The European Agency for the Evaluation of Medicinal products
Evaluation of Medicines for Human Use

17 April, 2000
CPMP/941/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 59th plenary meeting from 11 April 2000 to 12 April 2000.

The meeting was preceded by a meeting of the Ad Hoc Expert Group on antiretroviral agents, which took place on Monday, 10 April 2000.

The CPMP welcomed Dr Pekka Kurki from Finland as a new member, who was appointed at the March meeting, succeeding Dr Eva Alhava.

Centralised Procedures[1]

The Committee adopted:

- Three positive opinions on centralised marketing authorisation applications:
  - One positive opinion was adopted by consensus relating to a medicinal product containing a new active substance (Part A), an insulin for treatment of diabetes mellitus.
  - One positive opinion was adopted by majority vote relating to a medicinal product in a new delivery system (Part B), containing a cytotoxic agent for the treatment of metastatic breast cancer in women.
  - One positive opinion was adopted by consensus relating to a medicinal product containing a new active substance (Part B), a photosensitising agent indicated for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularisation, by means of Photodynamic Therapy.

- Two positive opinions by consensus for centralised type I variations following a type II procedure.

- Thirteen positive opinions by consensus for centralised type II variations.

- Two positive opinions by consensus following the annual re-assessment of
  - Viracept (nelfinavir) indicated for the treatment in combination of HIV-1 infected patients. The CPMP recommended that the marketing authorisation for this product should remain "under exceptional circumstances".
  - Viramune (nevirapine) indicated for the treatment in combination of HIV-1 infected patients. The CPMP recommended that the marketing authorisation for this product should remain "under exceptional circumstances".

- Four opinions by consensus recommending the suspension for a further year of the Marketing Authorisations for Trovan/ Turvel (trovafloxacin) and Trovan i.v./ Turvel i.v. (alatrofloxacin).

An urgent safety restriction concerning Viramune (nevirapine) to include new warnings on severe and life-threatening cutaneous and hepatic reactions has been finalised and an EMEA Public Statement (EMEA/11260/00) is available on the Internet.

[1] Note for Editors:
Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (+44-20) 74 18 84 00 Fax (+44-20) 74 18 84 20
E_Mail: mail@emea.eudra.org http://www.eudra.org/emea.html

Since the CPMP meeting in March 2000, the Committee noted the withdrawal of one application (Part B) from the centralised procedure.

An overview of centralised applications is given in Annex I.

The CPMP expressed concern regarding the limited number of substances so far for which an application has been submitted to the European Pharmacopoeia/EDQM to obtain a Certificate of Suitability for materials at risk of Transmissible Spongiform Encephalopathies (TSE) (TSE Certificate).

Marketing Authorisation Holders should check the origin of all starting materials and reagents used in the manufacture of their medicinal products, and encourage the manufacturers of animal derived materials, falling under the scope of the CPMP Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products, to apply for TSE Certificates.

The CPMP reminds all Applicants and Marketing Authorisation Holders that the dates of implementation of the new TSE requirements (Directive 1999/82/EC) are 1 July 2000 and 1 March 2001 respectively.

Scientific Advice

The Committee accepted eight new and one follow-up requests from companies for scientific advice. Co-ordinators were appointed.

Referrals

Referral under Article 11 of Council Directive 75/319/EEC, as amended
Following a referral under Article 11 the CPMP adopted by consensus an opinion for a medicinal product containing a recombinant Hepatitis B vaccine, authorised under the former concertation procedure, leading to a harmonised SPC for transmission to the Commission.

Referral under Article 12 of Council Directive 75/319/EEC, as amended
A procedure under Article 12 has been initiated for medicinal products containing calcitonins, in relation to efficacy of such products in osteoporosis and / or in any other indication which relates to anti-resorption effect.

Working Parties and Ad Hoc Expert Groups

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties, and from the Ad hoc Working Group on Blood Products.

BIOTECHNOLOGY WORKING PARTY

One document was adopted*:*

- Final EU recommendations for the Influenza vaccine composition for the season 2000/2001 (CPMP/BWP/840/00)

QUALITY WORKING PARTY

One document was adopted*:*

- Annex to Note for guidance on Development pharmaceuticals: Decision trees for the selection of sterilisation methods (CPMP/QWP/54/98 corr.) (*minor modification to text for clarification*)

SAFETY WORKING PARTY / PHARMACOVIGILANCE WORKING PARTY

One document was adopted*:*

- CPMP Position paper on Selective Serotonin Uptake Inhibitors (SSRIs) and dependency/ withdrawal reactions (EMEA/CPMP/2775/99)

Upcoming Meetings

The CPMP will on 26 June 2000 invite external experts from academia and clinical practice to discuss evaluation of anti-cancer treatment and the need to revise the current CPMP Note for guidance.

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 10 April 2000, which is circulated together with this Press Release (Annex II).

Pharm. Noël Wathion
Head of Sector
Regulatory Affairs and Pharmacovigilance

This Press Release and other documents are available on the Internet at the following address: http://www.eudra.org/emea.html

EMEA CENTRALISED PROCEDURES

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Scientific Advice	61	77	138	2	7	9	147
Follow-up to scientific advice	11	6	17	1	0	1	18

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	8	19	27	251
Withdrawals	12	26	38	0	4	4	42
Positive CPMP opinions	44	82	126	8	7	15	141[1]
Negative CPMP opinions[2]	1	3	4	0	0	0	4[3]
Marketing authorisations granted by the Commission	40	78	118	4	4	8	126[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	18	83	101	606
Positive opinions, variations type II	89	131	220	11	19	30	250
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	0	1	48

[1] 141 positive opinions corresponding to 108 substances
[2] In case of appeal the opinion will not be counted twice
[3] 4 negative opinions corresponding to 3 substances
[4] 126 Marketing Authorisations corresponding to 100 substances

Report from the meeting held on 10 April 2000

The MRFG noted that 22 new mutual recognition procedures were finalised during the month of March 2000, as well as 80 type I and 17 type II variations.

The status as of 31 March 2000 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
2000	41	57	206	83	58	138	--

28 new procedures (regarding 61 products) started in March 2000. The categories of these procedures are as follows:

New active substance[1]	Line extensions[2]	Fixed comb.	Generics	Herbal products[3]	OTC[4]	Blood products	Immuno-logicals	Others[5]
4	5	1	15	0	0	0	0	3

1. When in one of the involved Member States it concerns a new active substance according to the definition in the Notice to Applicants Volume IIA; the number given includes multiple applications and repeat use procedures.
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 other eight categories.

Each application can be classified in only one category.

Number of countries involved in the new applications procedures started in March 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (4)	10
AT (4)	10
AT (4)	10
DE (4)	11
DE (3)	12
DE (1)	5
DE (1)	15
DK (4)	14

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (1)	2
DK (2)	6
DK (3)	1
DK (3)	1
DK (1)	9
DK (3)	2
DK (4)	1
FI (3)	10
FI (1)	5
FI (2)	1
FI (1)	1
IT (2)	2
NL (1)	8
NL (1)	5
NL (1)	2
NL (1)	2
NL (1)	3
SE (2)	1
UK (1	5
UK (1)	1

General issues

- **Note for guidance on the Pharmacodynamic section of the SPC for antibacterial medicinal products**
  The MRFG agreed that recommendations in the Note for guidance made for section 5.1 should as of now also be followed in the SPC of antibiotics going through MRP.

- **Transfer of Marketing Authorisations in EFTA countries to Mutual Recognition**
  A harmonisation of several different marketing authorisations can be generally achieved by a referral according to article 11of Directive 75/319/EEC.

  In addition, the repeat MR-procedure is a tool by which NO/IC (or any MS) can easily switch existing national marketing authorisations into the Mutual Recognition. In that case the applicant should submit a separate new application to the country where repeat use is sought. The concerned country would then request the AR from the initial RMS and start a repeat use procedure. Once this procedure has been successfully completed, the existing national authorisations may have to be revoked or the name of the product may have to be changed. However, this would be decided at national level.

- **Joint MRFG/EFPIA survey**
  The MRFG, upon request by trade associations, would like to remind the pharmaceutical companies, to send completed questionnaires rapidly back to the respective contact point at the trade associations.

- **Guideline on Renewals**
  The MRFG noted the new Guideline on Renewals which was published on the European Commission-Enterprise DG WebSite.

All documents mentioned in this press release can be found at the MRFG WebSite at the European Medicines Authorities Windows under the heading SOP.

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

Dr. António MELO GOUVEIA
Head of the Medicines Division
INFARMED
Parque de Saude de Lisboa
Avenido do Brasil, n° 53
P - 1700 LISBOA

Phone: *+ 351 21 798 7201*
Fax: *+ 351 21 798 7217*
e-mail: *Melo.gouveia@infarmed.pt*

Alternatively, you could visit the ***MRFG WebSite*** *at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

http://heads.medagencies.org/