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

22 November 1999
CPMP/3091/99

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 54th plenary meeting from 16 November 1999 to 18 November 1999.

The CPMP welcomed Dr Tove Karlsrud from Norway, who replaces Dr Gro Wesenberg as an observer.

Centralised Procedures[1]

The Committee adopted:

- Two 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 immunomodulating anti-inflammatory agent indicated for the treatment of rheumatoid arthritis.
  - One positive opinion was adopted by consensus relating to a medicinal product containing a new active substance (Part B), an antiglaucoma preparation indicated for the treatment of ocular hypertension and open-angle glaucoma.
- One negative opinion on a centralised marketing authorisation application was adopted by majority vote relating to a medicinal product containing a new active substance (Part B), proposed as an antithrombotic agent.
- One positive opinion by consensus for a centralised type I variation following a type II procedure.
- Ten positive opinions by consensus and two by majority vote for centralised type II variations.
- One positive opinion by consensus following the annual re-assessment of BeneFIX (nonacog alfa) (Part A) indicated for the treatment of haemophilia B, factor IX deficiency.
- One positive opinion by consensus following the annual re-assessment of Norvir (ritonavir) (Part B) indicated in combination for the treatment of HIV infection.

Since the CPMP meeting in October 1999, the Committee noted the withdrawal of two applications (Part B) from the centralised procedure.

The Committee considered the need for GMP inspections for seven medicinal products (three Part A/ four Part B). Eight inspections for four of these products were requested (two Part A/two Part B).

An overview of centralised applications is given in Annex I.

[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.

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Scientific Advice

The Committee adopted the following scientific advice letters:

Part	Indication(s)	Topic
A	Hepatitis B	Quality Issues
A	Diabetes mellitus	Quality Issues
A	Systemic sclerosis	Pre-clinical and clinical development programme
B	Depression	Pre-clinical and clinical development programme
B	Parkinson's disease	Pre-clinical and clinical development programme
A	Anaemia due to chemotherapy	Clinical development programme
B	Parkinson's disease	Clinical development programme
B	Small cell lung cancer	Clinical development programme

The Committee accepted two new requests from companies for scientific advice. Co-ordinators were appointed.

The Committee adopted one follow-up scientific advice on quality issues concerning a new medicinal product (Part A), intended for the treatment of severe sepsis.

Referrals

Referral under Article 7(5) of Commission Regulation (EC) No 541/95
The CPMP noted the withdrawal of an application for a type II variation in the reference member state and all concerned member states which had been referred for arbitration.

Working Parties, Ad Hoc Expert Groups and Organisational Matters

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties and from the Ad Hoc Expert Working Group on Blood Products. The Committee also heard updates from the Ad Hoc Group on HIV Resistance and from the Ad Hoc Expert Group on Update of the Guideline on the Excipients on the Label and Package Leaflet of Medicinal Products for Human Use.

QUALITY WORKING PARTY

One document was finalised*:*

- Concept paper on the development of a Committee for Propriety Medicinal Products (CPMP) Note for guidance on Requirements for pharmaceutical documentation for metered dose inhalers (CPMP/QWP/2930/99)

ICH

The following documents were released for 6 months' consultation:

- ICH Topic M4: Common Technical Document for the Registration of pharmaceuticals for human use - Module V: Efficacy; Module III: Quality; Modules IIA, IIB and IV: Safety (CPMP/ICH/2887/99)

- ICH Topic Q1A: Note for guidance on Stability testing: Stability testing of new drug substances and products (CPMP/ICH/2736/99 draft, *rev. of CPMP/ICH/380/95*)

- ICH Topic Q3A: Note for guidance on Impurities testing: Impurities in new drug substances (CPMP/ICH/2737/99 draft, *rev. of CPMP/ICH/142/95*)

- ICH Topic Q3B: Note for guidance on Impurities in new drug products (CPMP/ICH/2738/99 draft, *rev. of CPMP/ICH/282/95*)

The following document was adopted for coming into operation in May 2000:

- ICH Topic Q6A: Note for guidance on Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances (CPMP/ICH/367/96)

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) of 15 November 1999, which is circulated together with this Press Release (Annex II).

Prof. Rolf Bass
Head of Unit
Evaluation of Medicines for Human Use

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

EMEA CENTRALISED PROCEDURES

	1995-1998			1999			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Scientific Advice	33	45	78	27	28	55	133
Follow-up to scientific advice	9	4	13	1	2	3	16

	1995-1998			1999			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	62	115	177	18	28	46	223
Withdrawals	11	19	30	1	7	8	38
Positive CPMP opinions	35	65	100	9	17	26	126[1]
Negative CPMP opinions[2]	1	2	3	0	4	4	7[3]
Marketing authorisations granted by the Commission	28	60	88	12	16	28	116[4]

	1995-1998			1999			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	99	168	267	57	170	227	494
Positive opinions, variations type II	41	77	118	45	49	94	212
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	25	6	31	7	8	15	46

[1] 126 positive opinions corresponding to 98 substances
[2] In case of appeal the opinion will not be counted again
[3] 7 negative opinions corresponding to 4 substances
[4] 116 Marketing Authorisations corresponding to 92 substances

Report from the meeting held on 15 November 1999

The MRFG noted that 38 new mutual recognition procedures were finalised during the month of October 1999, as well as 51 type I and 22 type II variations.

The status as of 31 October 1999 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
1999	164	78	569	57	272	94	1 N.A.+ 2 var.

7 new procedures (regarding 19 products) started in October 1999. 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]
1	0	0	5	0	0	0	0	1

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 October 1999:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	5
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
FR (1)	5
UK (1)	4

General issues

- The Position Paper on Repeat use of the Mutual Recognition Procedure was revised.
- The MRFG agreed to harmonise within the European Union the product information regarding the declaration of the content of oxytocin. The declaration of oxytocin content should be stated in mg and, under an intermediate period, the corresponding activity in IU within brackets. A transition period of 3 years for the changes was decided.
- The MRFG agreed that Reference Member States may release minutes of break-out meetings to concerned applicants.
- After its plenary meeting, the MRFG met with representatives of trade associations of pharmaceutical industry (EFPIA, AESGP, EGA).

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:

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

http://heads.medagencies.org/