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

CPMP/1095/96
18-12-96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 22nd plenary meeting on 17-18 December 1996 at the EMEA.

Centralised Procedures

The Committee adopted by consensus 2 positive opinions for two medicinal products; a product for the treatment of diabetes mellitus (Part A abridged application), and a product containing a new active substance for the treatment of CMV retinitis in patients with AIDS (Part B). These opinions will be forwarded to the Commission in due time.

The Committee also adopted by consensus 2 positive opinions for centralised type II variation procedures concerning recent Community Marketing Authorisations.

Mutual Recognition

Two opinions for arbitrations referred to the EMEA under the Mutual Recognition procedure were adopted by the CPMP and will be forwarded to the Commission.
For one procedure the positive opinion obtained by consensus specifies the conditions of use. The second one concerns a variation to existing national Marketing Authorisations and a majority of CPMP members was against this variation.

The Committee noted that 16 new mutual recognition procedures have been recently finalised as well as 9 type I and 5 type II variation procedures.

The status as at 18 December 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*
94	17	67	8	91	53	3

* two for full applications, one for variations

Referral under Article 11

Following a referral under Article 11, the CPMP adopted by consensus an opinion for a medicinal product authorised under the ex-concertation procedure, leading to a harmonised SPC.

Scientific Advice

The CPMP adopted 3 new scientific advice by consensus. Two companies gave oral presentations to CPMP consultation groups.

Multi-State Procedures

The Committee unanimously adopted (non-binding) positive opinions for three Multi-State Procedures, which had been initiated before 1995, to be forwarded to the concerned Member States' competent authorities for the granting of national marketing authorisations. This now concludes the series of outstanding Multi-State Procedures.

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Working Parties

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

The Note for Guidance for the pre-clinical evaluation of anti-cancer (CPMP/SWP/997/96) was released for consultation to interested parties until 17 March 1997.

The Note for Guidance on medicinal products in the treatment of Alzheimer's disease (CPMP/EWP/553/95) was released for consultation to interested parties until 17 March 1997.

The Note for Guidance on the clinical evaluation of anti-cancer (CPMP/EWP/205/95) was adopted and will come into operation on 17 March 1997.

In addition, the following ICH-topics Step 4 were adopted by the Committee and will come into operation in January 1998:

1. Q1B: Stability Testing: Photostability Testing of New Drug Substances and Products (CPMP/ICH/279/95)
2. Q1C: Stability Testing: Requirements for New Dosage Forms (CPMP/ICH/280/95)

and in June 1997:

3. Q2B: Validation of Analytical Procedures: Methodology (CPMP/ICH/281/95)
4. Q3B: Impurities in New Drug Products (CPMP/ICH/282/95
5. E2C: Clinical Data Safety Management: Periodic Safety Update Reports for Marketed Drugs (CPMP/ICH/288/95)

Prof. R. Bass

Prof. R. Bass
Head of Human Medicines Unit

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

CPMP dates		
Month	Day	
	1997 (agreed earlier)	**1998** (agreed now)
January	20, 21, 22 / 23	26, 27, 28 / 29
February	17, 18, 19 / 20	23, 24, 25 / 26
March	17, 18, 19 / 20	23, 24, 25 / 26
April	14, 15, 16 / 17	20, 21, 22 / 23
May	12, 13, 14 / 15	25, 26, 27 / 28
June	16, 17, 18 / 19	22, 23, 24 / 25
July	21, 22, 23 / 24	20, 21, 22 / 23
August		17, 18, 19 / 20
September	22, 23, 24 / 25	14, 15, 16 / 17
October	20, 21, 22 / 23	19, 20, 21 / 22
November	17, 18, 19 / 20	16, 17, 18 / 19
December	15, 16, 17 / 18	14, 15, 16 / 17

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ANNEX I to **CPMP - Dec. 96**
Press Release

CENTRALISED APPLICATIONS TO THE EMEA

	EX - CONCERTATION		NEW CENTRALISED		TOTAL *
	Part A	*Part B*	*Part A*	*Part B*	
APPLICATIONS SUBMITTED SINCE 1.1.95	9	9	20	33	71
WITHDRAWN	0	4	0	2	6
REVIEW ONGOING	0	1	9	17	27
OPINIONS GIVEN BY CPMP	9	4	11	14	38
MARKETING AUTHORIZATION GRANTED BY COMMISSION	9	4	3	11	27

** 39 Opinions corresponding to 34 substances*

	PENDING		FINAL		TOTAL
	Part A	*Part B*	*Part A*	*Part B*	
VARIATIONS TYPE I	7	3	8	11	29
VARIATIONS TYPE II	1	6	3	6	16
SCIENTIFIC ADVICE	5		24		29

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