The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 16th plenary meeting on 21-23 May 1996 at the EMEA and completed a significant number of centralised applications. The Committee also noted the growing success of the Mutual Recognition Procedure

Centralised Procedures

The Committee adopted six positive opinions (five Part A and one Part B) for five new active substances to be forwarded to the European Commission. One of the opinions was given after 69 days of reviewtime following submission of the application in March 1996. The quality of the dossier and the clinical outcomes allowed the Committee to react rapidly to the major public health need for making such treatments available to AIDS patients.

Other opinions concerned two monoclonal antibodies for specific diagnostic purposes, a combined vaccine and a thrombolytic agent.

In total 21 positive opinions have now been adopted by consensus by the CPMP since May 1995 (9 new centralised and 12 ex-concertation procedures).

Following the recent Commission decisions on Humalog (human insulin analogue), Puregon (follitropin) and Zerit (stavudine), nine European marketing authorisations have been granted. European Public Assessment Reports (EPAR) are available for the products authorised at Community level (see annex).

Three new applications have been assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (two Part A and one Part B).

Scientific Advice

The morning of 23 May 1996 was devoted to meetings with two companies to address scientific issues relevant to drug research and development.

Mutual Recognition

Since the last Press Release in April 1996 eight new Mutual Recognition Procedures have been finalised without the need for arbitration, as well as seven Type I and four Type II variation procedures to products previously authorised under the concertation procedure. The total numbers of products successfully finalised are 29 for new full Mutual Recognition applications and 34/29 for Variation Type I/II applications. The number of on-going procedures is 20, 3 and 31 respectively.

It should also be noted that a second Mutual Recognition procedure was referred to the Committee for arbitration.

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Working Parties and ICH guidelines

The Committee heard reports from their Biotechnology and Pharmacovigilance Working Parties. A report was also given from the ICH-Steering Committee and Working Group meetings held recently in the USA. As a result the Committee released two Step 2 guidelines for a six month consultation period:

- E2B, Clinical safety data management: "Data elements for transmission of individual case safety reports" (CPMP/ICH/287/95)
- S1B, Carcinogenicity: "Testing for carcinogenicity of pharmaceuticals" (CPMP/ICH/299/95)

Consultation with Interested Parties

In continuation of meetings with Interested Parties the Committee held discussions with European representatives from consumers, health professionals and trade associations from the pharmaceutical industry on 23 May 1996.

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This press release and other documents are available on the Internet (http://www.eudra.org/emea.html)