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 17th plenary meeting on 18-20 June 1996.

Centralised Procedures

The Committee adopted by consensus 5 positive opinions (1 Part A and 4 Part B) for 4 new active substances to be forwarded to the European Commission.
Two opinions relating to new treatments for AIDS patients were adopted by the Committee. For one it was possible to conclude this review in a shortened period.
The other opinions concerned an anti-psychotic agent and a monoclonal antibody for diagnosis of ovarian adeno-carcinoma.

In total 26 positive opinions have now been adopted by consensus by the CPMP since May 1995 (13 new centralised and 13 ex-concertation procedures).

The Committee noted that ten Community marketing authorisations have now been granted by the European Commission, following the recent adoption of an authorisation for Rilutek (riluzole). European Public Assessment Reports (EPARs) are now available for all ten products authorised by the Commission (see annex).

The Committee adopted a procedure for "Rapid Alert Systems in Pharmacovigilance products approved by the centralised and decentralised procedures" (CPMP/PhVWP/005/96).

Scientific Advice

The CPMP finalised three scientific advice by consensus, bringing the total to ten since this procedure was introduced in 1995.
Breakout sessions were held with two companies to address scientific issues relevant to drug research and development.

Mutual Recognition

The Committee noted that six new mutual recognition procedures have been recently finalised as well as 4 type I and 12 type II variation procedures.

A third arbitration was referred to the CPMP concerning a type II variation procedure for a product authorised under the previous concertation procedure.

The current status as at 18 June 1996 of procedures under the mutual recognition procedure is as follows:

New applications finalised	New applications pending	Type I variations finalised	Type I variations pending	Type II variations finalised	Type II variations pending	Arbitrations referred to CPMP
35	18	38	7	41	26	3

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Multi-State Opinions

The Committee unanimously adopted positive opinions on two (non-binding) Multi-State procedures which had been initiated before 1995, to be forwarded to the Member States' competent authorities for the granting of national marketing authorisations. This reduces the number of on-going procedures to be finalised to 11.

Working Parties (and ICH guidelines)

The CPMP heard reports from their Quality, Biotechnology, Efficacy, Safety and Pharmacovigilance Working Parties, elaborating on their work programmes and priorities which were adopted by the Committee.

The following guidelines were released for consultation:

- "Evaluation of anti-cancer medicinal products in man" (CPMP/EWP/205/95), with a three months consultation period.
- "Evaluation of new anti-bacterial medicinal products" (CPMP/EWP/558/95), with a six months consultation period.
- "Pharmacodynamic section of the SPC for anti-bacterial medicinal products" (CPMP/EWP/520/96), with a six months consultation period.
- Annexe to ICH/CPMP stability guidelines for medicinal products "Maximum shelf-life for sterile products for human use after first opening or following reconstitution" (CPMP/QWP/159/96), with a six months consultation period.
- Annexe to CPMP guideline on the manufacture of the finished dosage form (CPMP/QWP/489/95) "Start of shelf-life of the finished dosage form" (CPMP/QWP/072/96), with a six months consultation period.

Annexe: Medicinal Products with a Marketing Authorisation for the EU under the Centralised Procedure

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

Medicinal Products with a Marketing Authorisation for the EU under the Centralised Procedure

Product a) Brandname b) INN c) List A/B	**Company** a) Name b) Origin	**Therapeutic Area** a) ATC b) Indication	**Presentation** a) Form b) Dose c) Number of Presentations	**EMEA/CPMP** a) Validation b) Opinion c) Active Time d) Clock stop	**Commission** a) Date of decision b) OJ No.
a) **Gonal-F** b) Follitropin-alpha c) List A	a) Serono Laboratories b) IT/CH	a) L02A X b) Treatment of infertility	a) Powder for injection b) 75 IU, 150 IU c) 16 Presentations	a) 01.01.95 b) 17.05.95 c) 107 days d) 30 days	a) 23.10.95 b) OJ No.C 2 of 26.01.9(
a) **Betaferon** b) Interferon beta - 1b c) List A	a) Schering AG b) DE	a) LO3A A.... b) Immuno-stimulation, multiple sclerosis	a) Powder for injection b) 0.25 mg/ml c) 1 Presentation	a) 01.01.95 b) 12.07.95 c) 138 days d) 55 days	a) 30.11.95 b) OJ No.C 2 of 26.01.9(
a) **Taxotere** b) Docetaxel c) List B	a) Rhone-Poulenc Rorer b) FR	a) LO1X..... b) cytostatic	a) Concentrate for infusion b) 80 mg/2 ml 20 mg/0.5 ml c) 2 Presentations	a) 01.01.95 b) 12.07.95 c) 100 days d) 93 days	a) 27.11.95 b) OJ No.C 2 of 26.01.9(
a) **NovoSeven** b) Factor VIIa c) List A	a) Novo-Nordisk b) DK	a) B02B D05 b) Coagulation factor	a) Powder for injection b) 240 KIU c) Presentations	a) 01.01.95 b) 12.09.95 c) 210 days d) 80 days	a) 23.02.96 b) OJ No. C ! of 29.03.9(
a) **CellCept** b) Mycophenolate Mofetil c) List B	a) Hoffmann-La Roche b) CH	a) LO4AX b) Prevention of kidney trans-plant rejection	a) Capsules, Tablets b) 250 mg, 500 mg c) 2 Presentations	a) 01.01.95 b) 17.10.95 c) 243 days d) 47 days	a) 14.02.96 b) OJ No. C ! of 23.02.9(

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a) **Fareston** b) Toremifene c) List B	a) Orion b) FIN	a) LO2BA02 b) Treatment of certain breast tumors	a) Tablets b) 60 mg c) 2 Presentations	a) 01.01.95 b) 17.10.95 c) 240 days d) 50 days	a) 14.02.96 b) OJ No. C of 23.02.9
a) **Humalog** b) Insulin Lispro c) List A	a) Lilly Industries b) USA	a) b) Diabetes mellitus	a) Solution for injection b) 40 IU/ml vials 100 IU/ml vials + Cartridges c) 3 Presentations	a) 01.01.95 b) 22.11.95 c) 250 Days d) 86 Days	a) 30.04.96 b) OJ No. C156 of 31.05.96
a) **Puregon** b) Follitropin-beta c) List A	a) Organon b) NL	a) GO3GA b) Infertility treatment	a) Powder for injection b) 50 IU 100 IU 75 IU 150 IU c) 16 Presentations	a) 01.01.95 b) 20.12.95 c) 203 Days d) 151 Days	a) 03.05.96 b) 03.05.96
a) **Zerit** b) Stavudine c) List B	a) Bristol Myers Squibb b) BE	a) JO5AX04 b) Second line mono-therapy of HIV infection	a) Powder for oral solution capsules b) 1 mg/ml, 15 mg/ml 20 mg/ml, 30 mg/ml 40 mg/ml c) 8 Presentations	a) 14.08.95 b) 16.01.96 c) 150 Days d)	a) 08.05.96 b) 08.05.96
a) **Rilutek** b) Riluzole c) List B	a) Rhone-Poulenc Rorer b) FR	a) NO7X b) Amyo-trophic lateral sclerosis	a) Tablets b) 50 mg c) 1 Presentation	a) 19.07.95 b) 13.02.96 c) 161 Days d) 41 Days	a) 10.06.96 b)