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

22 April 1998
CPMP/808/98

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 37th plenary meeting on 21 – 22 April 1998.

CENTRALISED PROCEDURES

The Committee adopted the following Opinions:

- Four positive Opinions on Centralised Applications
  - Two positive Opinions adopted by a majority of votes relating to two medicinal products containing the same new active substance (Part B), a selective estrogen receptor modulator, indicated for the prevention of non-traumatic vertebral fractures in postmenopausal women at an increased risk of osteoporosis.
  - One positive Opinion adopted by consensus relating to a new pharmaceutical form of an active substance (Part B), already approved in a former Centralised Procedure, an antiretroviral, indicated for the treatment of HIV-1 infected adult patients in combination with antiretroviral agents.
  - One positive Opinion adopted by consensus relating to a medicinal product containing a new active substance (Part B), an oral blood glucose lowering drug, indicated in patients with type 2 diabetes whose hyperglycaemia can no longer be controlled satisfactorily by diet, weight reduction and exercise.
- Three positive Opinions by consensus for Centralised Type I Variations following the Type II procedure.
- Three positive Opinions by consensus for Centralised Type II Variations.

The CPMP noted the withdrawal of one Centralised Application (Part A) and two Centralised Type II Variations relating to two medicinal products containing the same active substance (Part B).

One Centralised Procedure for a new product has been started after validation (Part B).

The Committee heard seven Oral Presentations / Clarifications from Applicants.

An overview of Centralised Applications is given in Annex I.

SCIENTIFIC ADVICE

The Committee:

- Accepted one new request for Scientific Advice as justified. Co-ordinators were appointed.
- Adopted two Scientific Advice by consensus on preclinical and clinical issues as well as development plans concerning two new medicinal products (Part B) intended for the treatment of:
  - Acute pancreatitis
  - Myocardial perfusion tomography

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WORKING PARTIES, AD HOC WORKING GROUPS AND ORGANISATIONAL MATTERS

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties and Ad Hoc Expert Group on the update of the Note for Guidance on SPC.

QUALITY WORKING PARTY

The following documents were adopted and will come into operation in October 1998:

- 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 a Type II Variation to a Marketing Authorisation (CPMP/QWP/576/96)

The following document was released for six months consultation:

- Note for Guidance on Modified Release Oral and Transdermal Dosage Forms: Section II (Quality) (CPMP/QWP/604/96)

EFFICACY WORKING PARTY

The following document was released for six months consultation:

- Note for Guidance on Modified Release Oral and Transdermal Dosage Forms: Section I (Pharmacokinetic and Clinical Evaluation) (CPMP/EWP/280/96)

AD HOC WORKING GROUP ON BLOOD PRODUCTS

The revised mandate for the Ad Hoc Working Group on Blood Products was agreed.
Dr. Manfred Haase was appointed as Chairperson.

ORGANISATIONAL MATTERS

Following a CPMP meeting on Organisational Matters held on 10 March 1998, the following documents were adopted:

- Position Paper on Voting in the Framework of the Discussion and Adoption of CPMP Opinions (CPMP/040/98)
- Standard Operating Procedure "Referrals in Accordance with the Provisions of Council Directive 75/319/EEC in the case of Safety Concerns related to Medicinal Products marketed in the European Union (EMEA/SOP/001/97)
- Guidance paper on the Acceptability of Tradenames for Medicinal Products Processed through the Centralised Procedure (CPMP/328/98)

MUTUAL RECOGNITION

The CPMP noted the report from the Mutual Recognition Facilitation Group from the meeting held on 20 April 1998 which is circulated together with this Press Release (Annex II).

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.

CENTRALISED APPLICATIONS TO THE EMEA

	Part A	**Part B**	**Total**
Scientific Advice	26	28	54

	Centralised Applications		**Total***
	Part A	**Part B**	
Applications submitted since 1 January 1995	52	96	148
Withdrawn	4	10	14
Opinions given by the CPMP	26	48	74**
Marketing Authorisations granted by the Commission	24	32	56***

	Part A	**Part B**	**Total**
Variations type I	77	113	190
Variations type II	21	45	66
Extensions	10	2	12

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

** 74 Opinions corresponding to 59 substances

*** 56 Marketing Authorisations corresponding to 47 substances

Report from the meeting held on 20th April 1998

The MRFG noted that 10 new mutual recognition procedures have been finalised during the month of March 1998 as well as 26 type I and 17 type II variations.
The status as of 31st March 1998 of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type I variations finalised	Procedures from Type I variations pending	Procedures from Type II variations finalised	Procedures from Type II variations pending	Arbitrations referred to CPMP
1998	39	45	54	41	42	112	--

20 new procedures (regarding 30 products) have been started in March 1998. The categories of these procedures are as follows:

New active substance[1]	Line extensions[2]	Fixed combinations	Generics	Herbal products[3]	OTC[4]	Others[5]
5	2	2	5	0	0	6

1. When in one of the involved Member States it concerns a new active substance according to the definition in the Notice to Applicants Part IIA;
2. Line extensions are those applications which extend a range of products, e.g. an additional strength, or a new pharmaceutical form from the same Marketing Authorisation Holder;
3. In this category products are classified as herbals when the RMS has considered them as herbal product;
4. In this category products are classified as OTC products when the RMS has approved it for OTC use, although the legal status is not part of the Mutual Recognition Procedure;
5. When the product is not classified in the previous six categories.

Each application can be classified in only one category.

Number of countries involved in the started new applications procedures in March 1998:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	12
DE (1)	8
DK (1)	10

DK (1)	7
DK (2)	6
DK (1)	2
DK (1)	5
DK (3)	11
FR (1)	5
NL (4)	14
NL (4)	5
SE (1)	9
SE (2)	1
SE (1)	13
UK (1)	1
UK (1)	6
UK (1)	7
UK (1)	13
UK (1)	1
UK (1)	14

General issues

- The group noted with satisfaction the continued increase in the number of new products commencing in the system. The current level of activity suggests that in the calendar year 1998 the system will handle more applications than were received in the whole three years of the transition.

- The group finalised a paper on "informed consent applications and Mutual Recognition". This paper has been sent to the European Commission. It is hoped that this document will be made available as soon as possible by the Commission.

- The group also finalised the agenda for the important strategic MRFG Meeting which will be hosted by the MCA on the 7th and 8th May 1998 as part of the UK Presidency of the European Union.

- The group agreed the final details of the automatic validation procedure which will commence on the 1st May 1998.

Information on the above mentioned issues can be obtained by the presiding chair of the MRFG:

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