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

London, 15 February 1996
CPMP/179/96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 13th plenary meeting on 13-15 February 1996 at the EMEA.

Centralised Procedures

The Committee adopted positive opinions by consensus for four medicinal products (corresponding to three new substances) under the centralised procedure including three products submitted during 1995. These opinions will be forwarded to the Commission shortly.

The Committee also adopted by consensus a positive opinion for the first application for a type II variation procedure concerning a recent European Marketing Authorisation.

In total, positive opinions for 13 new medicinal products (four from new centralised procedures and nine from ex-concertation procedures) have been adopted by consensus since May 1995. The Committee took note that the European Commission had just granted a European marketing authorisation to Fareston (Toremifene) and Cellcept (Mycophenolate Mofetil). The relevant EPARs will immediately be made available on the Internet.

Scientific Advice

An eighth scientific advice had been prepared for a novel biotech product and was adopted.

The Committee discussed and approved the Standard Operating Procedure for scientific advice to be given by the CPMP for innovative medicinal products (EMEA/SOP/002/96).

Pharmacovigilance

The Committee finalised its opinions on anorectic agents which will be transmitted shortly to the companies concerned and the Commission.

Multistate Procedures

The Committee adopted unanimous positive opinions on two (non binding) multistate procedures, to be forwarded to the Member State competent authorities for the granting of national marketing authorisations.

7,Westferry Circus, Canary Wharf, London E14 4HB, UK
Switchboard: (+44-171) 418 84 00 Fax: (+44-171) 418 85 51

CPMP Guidance

The CPMP decided to release a document entitled "Points to Consider in the Assessment of Anti-HIV Medicinal Products" CPMP/602/95. This position paper is intended to establish the clinical requirements for granting a marketing authorisation for new anti-retroviral agents. This document will be reviewed later in the light of the scientific progress in this field.

The following new guidelines were adopted:

- Guideline to assess efficacy and safety of natural intravenous immunoglobuline products for marketing authorisation (CPMP/388/95 Final)
- Guideline to assess efficacy and safety of human plasma derived factor VIII.c. and factor IX.c. products in clinical trials before and after authorisation (CPMP/198/95 Final)
- Note for Guidance on virus validation studies: The design, contribution and interpretation of studies validating the inactivation and removal of viruses (CPMP/268/95 Final)

In relation with the guideline "Note for Guidance on the Need for Carcinogenicity Studies of Pharmaceuticals", (CPMP/ICH/140/95), adopted in December , the CPMP wanted to make it clear that this guideline had been prepared primarily for the development of new active substances.

CPMP Meeting dates 1996/1997

The CPMP has decided to make public its meeting dates for 1996/1997.

Prof. Josep Torrent-Farnell
Head of Sector, Human Medicines Evaluation Unit

N.B.: The Press Release as well as other general information concerning the EMEA (e.g. including the European Public Assessment Report) are also accessible via the Internet: **http.//www.eudra.org**

Dates for CPMP meetings in 1996

January	15, 16, 17, 18
February	12, 13, 14, 15
March	11, 12, 13, 14
April	15, 16, 17, 18
May	20, 21, 22, 23
June	17, 18, 19, 20
July	15, 16, 17, 18
September	9, 10, 11, 12
October	14, 15, 16, 17
November	18, 19, 20, 21
December	16, 17, 18, 19

Dates for CPMP meetings in 1997

January	20, 21, 22, 23
February	17, 18, 19, 20
March	17, 18, 19, 20
April	14, 15, 16, 17
May	12, 13, 14, 15
June	16, 17, 18, 19
July	21, 22, 23, 24
September	22, 23, 24, 25
October	20, 21, 22, 23
November	17, 18, 19, 20
December	15, 16, 17, 18