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

31 January 2001
CPMP/250/01 corr

PRESS RELEASE

67th MEETING OF THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

The Committee for Proprietary Medicinal Products (CPMP) held its 67th plenary meeting from 23 to 25 January 2001.

As already announced after the extraordinary CPMP meeting which took place on 11 and 12 January 2001, the election of a new CPMP Chairperson and Vice-Chairperson took place during this plenary meeting.

The CPMP elected Dr Daniel Brasseur as Chairman and Dr Eric Abadie as Vice-Chairman for a three-year mandate (for further details, please see separate EMEA Press Release (EMEA/D/1568/01), published on 23 January 2001).

Mr Thomas Lönngren, EMEA Executive Director, and Dr Philippe Brunet, DG Enterprise's Head of the Pharmaceuticals and Cosmetics Unit, joined the Committee in congratulating the newly elected Chair and Vice-Chair. Dr Brunet, as part of his welcoming speech to the new Committee, stressed the scientific role of the CPMP and the need for a close EMEA/DG Enterprise collaboration with regard to the forthcoming review of pharmaceutical legislation as well as the EU scientific representation at international level.

The following issues were discussed during the meeting:

Product related issues

Centralised procedures

The centralised procedures, both pre- and post-authorisation, finalised during this meeting, are summarised in Annex 1.

An overview of centralised procedures is given in Annex 2.

For marketing authorisations granted by the European Commission since the last CPMP in December 2000, see Annex 3.

Scientific Advice procedures

The CPMP adopted the outcome of the discussions of the Scientific Advice Review Group, which met, under the chairmanship of Dr. M. Toivonen, on 22 January 2001. For further details, please see Annex 4.

Referral procedures

A referral under article 10 (2) of Council Directive 75/319/EEC, as amended, has been initiated by the National Competent Authorities of the Netherlands, United Kingdom, Greece and Spain in relation to a mutual recognition procedure. A Rapporteur and Co-Rapporteur were assigned.

Other product related issues

The CPMP has been made aware of seven cases of lactic acidosis in pregnant women treated during pregnancy with the combination of Zerit® (stavudine) and Videx® (didanosine). Three of these cases were fatal. Stavudine and didanosine are nucleoside reverse transcriptase inhibitors (NRTIs) indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection. An EMEA Public Statement on "Reports of lactic acidosis in pregnant women treated with Zerit and Videx" is annexed to this Press Release (see Annex 5).

The Committee's scientific review of the third generation oral contraceptives in relation to cardiovascular risks has been forwarded to the companies concerned in December 2000. It is expected

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that preliminary comments from the companies will be available for a first discussion at the February 2001 CPMP meeting.

Non-product related issues

CPMP Working Parties and Ad-Hoc Groups

The Committee agreed that current Working Parties'/Ad Hoc Groups' Chairpersons will remain in charge until the February 2001 CPMP plenary meeting, during which new nominations will take place.

An overview of guidance documents adopted during the meeting or released for consultation to Interested Parties is attached as Annex 6.

In addition, the following should be noted:

A meeting took place on 22 January 2001 between CPMP/Biotechnology Working Party members and experts, DG Enterprise and European Department for the Quality of Medicines (EDQM) representatives and the EMEA. During the meeting a discussion took place on the practical aspects of the assessment of variations to demonstrate compliance with the TSE guideline as required by the Annex to Council Directive 75/318/EEC as amended by Commission Directive 1999/82/EC.

Further to consultation with the European Commission, the Committee adopted a joint CPMP/CVMP *Note for Guidance on Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*. Following adoption by the CVMP (Committee for Veterinary Medicinal Products) in February 2001, this Note for guidance will be published on the EMEA web site.

Organisational Matters

The Committee adopted the CPMP meeting schedule for 2002 (see Annex 7).

As a follow-up of the extraordinary CPMP meeting held on 11 and 12 January 2001 (see EMEA Press Release, EMEA/811/01), the CPMP continued its discussion on the involvement of experts groups in the assessment process.

A discussion also took place on the possibility to have further CPMP satellite groups; and although proposals for such satellite groups will have to be discussed further at the February 2001 plenary meeting, it was already agreed to establish a satellite group on Organisational Matters. This group will meet on 26 February 2001 under the Chairmanship of Dr Daniel Brasseur.

The Committee agreed on a new format of CPMP meetings which will be implemented as of the February 2001 CPMP meeting. An outline of this format is attached as Annex 8.

Mutual Recognition procedure

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG), held under the new Swedish presidency on 22 January 2001, which is circulated together with this Press Release (see Annex 9).

Next meeting

The 68th plenary meeting of the CPMP will be held from 27 February 2001 until 1 March 2001.

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This Press Release and other documents are available on the Internet at the following address:
http://www.emea.eu.int

OUTCOME OF THE JANUARY 2001 CPMP MEETING IN RELATION TO CENTRALISED APPLICATIONS

PRE-AUTHORISATION PHASE

Opinions			
Number of Opinions	**Number of Active Substances**	**Outcome**	**Comments**
4	2 (1 Part A/1 Part B)	Positive by consensus	-
1	1 (1 Part B)	Negative by majority vote	-

Withdrawals	
Number of withdrawals	**Number of Active Substances**
3	2 (2 Part B)

POST-AUTHORISATION PHASE

Opinions for Type I Variation applications following Type II Procedure	
Number of Opinions	**Outcome**
3	Positive by consensus

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
7 (SPC/PL update)	Positive by consensus
5 (pharmaceutical aspects)	Positive by consensus

Opinions for Annual Re-assessment		
Name of Medicinal Product	**Outcome**	**Comments**
Ammonaps (sodium phenylbutyrate)	Positive by consensus	Marketing Authorisation to remain under exceptional circumstances
BeneFIX (nonacog alpha)	Positive by consensus	Marketing Authorisation to remain under exceptional circumstances

Opinions for Renewal applications	
Name of Medicinal Product	**Outcome**
Cellcept	Positive by consensus
Fareston	Positive by consensus
NovoSeven	Positive by consensus

EMEA CENTRALISED PROCEDURES

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Scientific Advice	74	122	196	2	6	8	204
Follow-up to scientific advice	15	11	26	0	0	0	26

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	97	182	279	4	0	4	283
Withdrawals	12	37	49	0	3	3	42
Positive CPMP opinions	64	112	176	1	3	4	180[1]
Negative CPMP opinions[2]	1	3	4	0	1	0	5[3]
Marketing authorisations granted by the Commission	56	95	151	0	7	7	158[4]

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	265	551	816	31	14	45	861
Positive opinions, variations type II	159	224	383	7	5	12	395
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	34	20	54	0	0	0	54

[1] 180 positive opinions corresponding to 141 substances
[2] In case of appeal the opinion will not be counted twice
[3] 5 negative opinions corresponding to 4 substances
[4] 158 Marketing Authorisations corresponding to 120 substances

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

Brand name	Trizivir
INN	Lamivudine/zidovudine/abacavir
Marketing Authorisation Holder	Glaxo Group
ATC code	J05AF30
Indication	Treatment of HIV-1 infected patients
Opinion receipt date	29/06/00
Date of Commission Decision	28/12/00

Brand name	Azomyr
INN	Desloratadine
Marketing Authorisation Holder	S-P Europe
ATC code	R06AX27
Indication	Relief of symptoms associated with seasonal allergic rhinitis
Opinion receipt date	21/06/00
Date of Commission Decision	15/01/00

Brand name	Opulis
INN	Desloratadine
Marketing Authorisation Holder	S-P Europe
ATC code	R06AX27
Indication	Relief of symptoms associated with seasonal allergic rhinitis
Opinion receipt date	21/06/00
Date of Commission Decision	15/01/00

Brand name	Allex
INN	Desloratadine
Marketing Authorisation Holder	S-P Europe
ATC code	R06AX27
Indication	Relief of symptoms associated with seasonal allergic rhinitis
Opinion receipt date	21/06/00
Date of Commission Decision	15/01/00

Brand name	Aerius
INN	Desloratadine
Marketing Authorisation Holder	S-P Europe
ATC code	R06AX27
Indication	Relief of symptoms associated with seasonal allergic rhinitis
Opinion receipt date	21/06/00
Date of Commission Decision	15/01/00

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

Brand name	Neoclarityn
INN	Desloratadine
Marketing Authorisation Holder	S-P Europe
ATC code	R06AX27
Indication	Relief of symptoms associated with seasonal allergic rhinitis
Opinion receipt date	21/06/00
Date of Commission Decision	15/01/00

Brand name	Neurobloc
INN	Botulinum toxin type B
Marketing Authorisation Holder	Elan Pharma International Ltd.
ATC code	M03AX01
Indication	Treatment of cervical dystonia
Opinion receipt date	21/09/00
Date of Commission Decision	22/01/01

OUTCOME OF THE JANUARY 2001 CPMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Substance	Intended indication(s)	Topic				
		Type of Request		Pharmaceutical	Pre-Clinical	Clinical
		New	Follow-up			
Chemical	Treatment of HIV-1 infections	**X**	-	-	-	**X**
Chemical	Treatment of colorectal cancer	**X**	-	-	-	**X**
Chemical	Treatment of obstructive sleep apnea hypopnoea syndrome	**X**	-	-	-	**X**
Biological	Treatment of multiple sclerosis	**X**	-	-	-	**X**
Biological	Treatment of hepatocellular carcinoma	**X**	-	**X**	**X**	**X**
Chemical	Treatment of asthma	**X**	-	-	-	**X**
Chemical	Treatment of HIV-1 infections	**X**	-	-	**X**	**X**
Biological	Diphtheria containing vaccine	**X**	-	**X**	-	-

The Committee accepted four new requests from companies for scientific advice.

ANNEX 5 to CPMP January 2001
Press Release
London, 26 January 2001
EMEA/CPMP/228/01

PUBLIC STATEMENT

Reports of lactic acidosis in pregnant women treated with Zerit® and Videx®

The EMEA's scientific committee, the CPMP, has been made aware of seven cases of lactic acidosis in pregnant women treated during pregnancy with the combination of Zerit® (stavudine) and Videx® (didanosine). Three of these cases were fatal. Stavudine and didanosine are nucleoside reverse transcriptase inhibitors (NRTIs) indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Of the three women who died, one also had pathologically confirmed hepatic steatosis and two had pancreatitis. Two of these maternal deaths occurred in a multinational, randomised clinical study. One patient was taking the triple combination therapy of didanosine/stavudine/nelfinavir whilst the other was treated with the triple combination didanosine/stavudine plus an investigational protease inhibitor. The third death and the four additional non-fatal cases of lactic acidosis were identified through worldwide post-marketing surveillance. Of the three women who died, one baby survived; the other two died prior to the mother's death, at between 32-36 weeks gestation.

Lactic acidosis, sometimes fatal, is a known side effect of NRTIs. Consequently the Summaries of Product Characteristics of all NRTIs used in the treatment of HIV infection (stavudine, lamivudine, abacavir, zidovudine, didanosine and zalcitabine[1]) warn of the risk of lactic acidosis, which may be fatal. Prescribers are also informed of the need for caution when prescribing to any patient (particularly obese women) with a history of hepatomegaly, hepatitis or other known risk factors for liver disease.

Lactic acidosis is usually associated with severe hepatic damage and other organs may also be affected. Lactic acidosis can occur a few weeks to several years after the beginning of treatment with NRTIs. Symptoms which may be indicative of the development of lactic acidosis include: digestive symptoms (nausea, vomiting, anorexia, abdominal pain, diarrhoea), respiratory symptoms (dyspnea), neuromuscular symptoms (cramp, myalgia, paraesthesia) or a non specific general deterioration (asthenia, weight loss).

The CPMP has carefully reviewed the available data and considers that at present there is insufficient information to decide whether pregnancy is an additional risk for lactic acidosis. It is also uncertain whether any increased risk of lactic acidosis is specific to stavudine and didanosine or whether it might be increased with all combinations of nucleoside analogues. The EMEA also wishes to draw attention to the fact that, except for the use of zidovudine in the prevention of materno-foetal transmission of HIV, the use of nucleoside analogues during pregnancy is not recommended unless the potential clinical benefit clearly outweighs the potential risks.

The CPMP and National Agencies have requested additional information from all concerned marketing authorisation holders and these issues will be evaluated further by the CPMP for the whole class of NRTIs.

[1] These NRTIs are marketed under the following tradenames (in brackets): lamivudine (Epivir®); abacavir (Ziagen®); zidovudine (Retrovir®); zalcitabine (Hivid®); the combination product lamivudine/zidovudine (Combivir®); and the combination product lamivudine/zidovudine/abacavir (Trizivir®)

DOCUMENTS PREPARED BY THE CPMP WORKING PARTIES AND AD-HOC GROUPS ADOPTED DURING THE JANUARY 2001 CPMP MEETING

BIOTECHNOLOGY WORKING PARTY

Reference number	Document	Status
CPMP/BWP/4310/00	Concept paper on the development of a CPMP Points to consider on stability and traceability requirements for vaccines intermediates	Adopted in January 2001
CPMP/BWP/269/95 rev. 3	Note for guidance on plasma-derived medicinal products	Adopted in January 2001
CPMP/BWP/2490/00 draft	Cell culture inactivated influenza vaccines – *Annex to CPMP Note for guidance on harmonisation of requirements for influenza vaccines (CPMP/BWP/214/96)*	Released for 6 months' consultation in January 2001

SAFETY WORKING PARTY

Reference number	Document	Status
CPMP/SWP/2877/00 draft	Note for guidance on carcinogenic potential	Released for 3 months' consultation in January 2001
CPMP/SWP/4447/00	CPMP Discussion paper on environmental risk assessment of non-genetically modified organism (non-GMO) containing medicinal products for human use	Released for 6 months' consultation in January 2001
CPMP/SWP/4446/00 draft	Note for guidance on specification limits for residues of heavy metal catalysts in new active substances and in medicinal products	Released for 6 months' consultation in January 2001

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/552/95 rev. 1	Note for guidance on postmenopausal osteoporosis in women	Adopted in January 2001
CPMP/EWP/1776/99 draft	Points to consider on missing data	Released for 3 months' consultation in January 2001

CPMP meeting schedule for 2002

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

*Such meeting will normally not take place unless required.

NEW CPMP WEEK STRUCTURE

NEW STRUCTURE OF THE CPMP WEEK

<table>
<tr><th></th><th>MONDAY</th><th>TUESDAY</th><th>WEDNESDAY</th><th>THURSDAY</th></tr>
<tr><td rowspan="8">AM</td><td>Start 10.00am</td><td>Start 9.00am</td><td>Start 8.30am</td><td>Start 8.30am</td></tr>
<tr><td rowspan="7">CPMP SATELLITE GROUP MEETINGS
➢ Scientific Advice Review Group (SciARG)
➢ Other Satellite Groups if necessary</td><td>ADOPTION SLOT (30’)
➢ CPMP Agenda
➢ CPMP Time schedule
➢ CPMP Minutes from previous month</td><td>ADOPTION of FINAL DOCUMENTS slot 1</td><td rowspan="2">MISCELLANEOUS
(Part B requests, Rapporteur/ Co-Rapporteur appointments etc.)</td></tr>
<tr><td rowspan="2">REVIEW/ADOPTION of FINAL DOCUMENTS (PRODUCT-RELATED)
➢ Opinions on initial MA Applications</td><td rowspan="2">HEARING 1 Slot
(9.00-10.30am)</td></tr>
<tr><td>WORKING PARTY (WP) Reports
Quality WP,
Biotechnology WP, Safety WP, Efficacy WP, Blood Products WG,...</td></tr>
<tr><td>Coffee Break</td><td>Coffee Break</td><td>Coffee Break</td></tr>
<tr><td rowspan="2">REVIEW/ADOPTION of FINAL DOCUMENTS (PRODUCT-RELATED)
➢ Opinions on initial MA Applications (Cont’d)
➢ Extension of indications Opinions</td><td rowspan="2">HEARING 2 Slot
(11.00-12.30am)</td><td>CPMP SATELLITE GROUP Reports
SciARG, TRAHG, Organisational Matters Ad-Hoc Group, Other Satellite Groups,</td></tr>
<tr><td>ADOPTION of FINAL DOCUMENTS slot 3</td></tr>
<tr><td>LUNCH</td><td>LUNCH</td><td>LUNCH</td><td>LUNCH</td></tr>
<tr><td rowspan="7">PM</td><td rowspan="6">CPMP SATELLITE GROUP MEETINGS
➢ SciARG (Cont’d)
➢ Tradename Review Ad-Hoc Group (TRAHG)
➢ Organisational Matters Ad-Hoc Group
➢ Other Satellite Groups if necessary
➢ If necessary Rapporteur meetings or Expert Group meetings in preparation of CPMP discussions and Hearings</td><td>REVIEW/ADOPTION of FINAL DOCUMENTS (PRODUCT-RELATED)
➢ Lists of Questions
➢ Lists of Outstanding Issues</td><td>ADOPTION of FINAL DOCUMENTS slot 2</td><td rowspan="6"></td></tr>
<tr><td>REVIEW/ADOPTION of REFERRAL, APPEAL, SUSPENSION and WITHDRAWAL Opinions</td><td rowspan="2">HEARING 3 Slot
(2.00-3.30 pm)</td></tr>
<tr><td>Coffee Break</td><td>Coffee Break</td></tr>
<tr><td>PHARMACOVIGILANCE
➢ PharmacoVigilance (PhV) issues
➢ PhV Working Party (PhVWP) Report</td><td>HEARING 4 Slot
(4.00-5.30 pm)</td></tr>
</table>

Report from the meeting held on 22 January 2001

The MRFG noted that 21 new mutual recognition procedures were finalised during the month of December 2000, as well as 126 type I and 24 type II variations.

The status as of 31 December 2000 and for the period 1995–2000 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	306	71	1007	49	320	154	3 N.A. and 2 variations

The global status since 1 January 1995 is as follows (further detailed statistics can be found at the MRFG website):

Years	Procedures from New applications finalised	Procedures from Type I variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CPMP
1995	10	16	17	1 N.A.
1996	84	49	73	1 N.A. and 1 variation
1997	146	101	163	1 N.A. and 1 variation
1998	182	339	222	1 N.A. and 4 variations
1999	228	671	301	2 N.A. and 2 variations
2000	306	1007	320	3 N.A. and 2 variations
1995-2000	956	2183	1096	9 N.A. and 10 variations

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

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

The new procedures started this month relate to 1 full dossier, 2 bibliographic applications, 2 fixed combinations, 15 generics, and 3 for different use, route or dose.

The procedures consisted of 22 chemical substances and 1 as other biological[1].

22 of these procedures were prescription-only medicinal products in the reference Member State and 1 was considered as Non-Prescription - (including so called OTC) [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 December 2000

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (2)	12
DE (2)	12
DE (2)	7
DE (2)	1
FR (1)	13
NL (1)	6
NL (1)	2
NL (3)	13
NL (2)	4
NL (2)	5
NL (2)	1
NL (2)	2
NL (2)	8
NL (2)	1
SE (2)	5
SE (2)	3
SE (4)	12
SE (4)	1
SE (4)	1
SE (4)	1
UK (1)	1
UK (1)	3
UK (2)	1

General issues

Documents adopted for publication at the MRFG January 2001 meeting

The MRFG adopted the following documents that will be published on the Heads of Agencies Website accordingly:

- "Recommendations for Mutual Recognition Procedure after finalisation of an arbitration procedure with a positive opinion by the CPMP and a positive decision by the European Commission"
- "MRFG Best Practice Guide for the Handling of Renewals in the Mutual Recognition Procedure"

MRP statistics 2000

Statistics regarding new applications in the MRP in the year 2000 according to the new 5-level classification will be available on the Heads of Agencies Website by the end of January 2001.

TSE and Mutual Recognition Procedure

The MRFG continued discussions regarding TSE issues. The MAHs are once again requested urgently (deadline being 1 March 2001) to submit applications for compliance with TSE requirements. The

MRFG confirmed that if applications are not submitted by 1 March 2001, this could result in a suspension of the concerned medicinal product from the market.

Harmonisation of SPCs

As agreed at the December 2000 MRFG meeting, the first sub-group meeting on harmonisation of the SPCs took place on 22 January 2001. The aim of the group is to suggest a number of original products where harmonisation at the European level is most needed. The Group should also find practical ways for harmonisation of these products. Proposals from the Member States are awaited for discussion at the next sub-group meeting to be held in February.

Update of the MR-SPC on influenza vaccines

The MRFG agreed on some changes to the current version of the MR-SPC for the influenza vaccines. The revised MR-SPC will be published on the Heads of Agencies Website. The MAH will soon be informed about the timetable for implementation of these amendments, as it will foresee product information for the next season. It was agreed to set up an accelerated timetable (type II variation procedure following a type I variation timetable)

Liaison meeting with interested parties

The MRFG plenary meeting was followed by a meeting with interested parties. Two presentations, one regarding an overview of the analysis on withdrawals in the MRP and the other regarding possible improvements in the MRP, were given by the MRFG. The interested parties were also informed about the start of the MRFG exercise on the harmonisation of SPCs.

The interested parties were invited to send their comments and proposals for improvement of the information given in the Heads of Agencies Website.

Meeting schedule

The next MRFG meeting will be held on 26 February 2001.

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/