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

21 February 2000
CPMP/316/00 corr.

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 57th plenary meeting from 15 February 2000 to 17 February 2000.

The CPMP warmly thanked for their excellent achievements and collaboration Dr Eva Alhava, from Finland and Dr David Jefferys, from the United Kingdom, who resign from their CPMP membership.

Centralised Procedures[1]

The Committee adopted:

- Four positive opinions on centralised marketing authorisation applications:

- Two positive opinions were adopted by consensus relating to two medicinal products containing the same active substance (Part A), an antidiabetic substance indicated for parenteral treatment of diabetes mellitus.
- Two positive opinions were adopted by consensus relating to two medicinal products containing the same active substance (Part A), an immunomodulating agent indicated for treatment of chronic hepatitis C.

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

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

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

The Committee considered the need for GMP inspections for nine medicinal products (Part B) and requested an inspection for three of them.

The Committee heard two oral presentations from applicants concerning ongoing procedures.

An overview of centralised applications is given in Annex I.

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

[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 letter:

Part	Indication(s)	Topic
A	Maintenance treatment of moderate to severe persistent asthma	Pre-clinical & clinical development programme

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

Referrals

Referral under Article 7(5) of Commission Regulation (EC) No 541/95
The Committee noted that the assessment continued on a referral for arbitration initiated by France and relating to the CPMP of a Type II variation proposing an extension to the indication, for a medicinal product authorised through the Mutual Recognition procedure.

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 Working Group on Blood Products, 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 and the Ad Hoc Rapporteur's meeting on interferons and neutralising antibodies.

QUALITY WORKING PARTY

One document was adopted*:*

- QWP Workplan for 2000 (CPMP/QWP/583/99 rev. 3)

BIOTECHNOLOGY WORKING PARTY

One document was adopted*:*

- BWP Workplan for 2000/2001 (CPMP/BWP/3318/99)

SAFETY WORKING PARTY

Prof Beatriz Silva Lima was nominated as the acting Chairperson.

EFFICACY WORKING PARTY

One document was adopted for coming into operation in August 2000*:*

- Note for guidance on Clinical investigation of steroid contraceptives in women (CPMP/EWP/519/98)

Two documents were adopted for coming into operation immediately:

- Points to consider concerning Endpoints in clinical studies with haematopoietic growth factors for mobilisation of autologous stem cells (CPMP/EWP/197/99)

- Points to consider on the Clinical investigation of new medicinal products for the treatment of Acute Coronary Syndrome (ACS) without persistent ST-segment elevation (CPMP/EWP/570/98)

Two concept papers were adopted:

- Concept paper on the Development of a CPMP Note for guidance on the Clinical investigation of medicinal products in the treatment of asthma (CPMP/EWP/2922/99)

- Concept paper on the Development of a CPMP Points to consider on Biostatistical/methodological issues arising from CPMP discussions on licensing applications: Adjustment for baseline covariates (CPMP/EWP/2863/99)

ORGANISATIONAL MATTERS

The Calendar for CPMP meetings in 2000 and 2001, as well as the Calendar for submission of Full Applications, and the Calendar for submission of Responses to the List of Questions in 2000 and 2001 are distributed together with this Press Release (Annex III-V).

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 14 January 2000, which is circulated together with this Press Release (Annex VI).

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	1	4	5	143
Follow-up to scientific advice	11	6	17	0	0	0	17

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	6	16	22	246
Withdrawals	12	26	38	0	1	1	39
Positive CPMP opinions	44	82	126	4	1	5	131[1]
Negative CPMP opinions[2]	1	6	7	0	0	0	7[3]
Marketing authorisations granted by the Commission	40	78	118	1	3	4	122[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	6	46	52	557
Positive opinions, variations type II	89	131	220	5	6	11	231
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	0	1	48

[1] 131 positive opinions corresponding to 101 substances
[2] In case of appeal the opinion will not be counted again
[3] 7 negative opinions corresponding to 4 substances
[4] 122 Marketing Authorisations corresponding to 97 substances

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

Brand name	**Tractocile**
INN	atosiban
Marketing Authorisation Holder	Ferring AB, Sweden
ATC code	Not attributed
Indication	Preterm birth
Opinion receipt date	25/10/99
Date of Commission decision	20/01/00

Brand name	**Renagel**
INN	sevelamer
Marketing Authorisation Holder	Genzyme B.V., Netherlands
ATC code	VO3AE02
Indication	Control of hyperphosphataemia in adult patients on haemodialysis
Opinion receipt date	29/10/99
Date of Commission decision	28/01/00

Brand name	**Zyprexa Velotab**
INN	olanzapine
Marketing Authorisation Holder	Eli Lilly and Company Ltd., Netherlands
ATC code	NO5AH03
Indication	Antipsychotic
Opinion receipt date	22/11/99
Date of Commission decision	03/02/00

Brand name	**Enbrel**
INN	etanercept
Marketing Authorisation Holder	Wyeth Europa Ltd., UK
ATC code	LO4AA11
Indication	Treatment of active rheumatoid arthritis
Opinion receipt date	29/11/99
Date of Commission decision	03/02/00

Calendar of CPMP meetings in 2000

Month	Day
January	18, 19, 20
February	15, 16, 17
March	14, 15, 16
April	11, 12, 13
May	23, 24, 25
June	27, 28, 29
July	25, 26, 27
August	22, 23, 24
September	19, 20, 21
October	17, 18, 19
November	14, 15, 16
December	12, 13, 14

Calendar of CPMP meetings in 2001

Month	Day
January	23, 24, 25
February	27, 28, 1
March	27, 28, 29
April	24, 25, 26
May	29, 30, 31
June	26, 27, 28
July	24, 25, 26
August	21, 22, 23
September	18, 19, 20
October	16, 17, 18
November	13, 14, 15
December	11, 12, 13

Submission dates for full applications 2000

May	8
June	3
July	3
August	1
September	11
October	16
November	13
December	11

Submission dates for full applications 2001

January	15
February	12
March	12
April	9
May	7
June	4
July	2
August	31 July
September	N/A*
October	N/A*
November	N/A*
December	N/A*

* CPMP dates for 2002 are not yet assigned

Calendar for submission of responses to the List of Questions in 2000

Month	Day
January	N/A
February	N/A
March	N/A
April	N/A
May	19
June	16
July	14
August	11
September	8
October	23
November	24
December	15

Calendar for submission of responses to the List of Questions in 2001

Month	Day
January	19
February	23
March	23
April	20
May	18
June	15
July	14
August	10
September	7
October	To be defined later
November	To be defined later
December	To be defined later

Report from the meeting held on 14 February 2000

The MRFG noted that 3 new mutual recognition procedures were finalised during the month of January 2000, as well as 61 type I and 21 type II variations.

The status as of 31st January 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	3	62	61	68	21	115	--

24 new procedures (regarding 40 products) started in January 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]
7	0	3	5	0	0	0	2	7

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 January 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (3)	1
DE (1)	15
DE (2)	3
DE (1)	3
FI (1)	13
FI (2)	1
FR (1)	4

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FR (2)	5
IR (1)	14
IR (1)	10
IR (1)	2
IR (1)	4
IT (1)	15
IT (1)	15
NL (2)	13
NL (1)	16
NL (1)	8
NL (1)	2
NL (1)	3
SE (3)	12
SE (3)	1
UK (3)	6
UK (3)	3
UK (3)	1

General issues

- The MRFG adopted a revision of the EudraTrack classification of MR-procedures. The EudraTrack system will be updated accordingly.
- The work on the internal MRFG paper on combination packages was put on hold. This issue will be referred to the Pharmaceutical Committee and EMACOLEX for additional input.

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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http://heads.medagencies.org/