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

CPMP/960/96
20-11-96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 21st plenary meeting on 19-20 November 1996 at the EMEA.

Centralised Procedures

The Committee adopted by consensus four positive opinions for four medicinal products (3 Part A and 1 Part B - containing a known active substance in a new delivery system of significant therapeutic interest); a product for the treatment of heparin-associated thrombocytopenia, a product for the treatment of relapsing mutiple sclerosis, a product for treatment of diabetes mellitus and a product for the treatment of CMV retinitis in patients with AIDS.

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

The European Commission, since the October 1996 CPMP meeting, granted a marketing authorisation for Hycamtin (topotecan). The corresponding European Public Assessment Report (EPAR) will be made available by the EMEA following publication of the decision in the Official Journal.

Eleven new applications for nine active substances have been assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (1 List A and 10 List B).

Detailed figures are given in Annex I and II.

Scientific Advice

The CPMP adopted 1 new scientific advice by consensus.

Mutual Recognition

The Committee noted that 18 new mutual recognition procedures have been recently finalised as well as 8 type I and 19 type II variation procedures.

No new arbitration issues were raised.

The status as at 18 November 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*
77	26	58	11	86	51	3

* two for full applications, one for variations

Multi State Procedures

The Committee unanimously adopted (non binding) positive opinions for two 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.

Working Parties

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The CPMP heard reports from its Quality, Biotechnology and Efficacy Working Parties, especially in relation to the outcome of the recent ICH-Steering Committee meeting at the EMEA, and from the Ad Hoc Working Party on Harmonisation of SPC.

The Note for Guidance: "Clinical Investigation of Anti-anginal Medicinal Products in Stable Anginal Pectoris" (CPMP/EWP/234/95) was adopted and will come into operation on 20 May 1997.

The Note for Guidance: "Development Pharmaceutics" (CPMP/QWP/155/96) was released to interested parties for consultation until 20 May 1997.

The Note for Guidance "Involutional Osteoporosis in Women" (CPMP/EWP/552/95) was released for consultation to interested parties until 20 May 1997.

ICH

The CPMP heard the report from the ICH Steering Committee and its Expert Working Groups meetings held 4-8 November 1996 in London at EMEA and EFPIA offices.

I. The following ICH-topics have reached 'Step 2' and were released for a six month consultation period until 20 May 1996:
   1. Q3C: "Note for Guidance on Impurities: Residual Solvents" (CPMP/ICH/283/95)
   2. S1C (R): "Addendum on the Limit Dose Related to Dose Selection for Carcinogenicity Studies of Pharmaceuticals" (CPMP/ICH/366/96)
   3. S6: "Note for Guidance on Safety Studies for Biotechnology Products" (CPMP/ICH/302/95)
   4. E8: "Note for Guidance on General Considerations for Clinical Trials" (CPMP/ICH/291/95)
   5. M3: "Note for Guidance on Non-clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (CPMP/ICH/286/95)

II. The following ICH-topics have reached 'Step 4' and are expected to become available following the CPMP-December meeting:
   1. E2C: Note for Guidance on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (CPMP/ICH/288/95)
   2. Q1B: Note for Guidance on Photostability Testing of New Drug Substances and Products (CPMP/ICH/279/95)
   3. Q1C: Note for Guidance on Stability Testing: Requirements for New Dosage Forms (CPMP/ICH/280/95)
   4. Q2B: Note for Guidance on Validation of Analytical Procedures: Methodology (CPMP/ICH/281/95)
   5. Q3B: Note for Guidance on Impurities in New Drug Products (CPMP/ICH/282/95)

Consultation with Interested Parties

Continuing the cycle of meetings with Interested Parties, the CPMP and the EMEA Secretariat held discussions with European representatives from consumers, health professionals and trade associations from the pharmaceutical industry on 20 November 1996.

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)

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ANNEX I to **CPMP - Nov 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	18	28	64
WITHDRAWN	0	4	0	2	6
REVIEW ONGOING	0	1	8	13	22
OPINIONS GIVEN BY CPMP	9	4	10	13	36
MARKETING AUTHORIZATION GRANTED BY COMMISSION	9	4	3	11	27

** 36 Opinions corresponding to 32 substances*

	PENDING		FINAL		TOTAL
	Part A	*Part B*	*Part A*	*Part B*	
VARIATIONS TYPE I	5	3	8	10	26
VARIATIONS TYPE II	1	4	2	2	9
SCIENTIFIC ADVICE	8		21		29

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ANNEX II to **CPMP - Nov 96**
Press Release

Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure since the October 1996 CPMP meeting

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) Date of notification c) OJ No.
a) **Hycamtin** b) topotecan c) List B	a) SmithKline Beecham b) USA	a) L01X X17 b) Ovary metastatic carcinoma	a) Powder for infusion b) 4 mg c) 2 Presentations	a) 16.01.96 b) 19.07.96 c) 154 Days d) 28 Days	a) 12.11.96 b) c)

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