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

31 July 2000
CPMP/1964/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 62nd plenary meeting from 25 July 2000 to 27 July 2000.

The CPMP warmly thanked Dr Mary Teeling, who is resigning her CPMP membership, for her excellent achievements and collaboration.

Centralised Procedures[1]

The Committee adopted:

- two positive opinions (one by consensus / one by majority vote) and one negative opinion (by consensus) on initial centralised marketing authorisation applications
- four positive opinions by consensus for centralised type I variations following a type II procedure and twenty-two positive opinions by consensus for centralised type II variations
- one positive opinion by consensus following the annual re-assessment of Rebif (interferon beta-1a) (Part A) indicated for the treatment of multiple sclerosis. The CPMP recommended that the marketing authorisation for this product should no longer remain "under exceptional circumstances".

The CPMP adopted eight lists of questions (two Part A/ six Part B), and heard one oral presentation from an applicant concerning an ongoing procedure.

An overview of centralised applications is given in Annex I.

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

Scientific Advice

The Committee adopted the following scientific advice letters:

Product	Indication(s)	Topic
Chemical Entity	Autoimmune insulin-dependent diabetes	Pre-Clinical and Clinical development programme
Chemical Entity	Congestive heart failure	Clinical development programme
Chemical Entity	Schizophrenia	Pre-Clinical and Clinical development programme
Chemical Entity	Low Grade Cervical Dysplasia	Clinical development programme

The Committee accepted twelve new and two follow-up requests from companies for scientific advice.

The Committee adopted two follow-up scientific advice letters for two new medicinal products (Chemical Entities), intended for the treatment of

- Schizophrenia
- Parkinson's disease

[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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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.

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.

Quality Working Party

Reference number	Document	Status
CPMP/QWP/1719/00	Draft Note for guidance on Medicinal gases: pharmaceutical documentation	Released in July 2000 for 6 months' consultation
CPMP/QWP/1676/00	Concept paper on the Development of a CPMP/CVMP Note for guidance on Quality of water for pharmaceutical use	Adopted in July 2000

Biotechnology Working Party

Reference number	Document	Status
CPMP/BWP/1143/00	Position statement on the Use of tumorigenic cells of human origin for the production of biological and biotechnological medicinal products	Released in July 2000 for 3 months' consultation
CPMP/BWP/269/95 rev. 2	Revision of section 3.2.5 of CPMP Note for guidance on Plasma-derived medicinal products	Released in July 2000 for 2 months' consultation
CPMP/BWP/1244/00	Report of the EMEA Expert Workshop on human TSEs and plasma-derived medicinal products, 15-16 May 2000	Adopted in July 2000

Safety Working Party

Reference number	Document	Status
CPMP/SWP/1042/99	Note for guidance on Repeated dose toxicity	Adopted in July 2000

Efficacy Working Party

Reference number	Document	Status
CPMP/EWP/2284/99	Points to consider on Clinical investigation of medicinal products for the management of Crohn's disease	Released in July 2000 for 4 months' consultation
CPMP/EWP/2655/99	Points to consider on Pharmaco-kinetics and pharmacodynamics in the development of anti-bacterial medicinal products	Adopted in July 2000
CPMP/EWP/482/99	Points to consider on Switching between superiority and non-inferiority	Adopted in July 2000

Reference number	Document	Status
CPMP/EWP/1080/00	Concept paper on the Development of a CPMP Note for guidance on the Clinical investigation of medicinal products in the treatment of diabetes mellitus	Adopted in July 2000

Ad Hoc Expert Group for the revision of the anticancer guideline

Reference number	Document	Status
CPMP/EWP/205/95 rev.1	Note for guidance on Evaluation of anticancer medicinal products in man	Released in July 2000 for 4 months' consultation

Ad Hoc Group of Experts on antiretroviral medicinal products

Reference number	Document	Status
CPMP/602/95 rev. 2	Revision of Points to consider on the Assessment of anti-HIV medicinal products	Released in July 2000 for 4 months' consultation

ICH

Reference number	Document	Status
CPMP/ICH/364/96	ICH Topic E 10 – Final ICH guideline for Choice of control group in clinical trials ICH Step 4	Agreed in July 2000 for implementation
CPMP/ICH/2711/99	ICH Topic E 11 – Final ICH guideline for Clinical investigation of medicinal products in children ICH Step 4	Agreed in July 2000 for implementation
CPMP/ICH/2887/99	M4 – Draft ICH guideline for Organisation of the Common Technical Document for the registration of pharmaceuticals for human use ▪ CTD – Quality M4 Q ▪ CTD – Safety M4 S ▪ CTD – Efficacy M4 E ICH Step 2	Released in July 2000 for 2 months' consultation
CPMP/ICH/283/95	Q3C(M) – Maintenance of the guideline on Impurities: Residual solvents (CPMP/ICH/283/95): Permissible Daily Exposure (PDE) for Tetrahydrofuran and N. Methylpyrrolidone ICH Step 2	Released in July 2000 for 2 months' consultation

The Committee noted the release by the European Commission for 2 months' consultation of Q7A – Draft ICH guideline for Good Manufacturing Practice for active pharmaceutical ingredients; ICH Step 2.

Organisational Matters

The CPMP agreed that opinions adopted in August 2000 by written procedure will be addressed in the September 2000 CPMP Press Release.

The CPMP noted the nomination of Pharm. Noël Wathion as the Head of Unit responsible for post-marketing issues with effect from 1 September 2000. The press announcement is distributed together with this press release (EMEA/D/20840/00).

The Committee heard the report from the EMEA seminar on the use of pharmaco-genetics in drug development process (EMEA/CPMP/1483/00).

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 24 July 2000, which is circulated together with this Press Release (Annex III).

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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	4	18	22	160
Follow-up to scientific advice	11	6	17	1	4	5	22

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	15	24	39	263
Withdrawals	12	26	38	0	5	5	43
Positive CPMP opinions	44	82	126	13	14	27	153[1]
Negative CPMP opinions[2]	1	3	4	0	1	1	5[3]
Marketing authorisations granted by the Commission	40	78	118	8	9	17	135[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	48	156	204	709
Positive opinions, variations type II	89	131	220	25	54	79	299
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	1	2	49

[1] 155 positive opinions corresponding to 119 substances
[2] In case of appeal the opinion will not be counted twice
[3] 5 negative opinions corresponding to 4 substances
[4] 135 Marketing Authorisations corresponding to 105 substances

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

Brand name	Optisulin
INN	Insulin glargine
Marketing Authorisation Holder	Aventis Pharma Deutschland GmbH, DE
ATC code	A10AE
Indication	Diabetes mellitus
Opinion receipt date	23/03/00
Date of Commission Decision	27/06/00

Brand name	Avandia
INN	Rosiglitazone
Marketing Authorisation Holder	SmithKline Beecham Pharmaceuticals, UK
ATC code	A10BG02
Indication	Treatment of type 2 diabetes mellitus only in combination with metformin or a sulphonylurea and only in specific patient groups
Opinion receipt date	17/04/00
Date of Commission Decision	11/07/00

Brand name	Nyracta
INN	Rosiglitazone
Marketing Authorisation Holder	SmithKline Beecham Pharmaceuticals, UK
ATC code	A10BG02
Indication	Treatment of type 2 diabetes mellitus only in combination with metformin or a sulphonylurea and only in specific patient groups
Opinion receipt date	17/04/00
Date of Commission Decision	11/07/00

Brand name	Venvia
INN	Rosiglitazone
Marketing Authorisation Holder	SmithKline Beecham Pharmaceuticals, UK
ATC code	A10BG02
Indication	Treatment of type 2 diabetes mellitus only in combination with metformin or a sulphonylurea and only in specific patient groups
Opinion receipt date	17/04/00
Date of Commission Decision	11/07/00

Brand name	Myocet
INN	Doxorubicin
Marketing Authorisation Holder	The Liposome Company, UK
ATC code	L01DB
Indication	Treatment of metastatic breast cancer
Opinion receipt date	17/05/00
Date of Commission Decision	13/07/00

MRFG
Mutual Recognition Facilitation Group

Report from the meeting held on 24 July 2000

The MRFG noted that 26 new mutual recognition procedures were finalised during the month of June 2000, as well as 113 type I and 34 type II variations.

The status as of 30 June 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	99	85	451	82	135	144	1 N.A. and 2 variations

15 new procedures (regarding 23 products) started in June 2000. The categories of these procedures are as follows:

3 known active substances (already authorised in at least one member state).

11 abridged applications including **1** multiple application.

1 line extension application.

The new procedures started this month relate to 3 full dossiers, 11 generics and 1 for different use, route or dose.

The procedures consisted of 15 chemical substances[1].

15 of these procedures were prescription-only medicinal products in the reference Member State[2].

1. As considered by RMS.
2. In this category products are classified as prescription-only or Non-prescription (OTC) products when the RMS has approved them accordingly, although the legal status is not part of the Mutual Recognition Procedure.

Number of countries involved in the new applications procedures started in June 2000

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	15
DK(2)	1
FI (1)	1
FI (1)	5
FI (1)	4
NL (2)	9
NL (2)	1
NL (2)	7
NL (2)	3
NL (2)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (2)	6
UK (1)	1
UK (1)	12
UK (1)	12
UK (2)	2

General issues

Information about IT issues

- Problems relating to the Heads of Agencies Website have been solved and the website has been functioning again since 24 July 2000.
- The temporary pause in updating the MR-Index has ended. Continuous updating will resume on a regular basis.

Art. 11 and Art.12 (75/319/EEC as amended) referrals and MRP

The MRFG discussed how to handle applications (either national or MR) when a referral for arbitration under Art. 11 or Art. 12 has been made. The European Commission confirmed that, while an Art. 11 or Art. 12 procedure is ongoing, independent applications for a marketing authorisation can be launched and ongoing procedures can be finalised, even if they fall under the scope of this referral.

Meeting schedule

The next MRFG meeting will be held on 18 September 2000.

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/