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

4 July 2000
CPMP/1586/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 61st plenary meeting from 27 June 2000 to 29 June 2000.

The CPMP adopted the EMEA position statement on recent development concerning thiomersal in vaccines (EMEA/CPMP/1578/00) which is distributed together with this press release.

On 26 June 2000 a meeting of CPMP members and experts from European learned societies was convened to discuss the evaluation of anti-cancer treatment.

Centralised Procedures[1]

The Committee adopted:

- nine positive opinions (five by consensus/four by majority vote) on initial centralised marketing authorisation applications
  As previously announced a new EMEA transparency policy comes into effect from the beginning of July 2000. A summary of opinion will be published for each opinion (both positive and negative) on initial centralised marketing authorisation applications. Summaries of opinion will be published 15 days after notification of the opinion to the applicant, once the right of appeal has expired and the opinion has become final. Opinions that are appealed will therefore not be published until they are final. Further details of the transparency policy are given in "Outcome of public consultation on new EMEA transparency initiatives" (9 June 2000, reference EMEA/D/16909/00).

- one positive opinion on “line extension” applications (in accordance with Annex II of the Commission Regulation (EC) No 542/95 as amended) was adopted by consensus relating to an application for an additional strength concerning an already centrally authorised medicinal product containing an antiviral (Part B), indicated in combination with antiretroviral nucleoside analogues for the treatment of Human Immunodeficiency Virus (HIV)-1 infected patients

- two positive opinions by consensus for centralised type I variations following a type II procedure and nineteen positive opinions by consensus for centralised type II variations

The CPMP adopted two lists of questions (one Part A/one Part B), and heard four oral presentations from applicants concerning ongoing procedures (including one line extension application).

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.

[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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (+44-20) 74 18 84 00 Fax (+44-20) 74 18 84 20
E_Mail: mail@emea.eudra.org http://www.eudra.org/emea.html

Scientific Advice

The Committee adopted the following scientific advice letters:

Product	Indication(s)	Topic
Biological/Biotech	Congenital alpha-1-antitrypsin deficiency	Clinical development programme
Biological/Biotech	Acute stroke	Quality and clinical development programme
Chemical Entity	Obesity	Quality development programme
Chemical Entity	Anogenital herpes to prevent subsequent recurrences	Clinical development programme
Chemical Entity	Adjunctive therapy to prevent a premature LH surge, premature luteinization in women undergoing stimulation of multiple follicular development with gonadotropins	Clinical development programme
Chemical Entity	In hormone replacement therapy in association with estrogen	Pre-clinical development programme

The Committee accepted ten new and one follow-up requests from companies for scientific advice.

The Committee adopted one follow-up scientific advice letter on clinical development for a new medicinal product (Part B), intended for the treatment of schizophrenia.

Referrals

Referral under Article 7(5) of Commission Regulation (EC) No 541/95
The Committee noted the referral for arbitration to the CPMP of a type II variation relating to an extension for a new indication, concerning a medicinal product already authorised through the mutual recognition procedure. A Rapporteur and a Co-Rapporteur were assigned.

Referral under Article 10 of Council Directive 75/319/EEC, as amended
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.

Referral under Article 11 of Council Directive 75/319/EEC, as amended
A procedure under Article 11 for arbitration relating to harmonisation of the Summary of Product Characteristics has been initiated by Marketing Authorisation Holders. A Rapporteur and a Co-Rapporteur were assigned.

Referral under Article 12 of Council Directive 75/319/EEC, as amended
A procedure under Article 12 has been initiated by Germany for Cisapride-containing medicinal products regarding benefit/risk in the approved indications. A Rapporteur and Co-Rapporteurs were assigned.

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

The Committee adopted the Updated Workplan for the CPMP/CVMP QWP 2000 – status June 2000 (CPMP/QWP/583/99 rev. 4).

Biotechnology Working Party

The Committee adopted the Workplan for the BWP 2000/2001, revision June 2000 (CPMP/BWP/1577/00).

Safety Working Party

The Committee adopted the Workplan for the SWP 2000 – Status June 2000 (CPMP/SWP/1060/00).

Efficacy Working Party

The Committee adopted the Workplan for the EWP 2000/2001 - Status June 2000 (CPMP/EWP/478/96 rev. 22).

Reference number	Document	Status
(CPMP/EWP/707/98)	Points to consider on Clinical investigation of medicinal products for prophylaxis of intra- and post-operative venous thromboembolic risk	Adopted in June 2000
(CPMP/EWP/612/00)	Concept paper on the Development of a CPMP Note for guidance on the Clinical investigation of medicinal products in pain management	Adopted in June 2000

Pharmacovigilance Working Party

The Committee adopted the Workplan for the PhVWP 2000 – Status 1 July 2000 (CPMP/PhVWP/1338/00).

Ad Hoc Working Group on Blood Products

Reference number	Document	Status
(CPMP/BPWG/575/99)	Note for guidance on the Clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use	Adopted in June 2000
(CPMP/BPWG/388/95 rev. 1)	Note for guidance on the Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Adopted in June 2000
(CPMP/BPWG/198/95 rev. 1)	Note for guidance on the Clinical investigation of human plasma derived factor VIII and IX products	Released for 2 months' consultation in June 2000
(CPMP/BPWG/1561/99)	Note for guidance on the Clinical investigation of recombinant factor VIII and IX products	Released for 2 months' consultation in June 2000

(CPMP/BPWG/574/99)	Core SPC for Human anti-D immunoglobulin for intravenous and/or intramuscular use	Adopted in June 2000
(CPMP/BPWG/859/95 rev. 1)	Core SPC for Human normal immunoglobulin for intravenous administration (IVIg)	Adopted in June 2000
(CPMP/BPWG/1619/99)	Core SPC for Human plasma derived and recombinant coagulation factor VIII products	Adopted in June 2000
(CPMP/BPWG/1625/99)	Core SPC for Human plasma derived and recombinant coagulation factor IX products	Adopted in June 2000
(CPMP/PhVWP/BPWG/2231/99)	Core SPC for Human albumin	Released for 2 months' consultation in June 2000

ICH

Reference number	Document	Status
(CPMP/ICH/541/00)	E12A: Principles for clinical evaluation of new antiypertensive drugs	Adopted in June 2000

Organisational Matters

The CPMP agreed that the August 2000 meeting will not take place and applications will be dealt with by written procedure.

Upcoming meetings

An EMEA workshop on "Pre-clinical safety evaluation of vaccines: current experience, new adjuvants and future challenges" will be held on 9 October 2000.

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) 26 June 2000, which is circulated together with this Press Release (Annex III).

Pharm. Noël Wathion
Head of Sector
Regulatory Affairs and Pharmacovigilance
Tel. (+44-20) 74 18 85 92 Fax (+44-20) 74 18 86 68

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	14	18	156
Follow-up to scientific advice	11	6	17	1	2	3	20

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	10	23	33	257
Withdrawals	12	26	38	0	5	5	43
Positive CPMP opinions	44	82	126	12	13	25	151[1]
Negative CPMP opinions[2]	1	3	4	0	0	0	4[3]
Marketing authorisations granted by the Commission	40	78	118	7	5	12	130[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	40	150	190	695
Positive opinions, variations type II	89	131	220	17	40	57	277
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	1	1	2	49

[1] 151 positive opinions corresponding to 117 substances
[2] In case of appeal the opinion will not be counted twice
[3] 4 negative opinions corresponding to 3 substances
[4] 130 Marketing Authorisations corresponding to 103 substances

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

Brand name	PEG-Intron
INN	Peginterferon alfa-2b
Marketing Authorisation Holder	SP Europe
ATC code	L03AB
Indication	Treatment of chronic hepatitis C
Opinion receipt date	27/03/00
Date of Commission Decision	25/05/00

Brand name	PEG-Viraferon
INN	Peginterferon alfa-2b
Marketing Authorisation Holder	SP Europe
ATC code	L03AB
Indication	Treatment of chronic hepatitis C
Opinion receipt date	27/03/00
Date of Commission Decision	25/05/00

Brand name	Lantus
INN	Insuline glargine
Marketing Authorisation Holder	Hoechst Marion Roussel Deutschland GmbH, DE
ATC code	A10AE
Indication	Diabetes mellitus
Opinion receipt date	23/03/00
Date of Commission Decision	6/06/00

Report from the meeting held on 26 June 2000

The MRFG noted that 10 new mutual recognition procedures were finalised during the month of May 2000, as well as 65 type I and 27 type II variations.

The status as of 31 May 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	73	96	338	71	101	145	1 N.A.

26 new procedures (regarding 42 products) started in May 2000. The categories of these procedures are as follows:

- **5** new active substances (first authorisation in the European Community after RMS approval), including **3** multiple applications and **1** repeat use
- **5** known active substances (already authorised in at least one member state), including **1** multiple application and **3** repeat use
- **14** abridged applications including **1** multiple application and **1** repeat use
- **2** line extension applications

The new procedures started this month relate to 9 full dossiers, 3 informed consent applications, 1 bibliographic application, 10 generics, 1 fixed combination, and 2 for different use, route or dose.

The procedures consisted of 25 chemical substances and 1 blood product[1].

22 of these procedures were prescription-only medicinal products in the reference Member State and 4 were Non-prescription (including OTC) medicinal products[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 May 2000

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	5
DE (2)	1
DE (1)	4
DK(2)	7
FI (1)	2
FR (1)	11

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FR (1)	11
FR (1)	8
IR (1)	5
IR (3)	2
IR (1)	1
NL (1)	6
NL (1)	16
NL (1)	7
NL (1)	8
SE (3)	1
SE (3)	1
SE (3)	1
SE (2)	1
SE (1)	1
UK (4)	1
UK (1)	8
UK (1)	1
UK (1)	10
UK (1)	15
UK (4)	2

GENERAL ISSUES

Scientific/Regulatory recommendations given to the applicants by MSs

The Member States have noticed that applicants often contact several national agencies for scientific/regulatory recommendations and advice on borderline products prior to submitting the application. In order for Member States to be aware of the recommendations given by other competent authorities, the Group agreed on a set of information to be shared between the Member States.

SOP on Urgent Safety Restrictions

The SOP on Urgent Safety Restrictions was formally adopted by the MRFG and will be published on the MRFG website.

Harmonisation of generic medicinal products

The MRFG considered problems related to the disharmony between the SPC of the brand leader and the generic medicinal products. Within the MRP this often causes partial withdrawals of the dossier from the CMSs.

The MRFG discussed the possibility of harmonisation of generic medicinal products and respective brand leaders via Article 11 procedure.

TSE related requirements in Directive 75/318/EEC as amended by Directive 1999/82/EEC – implications on MRP

According to the above mentioned Directive the applicants/Marketing Authorisation Holders (MAHs) have to demonstrate compliance of their products with the requirements stated in the Note for guidance on minimising the risk of transmitting Animal Spongiform Encephalopathy agents via medicinal products. For existing Marketing Authorisations this needs to be done by 1 March 2001 and for new applications for Marketing Authorisations lodged by 1 July 2000.

The model declaration of compliance with the Annex to the above mentioned Directive has been published on the Internet on the EC-Enterprise DG' website. In order not to delay initiation of the MRP, the MRFG agreed that for products that have already been approved in the RMS for the subsequent MR-procedures the CMSs would accept those products as regards to TSE requirements under the same conditions as in the RMS.

Change of the Presidency

The June MRFG meeting was the last under the Portuguese Presidency. France will take over the Chairmanship as of July 2000. Prof. Jean-Michel Alexandre will be the next chairman.

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:

Dr. António MELO GOUVEIA	Phone:	+ 351 21 798 72 01
Head of the Medicines Division	Fax:	+ 351 21 798 72 17
INFARMED	e-mail:	Melo.gouveia@infarmed.pt
Parque de Saude de Lisboa		
Avenido do Brasil, n° 53		
P - 1700 LISBOA		
PORTUGAL		

From 1 July 2000:

Prof. Jean-Michel ALEXANDRE	Phone:	+ 33 1 55 87 32 99
Agence Française de Sécurité	Fax:	+ 33 1 55 87 32 92
Sanitaire des Produits de Santé	e-mail:	fr-h.eudranet@fr-h.eudra.org
143-147 Bd. Anatole France		
F-93285 Saint-Denis Cedex		
FRANCE		

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

http://heads.medagencies.org/