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PRESS RELEASE European Medicines Agency: Committee for Medicinal Products for Human Use 1-3 June 2004

The first meeting of the Committee for Medicinal Products for Human Use (CHMP) took place from 1-3 June 2004. The new Committee started its 3-year-term with the election of Daniel Brasseur as its chairman and Eric Abadie as its vice-chairman.

Following the entry into force of parts of the new pharmaceutical legislation the CHMP replaces the Committee for Proprietary Medicinal Products (CPMP); it is composed of one member and one alternate per Member State in addition to one member and one alternate each from Iceland and Norway.

It is also the first time after the enlargement of the European Union on 1 May that members from the 10 new Member States are fully included in the Committee's work.

The Committee adopted one positive opinion on the initial marketing authorisation application for **Apidra** (insulin glulisine) from Aventis Pharma Deutschland GmbH for the treatment of adult patients with diabetes mellitus. EMEA review began on 23 June 2003 and the opinion was adopted on 3 June 2004, with an active review time of 215 days.

A summary of this opinion, including the full indication, is available on the EMEA web site: http://www.emea.eu.int

The Committee also gave a positive opinion on extending the therapeutic indication for **Aldara** (imiquimod) from Laboratories 3M Sante, to include adult patients with small superficial basal cell carcinoma. Aldara was first authorised in the European Union on 18 September 1998.

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

A more detailed CHMP meeting report will be published shortly.

--ENDS--

NOTES:

- 1. A list of the membership of the Committee for Medicinal Products for Human Use (CHMP) may be found at the following location: http://www.emea.eu.int/htms/hotpress/d1515004.htm
- 2. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

Media enquiries only to:

Martin Harvey Allchurch, EMEA press officer Tel. (44-20) 74 18 84 27, e-mail: press@emea.eu.int