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

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CPMP/1304/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 60th plenary meeting from 23 May 2000 to 25 May 2000.

Centralised Procedures[1]

The Committee adopted:

- One positive opinion on a centralised marketing authorisation application by majority vote relating to a medicinal product containing a new active substance (Part A), an antineoplastic agent indicated for treatment of metastatic breast cancer.

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

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

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

The CPMP adopted sixteen lists of questions (four Part A /twelve Part B).

The Committee heard four oral presentations from applicants concerning ongoing procedures and one oral presentation regarding type II variations, as well as an oral presentation regarding a referral and an oral clarification relating to a planned submission of a type I variation.

An overview of centralised applications is given in Annex I.

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

Scientific Advice

The Committee adopted the following scientific advice letters:

Part	Indication(s)	Topic
B	HIV-1 infection in adults	Clinical development programme
B	Combination treatment of Parkinson's disease	Pre-clinical and Clinical development programme
B	Symptomatic treatment of benign prostatic hyperplasia	Clinical development programme

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

[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.

The Committee adopted one follow-up scientific advice on clinical development programme, concerning a new medicinal product (Part B) , intended for Management of pain.

Referrals

Referral under Article 7(5) of Commission Regulation (EC) No 541/95
A positive opinion for arbitration for a variation type II referred to the EMEA under the mutual recognition procedure was adopted by consensus and will be forwarded to the Commission.

Referral under Article 10(2) of Council Directive 75/319/EEC, as amended
A revision of a positive opinion for arbitration referred to the EMEA under the mutual recognition procedure was adopted by consensus and will be forwarded to the Commission.

Working Parties, Ad Hoc Expert Groups and Organisational Matters

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

BIOTECHNOLOGY WORKING PARTY

The following document was released for 6 months' consultation:

- Note for guidance on Comparability of medicinal products containing biotechnology-derived proteins as active substances (CPMP/BWP/3207/00)

PHARMACOVIGILANCE WORKING PARTY

The following document was released for 3 months' consultation:

- Joint Pilot Plan for the implementation of the electronic transmission of individual case safety reports between the EMEA, National Competent Authorities, and the Pharmaceutical Industry (EMEA/CPMP/PhVWP/205899)

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 22 May 2000, which is circulated together with this Press Release (Annex III).

Pharm. Noël Wathion
Head of Sector
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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	10	12	150
Follow-up to scientific advice	11	6	17	1	1	2	19

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	9	20	29	253
Withdrawals	12	26	38	0	5	5	43
Positive CPMP opinions	44	82	126	9	7	16	142[1]
Negative CPMP opinions[2]	1	3	4	0	0	0	4[3]
Marketing authorisations granted by the Commission	40	78	118	4	5	9	127[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	25	102	127	632
Positive opinions, variations type II	89	131	220	12	26	38	258
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	0	1	48

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[1] 142 positive opinions corresponding to 109 substances
[2] In case of appeal the opinion will not be counted twice
[3] 4 negative opinions corresponding to 3 substances
[4] 127 Marketing Authorisations corresponding to 101 substances

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

Brand name	Orgalutran
INN	Ganirelix
Marketing Authorisation Holder	N.V. Organon
ATC code	H01CC01
Indication	Prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation
Opinion receipt date	22/02/00
Date of Commission Decision	17/05/00

Report from the meeting held on 22 May 2000

The MRFG noted that 22 new mutual recognition procedures were finalised during the month of April 2000, as well as 67 type I and 16 type II variations.

The status as of 30th April 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	63	79	273	53	74	146	1 N.A.

45 new procedures (regarding 69 products) started in April 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]
10	9	5	12	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 April 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (3)	10
AT (3)	2
AT (1)	16
AT (1)	7
AT (1)	2
BE (1)	6
DE (1)	12
DE (1)	4

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	12
DE (1)	10
DE (2)	6
DK (2)	14
DK (1)	1
DK (4)	11
DK (1)	7
DK (2)	2
ES (1)	16
ES (1)	9
FI (1)	10
FR (4)	14
FR (1)	1
FR (1)	2
FR (2)	2
NL (2)	5
NL (2)	8
NL (2)	4
NL (2)	1
SE (1)	1
SE (2)	2
SE (1)	3
SE (1)	6
SE (4)	16
SE (2)	16
SE (1)	1
SE (1)	1
SE (1)	16
UK (1)	8
UK (1)	15
UK (1)	4
UK (1)	4
UK (1)	7
UK (1)	1
UK (1)	2
UK (1)	7
UK (2)	1

General issues

Analysis on withdrawals

An in-depth analysis of the reasons for withdrawals of applications within the MR-procedure has been going on since September 1999. The MRFG emphasises the importance of this exercise, especially in view of proposing solutions to avoid withdrawals in the future. The Member States are continuing to prepare such reports which are regularly discussed during the MRFG meetings.

TSE related requirements in MRP according to Directive 75/318/EEC as amended by Directive1999/82/EEC

Applicants/Marketing Authorisation Holders (MAHs) are reminded that according to the above Directive they have to demonstrate that their medicinal products are manufactured in accordance with the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products. MAHs have to demonstrate compliance of existing Marketing Authorisations by 1 March 2001 and for new applications for Marketing Authorisations lodged by 1 July 2000. The MRFG has been discussing implications for MR-procedures. Manufacturers of starting materials are encouraged to apply as soon as possible for TSE-certificates from the European Pharmacopoeial Commission. The implications for the administrative processing will be released after the next MRFG meeting on the European Commission's, Heads of Agencies' and their respective national health authorities' WebSites.

CFC replacement in medicinal products in the European Union

Subscribers to the Montreal Protocol had agreed measures to reduce depletion of the ozone layer including phasing out of CFCs in medicinal products in 1995. However, the protocol granted a temporary exemption under the 'Essential Use Criteria' for metered dose inhalers (MDIs) used for the treatment of asthma and chronic obstructive pulmonary disease. The EC, together with the MS agreed in 1998, principles and criteria to determine when the 'Essential Use Criteria' could be withdrawn in the EC. The MRFG has started reviewing the alternatives for non-CFC MDIs. The MRFG noted that not all MAs for non-CFC MDIs are systematically applied for within all Member States. Thus, insufficient alternatives exist to date in some Member States. Member States will continue with this exercise.

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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*Or you could visit the **MRFG web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*
http://heads.medagencies.org/