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

London, 16 October 1996
CPMP/871/96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 20th plenary meeting on 15-17 October 1996 at the EMEA followed on 17 October 1996 by a preparatory technical meeting for the next ICH Steering Committee in London during the week of 4 November 1996, held in part as a joint meeting with the European Federation of Pharmaceutical Industries Association (EFPIA).

Centralised Procedures

The Committee adopted by consensus 4 positive opinions (Part A) for four medicinal products; an antianaemic agent, a product for the treatment of diabetes, a diagnostic agent and a vaccine for the immunisation against Hepatitis A/B in children.

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

The European Commission, since the September CPMP meetings 1996 granted authorisations for Crixivan (indinavir), Olansek (olanzapine), Zyprexa (olanzapine), Invirase (saquinavir), Twinrix adult (combination vaccine), CEA-Scan (arcitumomab) and Indimacis 125.

The corresponding European Public Assessment Reports (EPARs) will be made available.

Four new applications have been assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (2 part A and 2 part B).

Detailed figures are given in Annex I and II.

The following Standard Operating Procedure was adopted and will be made available:

- "Centralised Procedure: From Assessment Reports To European Public Assessment Report (EPAR) (EMEA/SOP/005/96)"

A position paper on:

- "How To Proceed With Specific Obligations and Follow-up Measures for the Management of the Marketing Authorisation" (CPMP/725/96) was adopted.

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Scientific Advice

The CPMP adopted three new scientific advice by consensus.

Mutual Recognition

The Committee noted that 9 new mutual recognition procedures have been recently finalised as well as 3 type I and 10 type II variation procedures.

No new arbitration issues were raised.

The current status as at 14 October 1996 of procedures under mutual recognition 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*
59	36	50	12	67	63	3

* two for full applications , one for variations

It was also noted that a document "Best Practice Guide" had been adopted by the Mutual Recognition Facilitation Group and made available to the European trade associations. Copies are available from the Member State Authorities.

CPMP Working Parties

The CPMP heard reports from its Quality, Safety, Biotechnology and Pharmacovigilance Working Parties.

The ICH Guideline S2B "A standard battery for genotoxicity testing of pharmaceuticals" (CPMP/ICH/174/95) from the ICH process (Step 2) was released to interested parties for consultation until 17 April 1997.

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)

ANNEX I to **CPMP - Oct 96**
Press Release

CENTRALISED APPLICATIONS TO THE EMEA

	EX - CONCERTATION		NEW CENTRALISED		TOTAL *
	LIST A	*LIST B*	*LIST A*	*LIST B*	
APPLICATIONS SUBMITTED SINCE 1.1.95	9	8	15	26	58
WITHDRAWN	0	3	0	2	5
REVIEW ONGOING	0	1	8	12	21
OPINIONS GIVEN BY CPMP	9	4	7	12	32
MARKETING AUTHORIZATION GRANTED BY COMMISSION	9	4	3	10	26

** 32 Opinions corresponding to 28 substances*

	PENDING		FINAL		TOTAL
	LIST A	*LIST B*	*LIST A*	*LIST B*	
VARIATIONS TYPE I	3	4	9	2	18
VARIATIONS TYPE II	1	3	2	3	9
SCIENTIFIC ADVICE	1	3	14	4	22

Update 16/10/96

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ANNEX II to **CPMP-Oct 96**
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Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure

since the issue of the Sept. 96 CPMP Press Release on 11 Sept. 96

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) **Twinrix adult** b) comb. Vaccine c) List A	a) SmithKline Beecham b) BE	a) b) Vaccine for immunisation against hep. A and B	a) Suspension for injection b) 1.0 ml dose/day c) 6 Presentations	a) 16.08.95 b) 22.05.96 c) 197 Days d) 83 Days	a) 20.09.96 b)
a) **Zyprexa** b) Olanzapine c) List B	a) Eli Lilly b) USA	a) NO5AX b) antipsychotic	a) Tablet b) 2.5 mg 5.0 mg 7.5 mg 10 mg c) 22 Presentations	a) 09.10.95 b) 19.06.96 c) 198 Days d) 56 Days	a) 27.09.96 b)
a) **CEA-Scan** b) Arcitumomab c) List A	a) Immuno-medics b) USA	a) b) Diagnosis of colonic and rectal carcinoma	a) Powder for injection b) 1.25 mg/vial c) 1 Presentation	a) 01.01.95 b) 21.05.96 c) 110 Days d) 386 Days	a) 04.10.96 b)
a) **Crixivan** b) Indinavir c) List B	a) Merck Sharp & Dohme b) USA	a) J05 .... b) Treatment of patients with AIDS	a) Capsules b) 200, 400 mg c) 5 Presentations	a) 13.03.96 b) 19.06.96 c) 85 Days d) 12 Days	a) 04.10.96 b)

update 16.10.96

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a) **Invirase** b) Saquinavir c) List B	a) Hoffmann-La Roche b) CH	a) JO5AX b) Treatment of Zidovudine - exp. patients with advanced HIV disease	a) Capsule b) 200 mg c) 1 Presentation	a) 02.10.95 b) 19.06.96 c) 180 Days d) 80 Days	a) 04.10.96 b)
a) **Indimacis 125** b) Igovomab c) List A	a) CIS bio international b) FR	a) b) Diagnosis of ovarian adeno-carcinoma	a) Solution for injection b) 1mg in 1 ml ampule c) 1 Presentation	a) 01.01.95 b) 19.06.96 c) 154 Days d) 363 Days	a) 04.10.96 b)
a) **Olansek** b) Olanzapine c) List B	a) Eli Lilly Netherlands B.V. b) USA	a) NO5AX b) antipsychotic	a) Tablet b) 2.5 mg 5.0 mg 7.5 mg 10 mg c) 22 Presentations	a) 09.10.95 b) 19.06.96 c) 198 Days d) 56 Days	a) 07.10.96 b)