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

CPMP/502/97
20 June 1997

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 28th plenary meeting on 17-19 June 1997. The CPMP welcomed two new members, who are Dr. Christa Wirthumer-Hoche from Austria and Dr. Markku Toivonen from Finland replacing Dr. Walter Fuchs and Dr. C. Strömberg respectively.

Detailed figures of applications processed are given in Annex I and II.

Centralised Procedures

The Committee adopted by consensus positive opinions on three centralised applications relating to the same new active substance (Part B) indicated for the treatment of idiopathic Parkinson's disease.

The Committee also adopted by consensus 2 positive opinions for centralised type II variations and 3 positive opinions for type I variations following the type II procedure.

Since the CPMP meeting in May 1997 the European Commission has granted a marketing authorisation for Teslascan (mangafodipir) a paramagnetic contrast medium for MRI detection of liver lesions.

Scientific Advice

The CPMP adopted by consensus scientific advice for three requests presented by the industry.

ICH

The CPMP held 2 preparatory technical meetings to agree EU positions for ICH4 to be held in Brussels on 16-18 July 1997 in part jointly with the European Federation of Pharmaceutical Industries Association (EFPIA). EFPIA was given the opportunity to present the results of a feasibility study, carried out by ICH industry partners, on a "Common Technical Document" (technical data in support of an application for MA in the three regions) to be presented at ICH4 in Brussels, where a decision on establishing this as an ICH topic will be taken.

Working Parties

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

The following documents were adopted:

- Note for Guidance on the Pharmacodynamic section of the SPC for Anti-Bacterial Medicinal Products (CPMP/EWP/520/96).
- Position paper on "DNA and Host Cell Proteins (HCP), Impurities, Routine Testing Versus Validation Studies" (CPMP/BWP/382/97)

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The following documents were released for consultation:

- Note for Guidance on Pharmaceutical and Biological Aspects of Combined Vaccines (CPMP/BWP/477/97), for 6 months consultation.
- Annex to Note for Guidance on Stability Testing of New Active Substances and Medicinal Products: Maximum Shelf-Life for Sterile Products After First Opening of Following Reconstitution (CPMP/QWP/159/96), for 4 months consultation.
- Annex to Note for Guidance on Stability Testing of New Active Substances and Medicinal Products: Declaration of Storage Conditions for Medicinal Products (CPMP/QWP/609/96), for 6 months consultation.

Mutual Recognition

The MRFG noted that 11 new mutual recognition procedures have been finalised recently as well as 11 type I and 30 type II variations.

The status as of 16 June 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	48	37	50	12	65	41	2

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 - June 1997**
Press Release

CENTRALISED APPLICATIONS TO THE EMEA

	CENTRALISED		TOTAL*
	Part A	***Part B***	
Applications submitted since 01.01.95	37	60	97
Withdrawn	0	7	7
Review ongoing	13	25	38
Opinions given by CPMP	24	28	52**
Marketing Authorization granted by Commission	19	19	38

* These figures include the 18 ex-concertation procedures submitted before January 1995 of which 14 have been authorised and 4 withdrawn before end 1996
** 52 opinions corresponding to 43 substances

	PENDING		FINAL		TOTAL
	Part A	**Part B**	**Part A**	**Part B**	
Variations type I	8	0	30	35	73
Variations type II	6	1	5	19	31
Scientific advice	7		34		41

Updated 19 June 1997

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

Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure
Status: June 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) **Teslascan** b) mangafodipir c) Part B	a) Nycomed b) NO	a) V08CA05 b) Detection of liver lesions	a) Solution of injection b) 0.01 mmol/ml c) 2 Presentations	a) 22.07.96 b) 19.02.97 c) 171 Days d) 27 Days	a) 22.05.97 b) c)

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

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS MEETING

9-10 JUNE 1997

EMEA, 7 Westferry Circus, Canary Wharf, London E14 4HB

The first meeting of the ad hoc working group on herbal medicinal products took place at the EMEA in London on 9 and 10 June 1997 and was chaired by Dr Konstantin Keller (BfArM).

This ad hoc group was called upon by the EMEA Executive Director, in agreement with the Management Board, at the request of the European Commission. It was attended by delegates from national competent authorities, representatives from the European Commission and European Parliament. The European Pharmacopoeia sent observers. The meeting was supported by the EMEA secretariat.

The group started to gather the experience of Member States in the field of herbal medicinal products and established its mandate for the three meetings foreseen in 1997. It is aiming at proposing initiatives for development of guidance/assessment criteria to sufficiently prove quality, safety and efficacy of herbal medicinal products, making appropriate use of the available scientific literature as well as European Pharmacopoeia, WHO and ESCOP monographs where they exist.

During this first meeting, interested European associations such as AESGP, ESCOP, EFPIA and EHPM were invited to explain their position and experience. The ad hoc group then took up its work to review guidance for assessing the pharmaceutical quality of herbal medicinal products. It reviewed and confirmed the appropriateness of the Good Manufacturing Practice guidance available for herbal medicinal products, whilst proposals for revision of the Note for guidance "Quality of Herbal Remedies" were agreed. In addition to reviewing existing quality guidelines, Member States were invited to prepare proposals for additional and more specific guidance as seen necessary in the light of national experience.

The ad hoc working group agreed on the dates of the next two meetings (10-11 September and 24-25 November 1997) which will focus on safety and efficacy aspects.

Attached: Mandate of the Ad Hoc Working Group on Herbal Medicinal Products

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Human Medicines Evaluation Unit

London, 10 June 1997
EMEA/adhocHMPWP/497/97

AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

Mandate

Introduction

An ad hoc working group on herbal medicinal products has been created within the EMEA with a limited mandate of 3 meetings in 1997, upon the initiative of the European Commission and the EMEA Executive Director, which constitutes a pragmatic and useful approach to address the issue of quality, safety and efficacy of these products. The group will gather the experience of Member States in the field of herbal medicinal products, in liaison with the CPMP, and integrate industry's expertise in the development and manufacturing of such products.

Points for discussion

The discussion within the working group should serve the following purposes:

- provide guidance for applicants to Marketing Authorisations for herbal medicinal products
- provide guidance for competent authorities for the assessment of herbal medicinal products

The following points should be addressed :

- establishment of a common understanding of **existing legislation and guidelines**.
  In particular the group should discuss the need
  - to revise existing Quality guidelines[1]
  - to update existing provisions in the Good Manufacturing Practice of herbal medicinal products[2]
  - to develop European Pharmacopoeia monographs in collaboration with other bodies and authorities who have initiated activities in this area;

- development of **guidance and common criteria for assessment to sufficiently prove quality, safety and efficacy** of herbal medicinal products, with particular reference to scientific literature, WHO and ESCOP monographs where they exist; reviewing the usefulness of tabulated formats of the Notice to Applicants (NTA II B of January 1997);

- advice to the European Commission on the ongoing study on herbal medicinal products and on possible legislative measures to be envisaged after finalisation of the study and discussion of its results;

- discussion as to whether specific action is needed to ease the access to relevant information for both applicants and authorities.

Outcome of discussion

The ad hoc working group should prepare a report with proposals for initiatives which will highlight, for the different actions, their respective timeframe and required resources, for recommendation to the EMEA/CPMP and to the European Commission, respectively.

[1]In Particular the Note for Guidance "Quality of Herbal Remedies" (Vol. III Part I of the Rules governing Medicinal Products in the European Community)
[2]Annex 7 "Manufacture of Herbal Medicinal Products" of Good Manufacturing Practice for medicinal products (Vol. IV of the Rules governing Medicinal Products in the European Community)

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