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

CPMP/341/97
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PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 26th plenary meeting on 15-16 April 1997.

Centralised Procedures

The Committee adopted by consensus two positive opinions for two medicinal products; a product for the in vivo diagnostic of gastroduodenal Helicobacter pylori infection (Part B product) and a combined vaccine partially produced by genetically-engineered yeast cells (Part A Product).

The Committee also adopted by consensus four positive opinions for centralised type II variations.

Detailed figures are given in Annex I.

The document 'Conduct of Pharmacovigilance for centrally authorised products' (CPMP/183/97 Rev. 2) was adopted and is also made available to the public.

The CPMP noted that the European Commission has agreed to the authorisation of two further presentations for Humalog, which was originally authorised in April 1996.

Referrals

The CPMP adopted by majority an opinion on HibTITER which was subject of a referral under Article 15a of Council Directive 75/319/EEC, as amended, made by Italy (see February 1997 CPMP Press Release). HibTITER, a haemophilus influenzae B conjugate and diphtheria vaccine used for the immunisation of infants and young children against invasive diseases caused by haemophilus influenza type B (HIB), was first given a positive opinion by the former CPMP in 1993 (concertation procedure/list A). The CPMP found that this product is safe and that there is no reason with regard to the quality, safety or efficacy to withdraw the product from the market or to change the Marketing Authorisation. As a result of the referral, a harmonised SPC was agreed.

Scientific Advice

Following requests submitted earlier, the CPMP adopted two new scientific advice by consensus concerning questions about the clinical development programmes.

Transmitting animal Spongiform Encephalopathy (TSE)

The Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products (CPMP/BWP/877/96, revised from the first adopted version (1991)) was released for consultation to interested parties for 3 months following revision by the Biotechnology Working Party and the CPMP.

This Note for Guidance sets out the scientific principles which minimise the risk of transmission of spongiform encephalopathy via medicinal products. These principles include control measures such as the sourcing and the quality control of starting materials, and the design and control of the manufacturing procedure which, when combined with the categorisation of tissues, give assurance on product safety.

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For gelatin and tallow derivatives, the CPMP confirms 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

The CPMP heard reports from the Quality Working Party, the Pharmacovigilance Working Party and from the Ad Hoc Working Group on the standardisation of SPCs.

The following documents were adopted:

- Note for Guidance on Evaluation of New Anti-Bacterial Medicinal Products (CPMP/EWP/558/95)
- Q5A: Note for Guidance on Quality of Biotechnological Products; Viral Safety Evaluation of Biotechnological Products derived from Cell lines of Human or Animal Origin (CPMP/ICH/295/95)

The following document was released to interested parties for *(3)* months consultation:

- Revised Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encepalopathy Agents via Medicinal Products (CPMP/BWP/877/96 Rev. 1)

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

- Note for Guidance on Chemistry of New Active Substances (CPMP/QWP/130/96)
- Note for Guidance on Summary of Requirements to Active Substances in Part II of the Dossier (CPMP/QWP/297/97)

Mutual Recognition

The Committee noted that 9 new mutual recognition procedures have been recently finalised as well as 9 type I and 14 type II variation procedures.

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	27	39	26	14	34	51	1

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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 - April 1997**
Press Release

CENTRALISED APPLICATIONS TO THE EMEA

	CENTRALISED		TOTAL*
	Part A	***Part B***	
Applications submitted since 01.01.95	33	53	86
Withdrawn	0	7	7
Review ongoing	10	23	33
Opinions given by CPMP	23	23	46
Marketing Authorization granted by Commission	18	17	35

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

	PENDING		FINAL		TOTAL
	Part A	***Part B***	***Part A***	***Part B***	
Variations type I	6	1	20	30	57
Variations type II	4	5	4	13	26
Scientific advice	6		30		36

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