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

CPMP/234/97
21-03-97

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 25th plenary meeting on 18-20 March 1997.

Centralised Procedures

The Committee adopted by consensus two positive opinions for two medicinal products; a product containing as active substance an antithrombotic agent (part A) and a product to be used in the treatment of Parkinsons disease (part B). These opinions will be forwarded to the European Commission.

The Committee also adopted by consensus two positive opinions for centralised type II variations and two positive opinions for centralised type I variations following the type II procedure.

The European Commission, since the February 1997 CPMP meeting, granted a marketing authorisation for Leukoscan, a diagnostic agent, for Insuman, containing human insulin for the treatment of Diabetes Mellitus, for Avonex, an agent against progression of Multiple Sclerosis, for Refludan, an anti-coagulating agent for heparin-associated thrombo-cytopenia and for Vitrasert, Treatment of CMV retinitis in patients with AIDS. The corresponding European Public Assessment Reports (EPAR) are made available by the EMEA.

Twelve new applications for nine active substances and one new combination have been assigned to Rapporteurs and Co-Rapporteurs, to be submitted under the centralised procedure within the next two to three months (2 Part A and 10 Part B).

Detailed figures are given in Annex I + II.

Composition of Influenza Vaccines for 1997/1998

CPMP considered and adopted the WHO recommendation for the composition of influenza vaccines for the next season (see Annex III).

Scientific Advice

The CPMP adopted one new scientific advice by consensus for a product intended for the prevention of osteoporosis.

TSE

Following a very detailed review of the existing Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products (CPMP/BWP/877/96) the Committee reconfirmed the principles expressed in 1991 with exception of the concept of “well-monitored closed herds” which would require further multidisiplinary consideration. It is expected that an agreed text will be ready for consultation during the third week of April.

For gelatin and tallow derivatives, the CPMP confirmed its previous position cited in the EMEA document dated 16 April 1996 (EMEA/354/96) and remains satisfied with the safety of these products.

Working Parties

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The CPMP heard reports from its Biotechnology Working Party and from the Ad Hoc Group on Blood and Plasma Products and from the Ad Hoc Expert Group on Oral Contraceptives.

The following documents were adopted:

- Note for Guidance on harmonisation of requirements for influenza vaccines (CPMP/BWP/214/96).
- Note for Guidance on clinical investigation of medicinal products in children (CPMP/EWP/462/95).
- Note for Guidance on Core SPC for human normal immunoglobulin (I.V) (CPMP/BPWP/859/95).

The following documents were released to interested parties for a 3 months consultation period:

- Note for Guidance on ethnic factors in the acceptability of foreign clinical data (CPMP/ICH/289/95) which had reached Step 2 of the ICH process on 5 March 1997 (ICH Topic E5).
- Points to consider in the assessment of the potential of the QT interval prolongation by non cardiovascular medicinal products (CPMP/986/96).

The following documents were released to interested parties for a 6 months consultation period:

- Note for Guidance on stability testing of existing active substances and related finished products (CPMP/QWP/556/96).
- Note for Guidance on Stability testing for variation to marketing authorisation Type II (CPMP/QWP/576/96).
- Note for Guidance on investigation of drug interactions (CPMP/EWP/560/95).
- Note for Guidance on clinical investigation of drugs used in weight control (CPMP/EWP/281/96).

Mutual Recognition

The Committee noted that 7 new mutual recognition procedures have been recently finalised as well as 2 type I and 12 type II variation procedures.

One new arbitration procedure following an application for a type II variation has been referred to CPMP.

The status as 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	18	34	17	10	20	57	1

The CPMP was informed that a successful meeting between the Mutual Recognition Facilitation Group and EFPIA was held on the 17 March 1997.

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 - March 1997**
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	23	41	82
WITHDRAWN	0	4	0	2	6
REVIEW ONGOING	0	0	10	22	32
OPINIONS GIVEN BY CPMP	9	5	13	17	44
MARKETING AUTHORIZATION GRANTED BY COMMISSION	9	4	8	12	33

** 44 opinions corresponding to 38 substances*

	PENDING		FINAL		TOTAL
	Part A	*Part B*	*Part A*	*Part B*	
VARIATIONS TYPE I	4	5	20	23	52
VARIATIONS TYPE II	1	5	4	10	20
SCIENTIFIC ADVICE	6		28		34

Update 20 March 1997

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ANNEX II to **CPMP - March 1997**
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Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure
Status: March 1997

Product a) Brandname b) INN c) PartA/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) **Insuman** b) insulin human c) Part A	a) Hoechst AG b) DE	a) A10A b) Diabetes mellitus	a) Solution for Injection Suspension for Injection Solution for Infusion b) 40 IU/ml 100 IU/ml c) 27 Presentations	a) 06.12.95 b) 16.10.96 c) 158 Days d) 182 Days	a) 21.02.97 b) c)
a) **Avonex** b) interferon beta c) Part A	a) Biogen b) USA	a) LO3A A... b) An agent against progression of Multiple Sclerosis	a) Powder for injection b) 30 mg/vial c) 1 Presentation	a) 01.06.95 b) 20.11.96 c) 216 Days d) 307 Days	a) 13.03.97 b) c)
a) **Refludan** b) lepirudin c) Part A	a) Behringwerke AG b) DE	a) B01AX b) Anti-coagulation therapy for heparin-associated thrombocytopenia	a) Powder for injection or infusion b) 50 mg c) 1 Presentation	a) 15.01.96 b) 20.11.96 c) 200 Days d) 112 Days	a) 13.03.97 b) c)
a) **Vitrasert** b) ganciclovir c) Part B	a) Chiron b) USA	a) J05AB06 b) Treatment of CMV retinitis in patient with AIDS	a) Eye implant b) 4.5-6.4 mg c) 1 Presentation	a) 20.01.96 b) 20.11.96 c) 183 Days d) 119 Days	a) 18.03.97 b) c)

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ANNEX III to **CPMP - March 1997**
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Influenza Vaccines

Having considered the outcome of the CPMP Biotechnology Working Party's (BWP) Break-Out-Session on Influenza Vaccines concerning the WHO recommendation on the composition of the Influenza Vaccine for 1997/98, the CPMP decided to follow the advice of the BWP to adopt the WHO recommendation.

Trivalent vaccine containing

- an A/Wuhan/359/95 (H3N2)-like strain
- an A/Bayern/7/95 (H1N1)-like strain
- a B/Beijing/184/93-like strain

On the basis of cross-reactivity tests, the group agreed that for the purpose of vaccine manufacture:

a) RESVIR-9, which has been derived from A/Nanchang/933/95 is accepted as an A/Wuhan/359/95 (H3N2)-like strain

b) B/Harbin/7/94 is accepted as a B/Beijing/184/93-like strain

c) A/Shenzhen/227/95 and A/Johannesburg/82/96 are accepted as A/Bayern/7/95-like strains (A/Bayern/7/95 is not acceptable due to inappropriate passage history)

High yield reassortants for A/Shenzhen/227/95 and A/Johannesburg/82/96 are under development. An existing high yield reassortant for A/Perth/13/95 is being evaluated. A written procedure co-ordinated by the EMEA will be followed to establish EU consensus on the acceptability of reassortants for vaccine production. This procedure will be completed before the end of March.

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