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

31 July 2001
CPMP/2358/01 rev 1

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
24 to 26 JULY 2001 PLENARY MEETING

TECHNICAL MEETING REPORT

The Committee for Proprietary Medicinal Products (CPMP) held its 73rd plenary meeting from 24 to 26 July 2001.

Product related issues

Centralised procedures

For initial marketing authorisation applications, the CPMP adopted:

- A positive opinion by majority vote for Glivec (imitinib mesilate) from Novartis Europharm Ltd. which is intended for the treatment of adult patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia (CML) in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis. Glivec was designated as an orphan medicinal product in Europe on 14 February 2001. The CPMP recommends the granting of a marketing authorisation under exceptional circumstances. For further details, please the see the Summary of Opinion which has been published on the EMEA website: **http://www.emea.eu.int/pdfs/whatsnew/217701en.pdf**
- A positive opinion by majority vote for Caspofungin MSD (caspofungin) from Merck Sharp & Dohme (Europe) Inc. indicated for the treatment of invasive aspergillosis, a rare life threatening condition in immunocompromised patients. The CPMP recommends the granting of a Marketing Authorisation under exceptional circumstances. For further details, please the see the Summary of Opinion which has been published on the EMEA website: **http://www.emea.eu.int/pdfs/whatsnew/166601en.pdf**
- A positive opinion by consensus for Travatan (travoprost) from Alcon Laboratories (UK) Ltd. intended for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma who are intolerant or insufficiently responsive to another intraocular pressure lowering medication, as monotherapy or as adjunctive therapy. For further details, please the see the Summary of Opinion which has been published on the EMEA website: **http://www.emea.eu.int/pdfs/whatsnew/214301en.pdf**

The CPMP adopted one positive opinion by consensus on a "line extension" application (in accordance with Annex II of Commission Regulation (EC) No 542/95 as amended) related to one active substance (Part B).

The CPMP upheld its April 2001 negative opinion by consensus for EVOXAC, following the withdrawal of application and appeal by the applicant, Snow Brand France S.A.R.L. (CPMP/2203/00, 25 April 2001).

The Committee upheld its February 2001 negative opinion by majority votes for a extension of indication for a medicinal product, following the withdrawal of the Type II variation application and the appeal.

An overview of centralised procedures since 1995 is given in **Annex 1**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the last CPMP plenary meeting in May 2001 is provided in **Annex 2**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 3**.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eudra.org http://www.emea.eu.int

Scientific Advice procedures

The CPMP was informed of the outcome of the discussions of the Scientific Advice Review Group (SciARG) meeting, which was held on Monday 23 July 2001. For further details, please see **Annex 4**.

Other product related issues

The Committee continued its discussions on the scientific review of cardiovascular risks of third generation oral contraceptives, in particular taking into account recently published information. These discussions will resume at the next CPMP meeting on 18-20 September 2001.

CPMP Working Parties and Ad-Hoc Groups

The CPMP was informed of the outcome of the Ad Hoc Expert Group on Pharmacogenetics meeting which was held on 4 July 2001 under the Chairmanship of Dr Eric Abadie which discussed Pharmacogenetic terminology. A Points to Consider document on this particular topic is expected to be released for consultation by the end of the year. Another meeting is expected to be organised in Autumn 2001.

The CPMP was informed that the *Ad Hoc Working Group on the Update of the Anticancer Guideline*, under the chairmanship of Dr Frances Rotblat, is expected to meet in the near future (autumn 2001) in order to further develop requirements addressing special topics on paediatric oncology. Furthermore it was agreed that a forum for discussion with Interested Parties on novel approaches in oncology will be organised in the margins of a European or international cancer conference in 2002.

An overview of guidance documents adopted during the meeting or released for consultation to Interested Parties is attached as **Annex 5**.

Organisational Matters

The fifth meeting of the *CPMP Ad Hoc Group on Organisational Matters* (ORGAM) was held on 23 July 2001 and the following topics were discussed:

- Accelerated Review procedure: A revised document is expected to be released by the end of the year 2001.
- Revision of the status and composition of the SciARG: The discussion will continue at the September 2001 ORGAM meeting.
- Streamlining of CPMP oral explanation: A guidance document for Industry was adopted by CPMP and is published together with this report as **Annex 6** (Comments are requested until 15 October 2001 and should be addressed to EMEA (Marisa.Papaluca@emea.eudra.org). Applicants preparing for oral explanations as of September 2001, should note the request to provide EMEA, Rapporteur/Co-Rapporteur, CPMP Members with preparatory material documents for the hearing **2 weeks in advance of the oral explanation.**

PROCEDURAL ANNOUNCEMENT

- As of 1 July 2001, applicants may submit centralised applications using the Common Technical Document (CTD) format or the existing EU format for a transitional period of two years. From 1 July 2003 the CTD format will be mandatory in the EU. Applicants planning to submit in CTD format are advised to request a pre-submission meeting with EMEA (attention of Tony Humphreys, Head of Sector Regulatory Affairs and Organisational Support), particularly where a mixed format application containing both EU "parts" and CTD "modules" is proposed. When electronic submission is planned, this should be specifically mentioned in the request for pre-submission.
- Any information on electronic CTD can be found at the following internet address: http://esubmission.eudra.org/ectd.

Mutual Recognition procedure

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) first meeting under the Belgian Presidency on 23 July 2001, which is attached as **Annex 7**.

The new Chairperson of the MRFG, Natacha Grenier, presented a proposal on the creation of a new working group on Summary of Product Characteristics Harmonisation including representatives from Member States/MRFG, CPMP, EMEA and the European Commission. The first meeting of this group is scheduled to take place in September 2001 where it is expected to have the election of the Chairperson of this new group and define its mandate and objectives.

Future meeting/Workshops

The CPMP was informed of the following upcoming meetings/Workshops:

- EMEA internal Workshop on Plasma Master File to be held on 10 October 2001.
- EMEA internal Workshop on Viral Safety evaluation to be held beginning of 2002.
- EMEA internal Workshop on Xenogenic Cell Therapy to be held first quarter 2002.
- EMEA internal Workshop on Ethical Consideration in Clinical Trials to be held on 26 November 2001.
- EMEA training session for Junior Assessors to be held on 24-25 September 2001.

The 74th plenary meeting of the CPMP will be held from 18 to 20 September 2001.

Noël Wathion
Head of Unit Post-Authorisation
Evaluation of Medicines for Human Use
Tel. (+44-20) 74 18 85 92
This Technical Report and other documents are available on the Internet at the following address:
http://www.emea.eu.int

EMEA CENTRALISED PROCEDURES

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Scientific Advice	74	122	196	10	32*	42	258
Follow-up to scientific advice	15	11	26	3**	4	7	33

* Including one Protocol Assistance requests.
** Including one Protocol Assistance request.

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	97	182	279	22	23	45	324
Withdrawals	12	37	49	1	7	8	57
Positive CPMP opinions	64	112	176	9	10	19	195[1]
Negative CPMP opinions[2]	1	3	4	0	1	1	5[3]
Marketing authorisations granted by the Commission	56	95	151	12	23	35	186[4]

	1995-2000			2001			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	265	551	816	104	138	242	1058
Positive opinions, variations type II	159	224	383	64	96	160	543
Negative opinions, variations type II	0	2	2	1	1	2	4
Extensions (Annex II applications)	34	20	54	0	5	5	59

[1] 195 positive opinions corresponding to 153 substances
[2] In case of appeal the opinion will not be counted twice
[3] 5 negative opinions corresponding to 4 substances
[4] 186 marketing authorisations corresponding to 142 substances

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE JUNE 2001 PRESS RELEASE

Brand name	Nonafact
INN	human coagulation factor IX
Marketing Authorisation Holder	Sanquin CLB
ATC code	B02BD04
Indication	Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency)
CPMP Opinion date	01/03/2001
Date of Commission Decision	03/07/2001

Brand name	MabCampath
INN	alemtuzumab
Marketing Authorisation Holder	Millennium & ILEX UK Ltd.
ATC code	L01XC
Indication	Second-line treatment of chronic lymphocytic leukaemia
CPMP Opinion date	29/03/2001
Date of Commission Decision	06/07/2001

Brand name	Ketek
INN	telithromycin
Marketing Authorisation Holder	Aventis Pharma S.A.
ATC code	J01
Indication	Treatment of infections of the respiratory tract
CPMP Opinion date	29/03/2001
Date of Commission Decision	09/07/2001

Brand name	Levviax
INN	telithromycin
Marketing Authorisation Holder	Aventis Pharma S.A.
ATC code	J01
Indication	Treatment of infections of the respiratory tract
CPMP Opinion date	29/03/2001
Date of Commission Decision	09/07/2001

Brand name	Depocyte
INN	cytarabine
Marketing Authorisation Holder	Pharmacia & Upjohn
ATC code	L01BC01
Indication	Intrathecal treatment of lymphomatous meningitis
CPMP Opinion date	29/03/2001
Date of Commission Decision	11/07/2001

Brand name	Ceprotin
INN	Human Protein C
Marketing Authorisation Holder	Baxter AG
ATC code	B01 AX
Indication	Treatment and prophylaxis in patients with severe congenital protein C deficiency
CPMP Opinion date	29/03/2001
Date of Commission Decision	16/07/2001

OUTCOME OF THE JULY 2001 CPMP MEETING IN RELATION TO CENTRALISED APPLICATIONS IN THE 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**
17 (SPC/PL update)	Positive by consensus
7 (Pharmaceutical Aspects)	Positive by consensus
2 (Extension of indications)	Positive by consensus
1 (Extension of indications)	Negative by majority votes

Opinion for Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Epivir (Lamivudine) – Glaxo Group Ltd	Positive by consensus	----
Crixivan (indinavir) – Merck Sharp & Dohme Ltd	Positive by consensus	----
Invirase (saquinavir) – Roche Registration Ltd.	Positive by consensus	----
Rapilysin (reteplase) – Roche Registration Ltd	Positive by consensus	----
Tritanix HepB – SmithKline Beecham SA	Positive by consensus	----
Twinrix Adult – SmithKline Beecham SA	Positive by consensus	----
Twinrix Paediatric – SmithKline Beecham SA	Positive by consensus	----
Zyprexa (Olanzapine) – Eli Lilly Nederland BV	Positive by consensus	----
Olansek (Olanzapine) – Eli Lilly Nederland BV	Positive by consensus	----

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

Substance	Intended indication(s)	Topic				
		Type of Request		Pharma-ceutical	Pre-Clinical	Clinical
		New	Follow-up			
Chemical	Treatment of diabetic neuropathy	**X**				**X**
Chemical	Nosocomial pneumonia	**X**				**X**
Chemical	Treatment of depression	**X**			**X**	**X**
Chemical	Treament of otitis	**X**		**X**		**X**
Chemical	Treatment of external infections to the eye	**X**				**X**
Biological	Treatment of pancreatic insufficiency		**X**		**X**	**X**
Chemical	Treatment of oesophagitis	**X**			**X**	
Biological	Treatment of protein C deficiency	**X**				**X**
Biological	Treatment of diabetes mellitus	**X**		**X**		

In addition to the adoption of the above final Scientific Advice letters, the Committee accepted 6 new requests for Scientific Advice and follow-up Scientific Advice.

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

QUALITY WORKING PARTY

Reference number	Document	Status
CPMP/QWP/2819/00 CVMP/814/00	Note for guidance on Quality of herbal medicinal products	Adopted July 2001
CPMP/QWP/2820/00 CVMP/815/00	Note for guidance on Specifications: Test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products	Adopted July 2001

BIOTECH WORKING PARTY

Reference number	Document	Status
CPMP/BWP/2053/01	Notice to Applicants 2B: Contribution to Part S2.3 of the Structure of the Dossier for Applications for Marketing Authorisation – Control of Starting Materials for the Production of Plasma Derived Medicinal Products	Released for 6 months' consultation in July 2001

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/1533/01	Concept paper on the Development of an Addendum on Acute cardiac failure to the CPMP Note for guidance on Clinical investigation of medicinal products in the treatment of acute cardiac failure	Adopted July 2001
CPMP/EWP/1343/01	Concept paper on the Development of a CPMP Points to consider on the Evaluation of new anti-fungal agents for invasive fungal infections	Adopted July 2001
CPMP/EWP/561/98	Note for guidance on Clinical investigation of medicinal products for the treatment of multiple sclerosis	Adopted July 2001
CPMP/EWP/QWP/1401/98	Note for guidance on the Investigation of bio-availability and bioequivalence	Adopted July 2001
CPMP/EWP/908/99	Points to consider on Multiplicity issues in clinical trials	Released for 3 months' consultation in July 2001
CPMP/EWP/1080/00	Note for guidance on Clinical investigation of medicinal products in the treatment of diabetes mellitus	Released for 6 months' consultation in July 2001

Guidance to the Applicants for CPMP Oral Explanation (OE)

Introduction

The CPMP on the basis of the first five years experience and its benchmarking activities of the centralised procedure is considering the streamlining of its operation in a number of areas, to further reinforce the efficiency of the procedure itself and improve the quality of the scientific CPMP Opinions.

In order to optimise the efficiency of the OE, the CPMP provides the Applicant with guidance on the following action points in preparation of and following to a hearing with CPMP:

Scope

The following action points and recommendations should be considered every time an oral explanation in front of the CPMP is sought from the Applicant prior to the finalisation of a CPMP scientific opinion. This operational document should be read in conjunction with other relevant guidance documents specific to the CPMP and centralised procedures.

Applicant's request for the "Clock stop duration" prior to CPMP adoption of the List of outstanding issues (Day 180)

- The CPMP discusses the draft List of Outstanding Issues (OIs) to be answered by the Applicant, identifying those to be addressed in writing and the ones to be addressed during an OE.
- The Rapporteur/Co-Rapporteur liaises with the Applicant to verify whether a clock stop of 30 days or longer is needed by the Applicant to prepare for the oral explanation. The CPMP recognises that a 30-day clock stop should be the rule and 60 to 90 days duration of clock stop an exception (e.g. when extensive written answers are also required), and that justification needs to be provided for CPMP agreement.
- The List of Outstanding Issues to be addressed by the Applicant and the agreed date for the OE are adopted by the CPMP and communicated to the Applicant via the EMEA Product Team Leader.

Applicant's information package to be submitted in preparation for the OE (Post Day 180)

- **At least 14 days in advance of the OE**, the Applicant will provide the CPMP Members and the EMEA Product Team Leader with **relevant written preparatory documents** in paper and electronic format. The response to each OI expected to be addressed in the OE will be accompanied by a concise statement, describing the rationale of the approach chosen, description of impact on the SPC (if relevant) and conclusion.
- The package should also include the draft "material" presentation (slides + updated SPC and if applicable updated Follow-Up Measures [FUMs]/Specific Obligations [Sos] proposals). A list of the Applicant's team members participating in the OE should also be provided as well as details on their affiliation, their role in the OE and concise Curriculum Vitae.
- No new data should be presented at the oral explanation. However new analyses of existing data might be included in the preparatory documents.
- Written explanations on issues not to be addressed in the OE should be submitted in a separate document according to a specific timetable**.**

Preparation for the OE (Day 181)

The EMEA Product Team Leader will circulate during the CPMP plenary session the following documents/information, which will be summarised by the Rapporteur/Co-Rapporteur prior to the OE:

- Adopted list of OI
- OE written preparatory document and proposed rationale for each of the explanations
- New proposed SPC provided by the Applicant

- New proposal for FUMs/SOs

The CPMP, if appropriate, may

- further refine the limited set of OIs to be addressed in the OE and
- add related and detailed questions.

Feedback to the Applicant

- The Rapporteur/Co-Rapporteur will liaise with the Applicant to provide feedback after the plenary discussion on whether there is any change in the list of OIs to be addressed at the OE, and if there is a need to re-focus the proposed presentation.
- To allow flexibility for such an opportunity the Applicant's OE team representative will be on call from CPMP week Tuesday noon up to the actual assigned OE slot.
- At the initiative of the Rapporteur/Co-Rapporteur, for especially complex Lists of OIs, a formal Applicant briefing meeting might be requested 5 days in advance of the OE, taking into account CPMP schedule and workload. During such meeting between Rapporteur/ Co-Rapporteur, Applicant and EMEA Product Team Leader detailed feedback from the preparatory CPMP discussion may be provided to the Applicant.

Oral explanation

- The OE should be prepared by the Applicant taking into account the following format:
  - Overall duration 45' maximum
  - Sequential responses to each OI followed by a conclusive statement (20')
  - Main SPC amendments + main SOs/FUMs (up to 10')
  - Questions & Answers session (up to 10-15').

Follow-up to the OE, debriefing and finalisation of CPMP scientific opinion

The same day or the day after the OE and the subsequent CPMP discussion, the Rapporteur/Co-Rapporteur will provide feedback to the Applicant on the general orientation of the CPMP.

At the initiative of the Rapporteur/Co-Rapporteur in case of non-negative trend a de-briefing meeting may take place between the Applicant, the Rapporteur/Co-Rapporteur (or their experts team) and the EMEA Product Team to discuss:

- Key amendments of product information documents including a detailed review of the SPC and Patient Leaflet.
- Revision of draft proposal for FUM /SO following the OE.

The Applicant will provide the Rapporteur/Co-Rapporteur and the EMEA Product Team Leader with their full revised texts by day 7 following the OE.

The EMEA Product Team Leader will provide the Rapporteur/Co-Rapporteur and the Applicant at day 10 following the OE with the following documents for comments:

- Summary of CPMP Opinion + revised draft CPMP Assessment Report
- Revised proposal for SPC, PIL and Labelling + revised draft Letter of Undertaking FUM/SO, if appropriate.

Following receipt and implementation of comments in consultation with the Rapporteur/ Co-Rapporteur and the Applicant, the EMEA Product Team Leader shall finalise the draft documents to be provided to all CPMP members in advance of the next CPMP plenary session for final adoption.

Comments on this document should be made by 15 October 2001 to the EMEA (Marisa.Papaluca@emea.eudra.org)

Encl.

Annex A: Flow chart describing the oral explanations timelines
Annex B: Facilities in Meeting Room 3A (CPMP Plenary Meeting Room) at the EMEA.

Annex A

Day 180
List of Outstanding issues adopted by CPMP
Applicant requires clock-stop
(30 days as default, 60 or 90 days to be agreed at CPMP level)

⇩

Post Day 180 (clock stop)
OE written preparatory document

⇩

Post Day 180 (clock stop)
(First day of plenary CPMP meeting)
CPMP discussion on the outstanding issues
in the light of the preparatory documents from Applicant
<At request of Rapporteur/Co-Rapporteur: Applicant briefing meeting>

⇩

(Day 181 of the Centralised Procedure)
Day 0
Oral explanation

⇩

Day 0-1
Applicant de-briefing meeting

⇩

Day +7
[in case of non-negative CPMP trend]
Applicant provides EMEA Product Team Leader with revised product information
and revised draft undertaking letter, when appropriate

⇩

Day +10
PTL provides Rapporteur/Co-Rapporteur and Applicant, as appropriate,
with revised draft documents for comments

⇩

Day +20-25
Rapporteur/Co-Rapporteur feedback to applicant and to EMEA Product Team Leader
Pre-final drafts in the CPMP pack circulated to CPMP Members
in advance of the next CPMP plenary meeting

⇩

Day 210 of the procedure
CPMP adoption of opinion

Annex B
London, 2 August 2001
Doc. Ref: EMEA/CPMP/2358/01/Rev 1

FACILITIES IN MEETING ROOM 3A (CPMP plenary meeting room) AT THE EMEA

A new suite of meeting rooms has been completed on the 3rd floor at the EMEA. The main conference room has a capacity for 114 delegates, each delegate station being equipped with a screen, headphones and a microphone.

The meeting room is used by the CPMP on a monthly basis to accommodate the delegates and company's oral explanations.

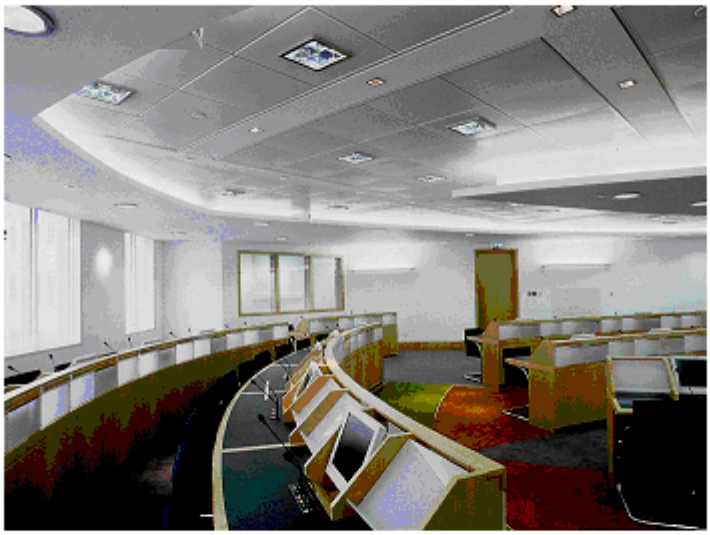
There are two large screens on either side of one end of the room which are linked to the facilities available at the lectern. Videoconferencing is available via ISDN or the LAN gateway to link up with delegates/experts who cannot be present at a particular meeting. Due to the size of the room, it is not feasible to have detailed videoconferencing meetings, room 3C has been fitted out specifically for this.

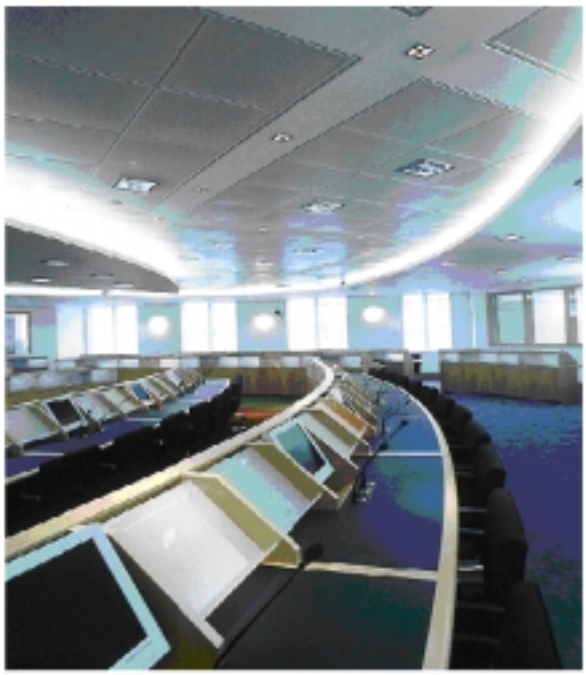
The lectern has a laptop connection for showing presentations using the two large screens and the individual delegate monitors.

Presentations can also be shown from a diskette, CD-Rom, multi-standard videos, slides, paper and transparencies.

It is advisable to inform your contact at the EMEA Product Team Leader prior to your oral explanation, what medium you will be using for your presentation.

Mobile telephones are not permitted in the meeting room.





Report from the meeting held on 23 July 2001

General Issues

Possibilities for a medicinal product authorised through a national procedure to transfer to the Mutual Recognition Procedure

The MRFG would like to remind that a harmonisation of several different marketing authorisations can be generally achieved by a referral according to article 11 of Directive 75/319/EEC.

Nevertheless, the repeat MR-procedure is a tool by which NO/IC (or any MS) can easily switch existing national marketing authorisations into the Mutual Recognition. In that case the applicant should submit a separate new application to the country where repeat use is sought. The country concerned would then request the AR from the initial RMS and start a repeat use procedure. Once this procedure has been successfully completed, the existing national authorisations may have to be revoked or the name of the product be changed. However this would be decided at national level.

In addition, the MRFG agreed that the renewal procedure is not a proper tool for transferring a medicinal product authorised through a national procedure to the Mutual Recognition Procedure.

This statement supersedes all the information published in the previous MRFG Press Releases with regard to this issue.

Acceptability to submit a dossier in a Common Technical Document (CTD) format

The MRFG confirmed that within mutual recognition procedures CMS's would accept the same dossier format as the RMS.

Contact Points for Mutual Recognition Procedure

The MRFG adopted the revised list of Contact Points for Mutual Recognition Procedure, which will be published on the Heads of Agencies Website.

Meeting schedule

The next MRFG meeting will be held on 17 September 2001.

Mutual Recognition Monitoring

The MRFG noted that 39 new mutual recognition procedures were finalised during the month of June 2001, as well as 154 type I and 64 type II variations.

The status as of 30 June 2001 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
2001	170	119	684	92	249	190	--

29 new procedures (regarding 40 products) started in June 2001. The categories of these procedures are as follows:

1 new active substance classified as repeat use.

8 known active substances (already authorised in at least one member state), including **5** multiple applications and **2** repeat use.

18 abridged applications including **2** repeat use.

2 line extension applications.

The new procedures started this month relate to 2 full dossiers, 23 generics and 4 bibliographic applications.

The procedures consisted of 28 chemical substances and 1 biological - vaccine[1].

21 of these procedures were prescription-only medicinal products in the reference Member State and 8 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 June 2001

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	14
DE (2)	2
DE (1)	1
DE (1)	1
DE (1)	1
DE (4)	8
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (1)	16
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	2
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	2
DK (2)	2
DK (1)	4
DK (1)	1
DK (1)	1
DK (1)	1
FR (1)	10
NL (1)	13
UK (2)	8
UK (1)	10

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:

Ms. Natacha **GRENIER**
Ministry of, Public Health
Pharmaceutical Inspectorate
Bd. Bischoffsheim 33, local 411
1000 BRUSSELS - BELGIUM

Phone: + 32 2 227 5516
Fax: + 32 2 221 0355
e-mail: natacha.grenier@afigp.fgov.be

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

http://heads.medagencies.org/