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

London, 11 September 1996
CPMP/741/96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 19th plenary meeting on 10-11 September 1996.

Centralised Procedures

The CPMP noted that 19 community marketing authorisations have now been granted by the European Commission, following the recent adoption of authorisations for Tritanrix HB10 (combination vaccine), Epivir (lamivudine), Tecnemab (anti-melanoma antibody), Rapilysin (reteplase), Ecokinase (reteplase) and Norvir (ritonavir), (for further details see annex I). The new European Public Assessment Reports (EPAR) will be made available.

Seven new applications have been assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (1 Part A and 6 Part B).

Scientific Advice

The CPMP adopted three scientific advice by consensus, bringing the total to 15 since the procedure was introduced in 1995. Break-out sessions were held with two companies.

Mutual Recognition

The CPMP noted that 10 new mutual recognition procedures have recently been finalised as well as 8 type I and 8 type II variation procedures.

The current status as at 9 September 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	Arbitration referred to CPMP
50	29	47	4	57	40	3*

*two for full applications, one for variations

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Working Parties/ICH

The CPMP heard reports from its Quality, Safety, Biotechnology and Pharmacovigilance Working Parties and from the last ICH-Steering Committee Meeting held in July in Geneva.

One Annex to the Note for Guidance on the Stability Testing of New Drug Substances and Products (CPMP/ICH/380/95): "Reduced Stability Testing - Bracketing and Matrixing" (CPMP/QWP/157/96), was released for consultation until 13 March 1997.

Revision of one Note for Guidance on Clinical Investigation of Medicinal Products in Children (CPMP/EWP/462/96) was released for consultation until 13 January 1997.

Rolf Bass

Prof. Rolf Bass
Head of Human Medicines Unit

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

Annexe: 1. Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure and earlier decisions which have now been published in the O.J. since the July 1996 CPMP meeting.

Annexe: 2. EMEA Human Unit Structure for 1996, for information.

Annexe 1

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) **Caelyx** b) Doxorubicin-HCl c) List B	a) Sequus Pharmaceutical Inc b) UK	a) LO1DB b) AIDS-related Kaposi's Sarcoma	a) Concentrate for infusion b) 20 mg in 10 ml/vial c) 1 Presentation	a) 01.01.95 b) 13.02.96 c) 222 Days d) 150 Days	a) 21.06.96 b) OJ No. C 216 of 26.07.96
a) **Bondronat** b) Ibandronic acid c) List B	a) Boehringer Mannheim b) DE	a) MO5BA b) Hyper-calcemia of malignancy	a) Concentrate for infusion b) 1mg in 1ml/ ampulle c) 1 Presentation	a) 01.06.95 b) 13.02.96 c) 203 Days d) 52 Days	a) 25.06.96 b) OJ No. C 216 of 26.07.96
a) **Bonviva** b) Ibandronic acid c) List B	a) Galenus Mannheim b) DE	a) MO5BA b) Hyper-calcemia of malignancy	a) Concentrate for infusion b) 1mg in 1ml/ ampulle c) 1 Presentation	a) 01.06.95 b) 13.02.96 c) 203 Days d) 52 Days	a) 25.06.96 b) OJ No. C 216 of 26.07.96
a) **Tritanrix HB10** b) comb. Vaccine c) List A	a) SmithKline Beecham b) BE	a) J07CA..... b) Comb. vaccine Hepatitis B, DPT	a) Suspension for injection b) c) 2 Presentations	a) 01.01.95 b) 12.03.96 c) 180 Days d) 240 Days	a) 19.07.96 b)
a) **Epivir** b) Lamivudine c) List B	a) Glaxo-Wellcome b) UK	a) JO5AB10 b) comb. treatment of HIV	a) Tablets Oral solution b) 150 mg 10 mg/ml c) 2 Presentations	a) 25.07.95 b) 16.04.96 c) 150 Days d) 105 Days	a) 08.08.96 b)

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a) **Rapilysin** b) Reteplase c) List A	a) Boehringer Mannheim b) DE	a) BO1AD b) Thrombolytic therapy of ac. myoc. infarction	a) Freeze-dried powder b) 10 IU c) 2 Presentations	a) 01.08.95 b) 21.05.96 c) 204 Days d) 83 Days	a) 29.08.96 b)
a) **Ecokinase** b) Reteplase c) List A	a) Galenus Mannheim b) DE	a) BO1AD b) Thrombolytic therapy of ac. myoc. infarction	a) Freeze-dried powder b) 10 IU c) 2 Presentations	a) 01.08.95 b) 21.05.96 c) 204 Days d) 83 Days	a) 29.08.96 b)
a) **Norvir** b) Ritonavir c) List B	a) Abbott b) USA	a) J05 .... b) comb. treatment of HIV	a) Capsule, Oral solution b) 200 mg, 80 mg/ml c) 3 Presentations	a) 13.03.96 b) 21.05.96 c) 69 Days d) ----------	a) 26.08.96 b)
a) **Tecnemab** b) anti-melanoma antibody c) List A	a) Sorin b) IT	a) b) Visualisation of cutaneous melanoma lesions	a) Lyophilisate for injection b) 3×6 ml vials c) 1 Presentation	a) 01.01.95 b) 21.05.96 c) 187 Days d) 320 Days	a) 05.09.96 b)

EMEA Human Unit Structure for 1996

11.9.96