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

CPMP/389/97
16-05-97

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 27th plenary meeting on 13-14 May 1997.

Detailed figures are given in Annex I and II.

Centralised Procedures

The Committee adopted by consensus positive opinions on three centralised applications; two relating to the same new active substance (Part B) indicated for essential hypertension and one biotechnology product (Part A) for the treatment of haemophilia B.

The Committee also adopted by consensus one positive opinion for a centralised type II variation and 4 positive opinions for centralised type I variations following the type II procedure.

The Committee agreed on an 'Urgent Safety Restriction' proposed by the Marketing Authorisation Holder for indinavir. At the same time, a corresponding positive opinion on a Variation Type II was adopted to follow-up on this matter.

Since the CPMP meeting in April 1997, the European Commission has granted a marketing authorisation for Vistide (cidofovir) for treatment of CMV retinitis in AIDS patients and for Liprolog Bio-Lysprol (recombinant human insulin).

Three new applications for three active substances were assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (1 Part A and 2 Part B).

Scientific Advice

The CPMP adopted by consensus scientific advice for a product intended for use in 'Acute Respiratory Distress Syndrome'.

Working Parties

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

The following document was adopted:

- Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95)

Mutual Recognition

The Committee noted that 10 new mutual recognition procedures have been finalised recently as well as 13 type I and 1 type II variation procedures.

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One new arbitration procedure for a new application, relating to an application for a new chemical entity, has been referred to the CPMP.

The status as of 12 May 1997 of procedures under mutual recognition is as follows:

Year	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
1997	37	37	39	11	35	65	2

Meeting with Interested Parties

The regular meeting with Interested Parties was held in the afternoon of 14 May 1997.

Development of Performance Indicators (see Annex III)

A meeting with EFPIA to discuss the evaluation of questionnaires developed for the joint EPFIA/EMEA project on performance indicators took place on 15 May 1997.

Any other business

In recent months and reflecting the increase in the volume of CPMP work and that of the Mutual Recognition Facilitation Group, the number of company experts coming to the EMEA has risen constantly.

Companies involved in hearings, break-out sessions and other meetings at the EMEA should be aware of the limited waiting space available at the EMEA offices. Alternative facilities for large delegations are available, including those at the nearby EFPIA and AESGP satellite offices. A company representative could therefore be available at the EMEA and could call colleagues when their presence is required.

Companies should note that in all circumstances they must inform the EMEA at least 2 working days before a meeting of the names of attendees so that appropriate access can be arranged and security passes prepared in advance.

Prof. R. Bass
Head of Human Medicines Evaluation Unit

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

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ANNEX I to **CPMP - May 1997**
Press Release

CENTRALISED APPLICATIONS TO THE EMEA

	CENTRALISED		TOTAL*
	Part A	***Part B***	
Applications submitted since 01.01.95	36	55	91
Withdrawn	0	7	7
Review ongoing	12	23	35
Opinions given by CPMP	24	25	49**
Marketing Authorisation granted by Commission	19	18	37

* These figures include the 18 ex-concertation procedures submitted before January 1995 of which 14 have been authorised and 4 withdrawn before end 1996
** 49 opinions corresponding to 42 substances

	PENDING		FINAL		TOTAL
	Part A	***Part B***	***Part A***	***Part B***	
Variations type I	4	8	24	30	66
Variations type II	6	4	4	16	30
Scientific advice	8		31		39

Update 19 May, 1997

ANNEX II to **CPMP - May 1997**
Press Release

Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure

Status: May 1997

Product	**Company**	**Therapeutic Area**	**Presentation**	**EMEA/CPMP**	**Commission**
a) Brandname b) INN c) Part A/B	a) Name b) Origin	a) ATC b) Indication	a) Form b) Dose c) Number of Presentations	a) Validation b) Opinion c) Active Time d) Clock stop	a) Date of decision b) Date of notification c) OJ No.
a) **Vistide** b) cidofovir c) Part B	a) Gilead b) USA	a) J05 .... b) Treatment of CMV renititis in patient with AIDS	a) Concentrate for infusion b) 375 mg c) 1 Presentation	a) 16.01.96 b) 18.12.96 c) 209 Days d) 112 Days	a) 23.04.97 b) c)
a) **Liprolog Bio-Lysprol** b) insulin lispro c) Part A	a) Lilly Industries b) USA	a) A10AB04 b) Diabetes mellitus	a) Solution for injection b) 40 IU/ml vials 100 IU/ml vials + Cartridges c) 3 Presentations	a) 28.10.96 b) 18.12.96 c) 48 Days d) --------	a) 07.05.97 b) c)

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ANNEX III to **CPMP - May 1997**
Press Release

First meeting of the Joint Industry / Regulatory Review Panel

PERFORMANCE INDICATORS:
JOINT EMEA/EFPIA QUESTIONNAIRE ON THE NEW EUROPEAN REGISTRATION SYSTEM
- CENTRALISED PROCEDURE -

Following discussions on performance indicators for centralised procedures between EFPIA and EMEA in 1996 and further to the initiative of the EMEA Management Board and the Executive Director, a joint EMEA/EFPIA questionnaire has been developed to implement such performance indicators.

A joint panel constituted of experts from industry and experts from EMEA/CPMP was set up to review responses to the questionnaire. The first meeting of the review panel took place on 15 May 1997, under the co-chairmanship of Prof. J.-M. Alexandre (CPMP Chairman) and Mr B. Ager (Director General of EFPIA).

The objective of the meeting was to evaluate the suitability of the questionnaire and to assess the preliminary results from retrospective analysis of 21 finalised procedures for which applications were submitted between June 1995 and May 1996.

A second batch of procedures finalised up until September 1997 (Marketing Authorisation granted by the European Commission) will be dealt with before presentation of the results at the next EFPIA Info Day on 23 October 1997 in London.

From the experience gained during this first pilot phase, the questionnaire will be reviewed to better meet its aims and provide the necessary information to assess performance of the centralised procedure.

ANNEX IV to **CPMP - May 1997**
Press Release

EMEA v Pharmaceutical Industry Football Match

12 May 1997, 19.30 hrs - Mile End

To celebrate Europe Day, the European Medicines Evaluation Agency (EMEA) played football against the European Federation of Pharmaceutical Industries' Associations (EFPIA) on 12 May at Mile End (London).

The EMEA team comprised representatives from the Committee for Proprietary Medicinal Products (CPMP) and the EMEA Secretariat. The composition of a very strong and able industry team was arranged by EFPIA, with the participation of AESGP.

A collection took place in support of the Cancer Research Campaign.

The score was as follows: Industry: 5 EMEA: 1

Congratulations to the winning team!