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

20 March 2000
CPMP/543/00 corr.

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 58th plenary meeting from 14 March 2000 to 16 March 2000.

The CPMP welcomed as a new member Dr Frances Rotblat from UK, succeeding Dr David Jefferys, and noted the appointment of Dr Pekka Kurki from Finland, succeeding Dr Eva Alhava.

Centralised Procedures[1]

The Committee adopted:

- Four 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), a recombinant hepatitis B vaccine.
  - Two positive opinions were adopted by consensus relating to two medicinal products containing the same active substance (Part A), a blood coagulation factor indicated for congenital factor VIII deficiency.
  - One positive opinion was adopted by majority vote relating to a medicinal product containing a new active substance (Part B), a radiopharmaceutical product to help refine the diagnosis in patients with clinically uncertain Parkinsonian syndromes.

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

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

- The Committee, following an appeal procedure and after involvement of an ad hoc expert panel of highly specialised experts, adopted by majority vote opinions recommending the granting of marketing authorisations for Avandia/Venvia/Nyracta (rosiglitazone maleate), indicated for the treatment of type II diabetes mellitus only in combination with metformin or a sulphonylurea and only in specific groups of patients.

Since the CPMP meeting in February 2000 the Committee noted the withdrawal of two applications (Part B) from the centralised procedure.

The Committee considered the need for GMP inspections for four medicinal products (two Part A / two Part B) and requested six inspections for two of these products (Part A).

[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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The Committee heard five oral presentations from applicants:
- Two concerning ongoing procedures
- One oral presentation regarding appeal procedures
- One concerning type II variations
- One oral presentation on a manufacturing problem occurring with the centrally authorised product INSUMAN INFUSAT 100 IU/ml solution for injection in cartridges of 3.25 ml (insulin human) (Public Statement EMEA/3794/00, available on the Internet).

An overview of centralised applications is given in Annex I.

For marketing authorisations granted by the European Commission since the last CPMP in February 2000, see Annex II.

Scientific Advice

The Committee adopted the following scientific advice letters:

Part	Indication(s)	Topic
A	Diabetes mellitus	Pre-clinical development programme
B	Vascular dementia	Clinical development programme
B	Pancreatic adenocarcinoma	Clinical development programme
B	Treatment of breast cancer	Clinical development programme

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

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

Working Parties, Ad Hoc Expert Groups and Organisational Matters

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties, from the Working Party on Herbal Medicinal Products, 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 released for 6 months' consultation*:*

- Note for guidance on Parametric release[2] (CPMP/QWP/3015/99 draft)

AD HOC EXPERT GROUP ON UPDATE OF THE GUIDELINE ON THE EXCIPIENTS ON THE LABEL AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE

One updated document was adopted and will be forwarded to the Commission to be released for 3 months' consultation*:*

- Guideline on excipients in the label and package leaflet of medicinal products for human use (3B 17a) (CPMP/463/00)

[2] Parametric release: system of release that gives assurance that the product is of the intended quality based on the information collected during the manufacturing process and on compliance with specific GMP requirements related to parametric release (definition given by European Organisation of Quality).

The following document was adopted and will be made available on the Internet:

- Applications in the Centralised System 1995 to July 1999 – an analysis of outcomes (CPMP/602/00)

The Committee noted the following guidance document for industry which is published together with this Press Release:

- Guidance Document for industry, with regard to the extension of the Centralised Procedure to Norway and Iceland (EMEA/8518/00)

ICH

The following document was released for 6 months' consultation:

- ICH topic S7: Note for guidance on Safety pharmacology studies for human pharmaceuticals (CPMP/ICH/539/00)

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

- ICH topic M2: Recommendations on Electronic transmission of individual case safety reports message specification (CPMP/ICH/285/95)

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 13 March 2000, which is circulated together with this Press Release (Annex III).

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

	1995-1999			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	7	17	24	248
Withdrawals	12	26	38	0	3	3	41
Positive CPMP opinions[2]	44	82	126	7	5	12	138[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	15	74	89	594
Positive opinions, variations type II	89	131	220	5	11	16	236
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	0	1	48

[1] 138 positive opinions corresponding to 105 substances
[2] In case of appeal the opinion counted will be the final one
[3] 4 negative opinions corresponding to 3 substances
[4] 126 Marketing Authorisations corresponding to 100 substances

Medicinal products granted a Community Marketing Authorisation under the Centralised Procedure since the February 2000 Press Release

Brand name	**Thyrogen**
INN	thyrotropin alfa
Marketing Authorisation Holder	Genzyme B.V., NL
ATC code	V04CJ01
Indication	Detection of thyroid cancer
Opinion receipt date	29/07/99
Date of Commission decision	9/03/00

Brand name	**Alfatronol**
INN	interferon alfa-2b
Marketing Authorisation Holder	SP Europe, BE
ATC code	L03AB05
Indication	Treatment of chronic hepatitis B and C, hairy cell leukaemia, chronic myelogenous leukaemia, multiple myeloma, follicular lymphoma, carcinoid tumours and malignant melanoma
Opinion receipt date	21/10/99
Date of Commission decision	9/03/00

Brand name	**Virtron**
INN	interferon alfa-2b
Marketing Authorisation Holder	SP Europe, BE
ATC code	L03AB05
Indication	Treatment of chronic hepatitis B and C
Opinion receipt date	21/10/99
Date of Commission decision	9/03/00

Brand name	**Azopt**
INN	brinzolamide
Marketing Authorisation Holder	Alcon Laboratories
ATC code	S01EC
Indication	Treatment of elevated intraocular pressure in ocular hypertension and open-angle glaucoma
Opinion receipt date	18/11/99
Date of Commission decision	14/03/00

Report from the meeting held on 13 March 2000

The MRFG noted that 16 new mutual recognition procedures were finalised during the month of February 2000, as well as 65 type I and 20 type II variations.

The status as of 29th February 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	19	52	126	63	41	118	--

7 new procedures (regarding 11 products) started in February 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]
0	0	0	6	0	0	0	1	0

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 February 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (3)	6
DE (3)	6
DE (1)	14
DK (1)	11
NL (1)	9
NL (1)	4
NL (1)	3

General issues

- **MR-related documentation to be submitted by applicants to the EMEA:**
  Applicants are reminded to limit the documentation to be submitted to the EMEA (MRFG support) to those currently listed in the Notice to Applicants (Chapter II): notification of an application, in case of arbitration a full copy of the dossier as submitted in the MR-procedure, for arbitrations relating to variations an updated full dossier and documentation related to the relevant respective variations. In addition, the applicants shall submit notifications of withdrawals.

- **MR-SPC for influenza vaccines: amendment regarding Gullain Barré Syndrome (GBS) and Thiomersal**
  The MRFG agreed to amend the MR-SPC for influenza vaccines regarding GBS and Thiomersal. The revised MR-SPC is published on the Heads of Agencies website. Applicants may update their product information accordingly through one single type II variation.

- **Meeting with interested parties:**
  The MRFG plenary meeting was followed by a meeting with interested parties. In the future this forum will be more used to discuss identified issues necessitating clarification from both sides. The MRFG presented the new classification of Eudra Track subtypes, which will translate to a new format of statistics presented in the MRFG Press Release. The MRFG invited interested parties to present additional proposals for improvement of the information given in the MRFG Press Release. The MRFG presented the progress made in the projects on withdrawal reports and MR-SPC. The MRFG will further consider industry's proposal regarding timing of variations of MR authorised Medicinal Products and simplified procedures to update marketing authorisations in EFTA countries regarding MR- authorisations.

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/