product, are available on the EMEA web site: http://www.emea.eu.int

The CHMP completed its safety review of the benefit-risk balance of **SonoVue** (sulphur hexafluoride), from Bracco International B.V., and decided to reinstate the echocardiography indication, to extend the contraindications to patients with recent acute coronary syndrome or clinically unstable ischaemic cardiac disease, and to add several warnings and precautions. This follows the urgent safety restriction introduced in May 2004. The revised information for healthcare professionals and patients will be published on the EMEA web site once the final decision has been taken by the European Commission.

The Committee also gave positive opinions on the extension of indication for medicinal products that are already authorised in the EU:

- **Arixtra** and **Quixidar** (fondaparinux), Sanofi Synthelabo, to include the treatment of acute deep vein thrombosis and the treatment of acute pulmonary embolism except in haemodynamically unstable patients or patients who require thrombolysis or pulmonary embolectomy. Arixtra and Quixidar were first authorised in the European Union on 21 March 2002.
- **Enbrel** (etanercept), Wyeth Europe Ltd, to extend its use to the treatment of adult patients with moderate to severe plaque psoriasis. Enbrel was first authorised in the European Union on 3 February 2000.
- **Remicade** (infliximab), Centocor B.V., to extend its use to the treatment of patients with active and progressive psoriatic arthritis. Remicade was first authorised in the European Union on 13 August 1999.

Further information on these extensions will be included in the public assessment report (EPAR) once the European Commission has granted final approval.

Five additional Committee Members

The CHMP elected five new members to join the Committee as of September 2004, adding specific areas of complementary expertise in the fields of blood products and vaccines; quality - chemical substances; quality and safety – biotech substances, cell therapy and gene therapy; pharmacovigilance and pharmacoepidemiology. The possibility of co-opting five additional members is part of the new

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legislation that came into force in May 2004. The CHMP now has 32 members, including one from each of the 25 Member States, one each from Iceland and Norway. The five co-opted members are:

- Manfred Haase
- Pekka Kurki
- Ingmar Persson
- Jean-Louis Robert
- Frances Rotblat

A more detailed CHMP meeting report will be published shortly.

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