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

23 October 2000
CPMP/2849/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 64th plenary meeting from 17 to 19 October 2000.

The revised 2001 CPMP meetings dates are circulated together with this Press Release (see Annex III).

Centralised Procedures[1]

The Committee adopted:

- Seven positive opinions on initial centralised marketing authorisation applications by consensus relating to six active substances (four Part A/two Part B). One of these opinions (Part B) was adopted under exceptional circumstances.
- Three positive opinions by consensus for centralised type I variations following a type II procedure.
- Twenty positive opinions by consensus for centralised type II variations of which ten were related to SPC/PL update and ten to pharmaceutical aspects.

The Committee adopted two lists of questions (one Part A/one Part B).

The Committee heard one oral presentation from an applicant concerning an ongoing procedure.

Following an oral explanation from the marketing authorisation holder, the Committee adopted an opinion by consensus recommending the renewal of the suspension of the Marketing Authorisation for Tasmar for another year (see updated EMEA Press Release (CPMP/2457/98 rev.1)).

An overview of centralised applications is given in Annex I.

For marketing authorisations granted by the European Commission since the last CPMP in September 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
Chemical Substance	Malignant pleural mesothelioma, Non-Small Cell Lung Cancer (NSCLC), breast cancer and gastric cancer	New Scientific Advice request on clinical development programme
Chemical Substance	Management of chronic pain	New Scientific Advice request on pharmaceutical, pre-clinical and clinical development programmes
Biological Substance	Type 1 and 2 diabetes mellitus	New Scientific Advice request on pharmaceutical and clinical development programmes
Biological Substance	Rheumatoid Arthritis	Follow-up Scientific Advice request on pharmaceutical and clinical development programmes
Biological Substance	Prevention of Lyme borreliosis	New Scientific Advice request on pre-clinical and clinical development programmes
Chemical Substance	Chronic obstructive pulmonary disease (COPD)	New Scientific Advice request on clinical development programme
Chemical Substance	Hyperlipidemias	New Scientific Advice request on pre-clinical development programme
Biological Substance	Pancreatic exocrine insufficiency	New Scientific Advice request on pre-clinical and clinical development programmes
Chemical Substance	Sedative in intensive care	New Scientific Advice request on clinical development programme
Biological Substance	AT III hereditary deficiency in situations at high risk for thromboembolic events	Follow-up Scientific Advice request on clinical development programme
Chemical Substance	Gastroesophageal reflux disease and diabetic gastroparesis	New Scientific Advice request on clinical development programme
Chemical Substance	Respiratory distress syndrome	New Scientific Advice request on pharmaceutical, pre-clinical and clinical development programmes
Chemical Substance	Attention deficit hyperactivity disorder	New Scientific Advice request on clinical development programme
Chemical Substance	Adjuvant treatment in beast and prostate cancers.	New Scientific Advice request on clinical development programme

The Committee accepted six new and one follow-up request from companies for scientific advice and Co-ordinators were appointed. Two Scientific advice oral explanations took place on ongoing Scientific Advice requests.

Referrals

- Referral under Article 7(5) of Commission Regulation (EC) No 541/95
  The Committee noted the referral for arbitration from the UK to the CPMP of a type II variation relating to the posology section of the SPC, concerning a medicinal product already authorised through the mutual recognition procedure. A Rapporteur and a Co-Rapporteur were assigned and the referral procedure started at the October 2000 CPMP plenary meeting.
- Referral under Article 10 of Council Directive 75/319/EEC, as amended
  The Committee noted the referral under Article 10 for arbitration to the CPMP of a mutual recognition procedure. A Rapporteur and a Co-Rapporteur were assigned and the referral procedure started at the October 2000 CPMP plenary meeting.
- Referral under Article 11 of Council Directive 75/319/EEC, as amended
  Following a referral under Article 11, the CPMP adopted a positive opinion by consensus for a medicinal product, containing metformin, nationally authorised leading to a harmonised SPC for transmission to the Commission.
- Referrals under Article 15a of Council Directive 75/319/EEC, as amended
  Further to the Commission Decision concerning the suspension of Sertindole containing medicinal products, the CPMP adopted an opinion by consensus recommending the renewal of the suspension of the Marketing Authorisation for another year. This opinion will be transmitted to the Commission.

Working Parties, Ad Hoc Expert Groups and Organisational Matters

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

Efficacy Working Party

Reference number	Document	Status
CPMP/EWP/560/98	Points to consider on Clinical investigation of medicinal products in the treatment of acute stroke	Released for 3 months' consultation in October 2000
CPMP/EWP/2330/99	Points to consider on Validity and interpretation of meta-analyses, and one pivotal study	Released for 3 months' consultation in October 2000
CPMP/EWP/565/98	Points to consider on Clinical investigation of medicinal products for treatment of Amyotrophic Lateral Sclerosis (ALS)	Adopted in October 2000

Ad Hoc Expert Working Group on Blood Products

Reference number	Document	Status
CPMP/BPWG/198/95 rev. 1	Note for guidance on the Clinical investigation of human plasma derived factor VIII and IX products	Adopted in October 2000
CPMP/BPWG/1561/99	Note for guidance on the Clinical investigation of recombinant factor VIII and IX products	Adopted in October 2000
CPMP/PhVWP/BPWG/2231/99	Core SPC for Human albumin	Adopted in October 2000

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) meeting held on 16 October 2000, which is circulated together with this Press Release (Annex IV).

Pharm. Noël Wathion
Head of Unit
Evaluation of Medicines for Human Use
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	8	35	43	181
Follow-up to scientific advice	11	6	17	3	4	7	24

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	17	31	48	272
Withdrawals	12	26	38	0	6	6	44
Positive CPMP opinions	44	82	126	18	22	40	166[1]
Negative CPMP opinions[2]	1	3	4	0	1	1	5[3]
Marketing authorisations granted by the Commission	40	78	118	12	15	27	145[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	79	179	258	763
Positive opinions, variations type II	89	131	220	48	71	119	339
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	2	2	4	51

[1] 166 positive opinions corresponding to 127 substances
[2] In case of appeal the opinion will not be counted twice
[3] 5 negative opinions corresponding to 4 substances
[4] 145 Marketing Authorisations corresponding to 111 substances

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

Brand name	Keppra
INN	levetiracetam
Marketing Authorisation Holder	UCB S.A.
ATC code	N03A
Indication	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy
Opinion receipt date	31/07/00
Date of Commission Decision	29/09/00

Brand name	Panretin
INN	alitretinoin
Marketing Authorisation Holder	Ligand Pharmaceuticals Ltd.
ATC code	L01X
Indication	Indicated for the topical treatment of cutaneous lesions in patients with AIDS related Kaposi's sarcoma
Opinion receipt date	31/07/00
Date of Commission Decision	11/10/00

Brand name	Glustin
INN	pioglitazone
Marketing Authorisation Holder	Takeda Europe
ATC code	A10BG03
Indication	Type II Diabetes mellitus
Opinion receipt date	31/07/00
Date of Commission Decision	11/10/00

Brand name	Actos
INN	pioglitazone
Marketing Authorisation Holder	Takeda Europe
ATC code	A10BG03
Indication	Type II diabetes mellitus
Opinion receipt date	31/07/00
Date of Commission Decision	13/10/00

CPMP MEETING DATES FOR 2001 (REVISED)

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

** Such meeting will normally not take place unless required.*

Report from the meeting held on 16 October 2000

The MRFG noted that 15 new mutual recognition procedures were finalised during the month of September 2000, as well as 67 type I and 26 type II variations.

The status as of 30 September 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	183	126	717	58	230	148	2 N.A. and 2 variations

25 new procedures (regarding 50 products) started in September 2000. The categories of these procedures are as follows:

6 new active substances (first authorisation in the European Community after RMS approval), including **1** multiple application and **1** repeat use.

11 known active substances (already authorised in at least one member state), including **2** repeat use.

7 abridged applications including **1** for an additional form or strength and **2** repeat use.

1 line extension application.

The new procedures started this month relate to 9 full dossiers, 2 informed consent applications, 3 bibliographic applications, 4 generics, 5 fixed combinations, and 2 for different use, route or dose.

The procedures consisted of 21 chemical substances, 2 biological products, 1 herbal product and 1 blood product[1].

19 of these procedures were prescription-only medicinal products in the reference Member State and 6 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 September 2000

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	14
DE (1)	9
DK(2)	3
DK(4)	11
FI (1)	16
FI (1)	6
IR (1)	2
SE (3)	2

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

General issues

Calendar for MRFG meetings in 2001

January 22 July 23
February 26 August 20
March 26 September 17
April 23 October 15
May 28 November 12
June 25 December 10

Meeting schedule

The next MRFG meeting will be held on 13 November 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:

Prof. Jean-Michel ALEXANDRE
Agence Française de Sécurité Sanitaire des Produits de Santé
143-147 Bd. Anatole France
F-93285 Saint-Denis Cedex FRANCE

Phone: +33 1 5587 3299
Fax: +33 1 5587 3292
e-mail: fr-h.eudranet@fr-h.eudra.org

*Alternatively, you can visit the **MRFG website** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

http://heads.medagencies.org/