European Medicines Agency
Evaluation of Medicines for Human Use

17 November 2005
EMEA/CHMP/362348/2005, rev.

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
OCTOBER 2005 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its October plenary meeting from 10 – 13 October 2005.

Centralised procedure

Initial applications for marketing authorisation

The CHMP adopted positive opinions on two initial marketing authorisation applications at this meeting:

- **Exubera** (insulin human), Aventis/Pfizer EEIG. Exubera is human insulin that is administered through inhalation. It is indicated for the treatment of adult patients with Type 2 diabetes mellitus who are not adequately controlled with oral antidiabetic agents and require insulin therapy. Exubera is also indicated for the treatment of adult patients with Type 1 diabetes mellitus, in addition to long- or intermediate-acting subcutaneous insulin, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns. EMEA review began on 23 February 2004 with an active review time of 208 days.
- **Ionsys** (fentanyl hydrochloride iontophoretic (HCI) transdermal patch), Janssen-Cilag International N.V. Ionsys is an iontophoretic transdermal patch indicated for the management of acute, moderate to severe post-operative pain, for use in a hospital setting only. EMEA review began on 19 July 2004 with an active review time of 199 days.

Summaries of opinion for these medicinal products are available on the EMEA website: http://www.emea.eu.int. Further information will be included in the European Public Assessment Report (EPAR) once the European Commission has granted final approval.

Extensions of indication and other recommendations

The Committee also adopted positive opinions on extensions of indication for medicinal products that are already authorised in the European Union (EU) for:

- **Avandamet** (rosiglitazone/metformin), from SmithKline Beecham plc, to extend the indication to triple oral combination treatment with sulphonylurea. Avandamet was first authorised in the EU on 20 October 2003 and is indicated in the treatment of Type 2 diabetes.

- **Axura** (memantine), from Merz Pharmaceuticals, and **Ebixa** (memantine), from Lundbeck A/S, to extend the indication to the treatment of patients with moderate to severe Alzheimer's disease. Axura and Ebixa were previously indicated for the treatment of patients with moderately severe to severe Alzheimer disease. Axura was first authorised in the EU on 17 May 2002 and Ebixa on 15 May 2002.

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The Committee recommended that the indication of **Exelon** and **Prometax** (rivastigmine), from Novartis Europharm Ltd, should not be extended to add dementia associated with Parkinson's disease. Exelon was first authorised in the EU on 12 May 1998 and Prometax on 4 December 1998. Both products are indicated for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

> Summaries of opinion for these medicinal products are available on the EMEA website: http://www.emea.eu.int. Further information will be included in the EPAR once the European Commission has granted final approval.

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (one Part A and two Part B) and one List of Questions on a "line extension" applications (Part B) (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Applications for marketing authorisation for orphan medicinal products

Details on those orphan medicinal products that have been subject of a centralised application for marketing authorisation since the September 2005 CHMP meeting are provided in **Annex 4**.

Core Dossiers for Pandemic Influenza Vaccines

In the context of the EMEA's preparedness for pandemic influenza, the CHMP made a commitment to accelerate the scientific evaluation of applications for scientific advice and marketing authorisation for pandemic influenza vaccines 'core dossiers', thus increasing pandemic influenza preparedness and helping to ensure that such vaccines are available to EU citizens as soon as possible in the event of an outbreak.

The EMEA has developed the concept of 'core dossiers' to facilitate the submission and review of applications for pandemic influenza vaccines. This concept allows the CHMP to review the bulk of an application prior to the actual outbreak of a pandemic. Once the specific strain of the influenza virus is known, the Committee could approve a variation to this core dossier, following a 'rolling review', within a few days. More information on the core dossier concept can be found in the CHMP 'Guideline on dossier structure and content for pandemic influenza vaccine marketing authorisation application' (please see: http://www.emea.eu.int/pdfs/human/vwp/471703en.pdf).

Detailed information on the centralised procedure

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 CHMP plenary meeting in September 2005 is provided in **Annex 2.** The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 3**.

Other procedures

- **Update on non-selective NSAIDs**

The Committee concluded, at its meeting of 10-13 October 2005, that, on the basis of the data reviewed, there are no new safety concerns regarding cardiovascular and gastrointestinal safety and serious skin reactions with non-selective NSAIDs (non-steroidal anti-inflammatory drugs). NSAIDs remain important treatments for arthritis and other painful conditions. Please see relevant Press Release at the EMEA Website: http://www.emea.eu.int/pdfs/human/press/pr/29896405en.pdf

CHMP Working Parties

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Party (SAWP) meeting, which was held on 27-29 September 2005. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the October 2005 CHMP meeting are listed in **Annex 6**.

Upcoming meetings following the October 2005 CHMP plenary meeting:

- The 16th meeting of the CHMP will be held at the EMEA on 14 –17 November 2005.
- The next Invented Name Review Group meeting will be held at the EMEA on 14 November 2005.
- The first meeting of the CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures), replacing the Mutual Recognition Facilitation Group, will be held at the EMEA on 14 – 15 November 2005.

Organisational matters

The main topics addressed during the October 2005 CHMP meeting related to:

- The adoption of the revised mandate of the Scientific Advice Working Party (SAWP).
- The adoption of the Quality Working Party (QWP) Work plan for 2006.
- The adoption of the Guidance on the Co-optation of additional Pharmacovigilance Working Party (PhVWP) Members.
- The confirmation of the PhVWP composition.
  In addition, the CHMP elected Dr June Raine as the new Chair of the PhVWP.
  Dr Raine is a member of the Executive Board of the UK's Medicines and Healthcare Products Regulatory Agency (MHRA)

EMEA Implementation of the New EU Pharmaceutical Legislation

The eighth CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 10 October 2005.

The following documents were agreed by the CHMP and will be transmitted to the European Commission:

- Mandatory Scope of the centralised procedure: Operational measures for submission of ongoing national marketing authorisation applications for medicinal products for human use to the EMEA.
  The document will be transmitted to the European Commission for information and published on the EMEA website for 4 weeks external consultation.

- Proposal on "Transitional measures for submission of Periodic Safety Update Reports (PSURs) for Centrally authorised products".
  This proposal will be transmitted to the European Commission for comments and agreement. In addition this proposal will also be sent to Mutual Recognition Facilitation Group (MRFG) for information.

- Operational procedure on Handling of "Consultation with target patient groups" on Package Leaflets for Centrally Authorised Products for Human Use.
  This document will be transmitted to the European Commission for information and published on the EMEA website for implementation.

- Actual marketing and cessation and Sunset Clause.
  These documents will be transmitted to the European Commission for information and published on the EMEA website for 4 weeks external consultation. These documents will also be sent to the MRFG for information.

- Revised Linguistic Review Process of Product Information in the centralized procedure (PIPIT).
  This document will be transmitted to the European Commission for information and published on the EMEA website for implementation.

- Volume 9A of the Rules Governing Medicinal Products in the European Union.
  The document will be transmitted to the European Commission for publication and external consultation.

Follow up discussion took place on the following topic:

- Generic applications (draft procedural Timetable and CHMP Assessment Report template).

Initial discussion took place on the following topic:

- Draft Rules of procedure for the involvement of member(s) of patients' and/or Consumers' organisations in the Committee related activities.

PROCEDURAL ANNOUNCEMENTS

- **CHMP Peer Review**

  The EMEA Committee for Human Medicinal Products (CHMP) has adopted a procedure describing a Peer Review during the initial phase of the assessment of new Marketing Authorisation Applications (MAA's).

  The Peer Review procedure - which is in addition to the established activities of CHMP members following an initial assessment report from the appointed (Co) Rapporteurs - applies specifically to those CHMP members assigned as peer reviewers, and EMEA staff. The overall aim of the Peer Review is to contribute to the quality assurance of the list of questions intended for the applicant by reviewing the proposed questions in conjunction with the scientific assessment made by the (Co) Rapporteurs in their initial assessment reports.

  Peer Reviewer's comments are not made available to applicants. Moreover, it is not intended that applicants contact peer reviewers or other CHMP members in the context of an ongoing CHMP assessment of a MAA.

  The procedure is in a pilot phase and will be evaluated in the coming months after sufficient experience has been gained. A strengthened peer review system that can improve the consistency of scientific assessments is one of the objectives set out in the EMEA Road Map (http://www.emea.eu.int/pdfs/general/direct/directory/3416303enF.pdf).

  The EMEA will communicate the outcome of this evaluation and publish relevant documents, as appropriate.

- **Parallel Distribution and change in the method of payment of administrative charges for notifications**

  The European Medicines Agency (EMEA) will change the method for payment of administrative charges for all parallel distribution notifications submitted on or after the 1st December 2005.
  For all such notifications the parallel distributor should not pay the corresponding administrative charge in advance. Instead the EMEA will issue an invoice on the date of receipt of the notification and the administrative charge will be payable within 30 calendar days of the date of the invoice. The invoice will be sent to the billing address indicated by the parallel distributor and will contain clear details of the product involved, the amount of the administrative charge, the bank account to where the administrative charge should be paid and the due date for payment.
  In order to prepare for a smooth transition, the EMEA will shortly be contacting all parallel distributors to confirm their billing addresses and to verify their balance as of the 30th September 2005.

Mutual Recognition procedure

The CHMP noted the report from the Mutual Recognition Facilitation Group meeting held on 10 – 11 October 2005. For further details, please see **Annex 7**.

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

EMEA CENTRALISED PROCEDURES

	1995 - 2004	2005	Overall Total
Scientific Advice	433	88	521
Follow-up to Scientific Advice	71	17	88
Protocol Assistance	59	36	95
Follow-up to Protocol Assistance	12	10	22

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Applications submitted	153	303	456	4	28	32	488
Consultation for Medical Device[1]	0	1	1	0	2	2	3
Withdrawals	22	62	84	0	5	5	89
Positive opinions[2]	107	197	304	5	15	20	324[3]
Negative opinions[4]	2	5	7	0	0	0	7[5]
Marketing authorisations granted by the Commission	98	190	288	4	9	13	301[6]

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Variations type I	863	1937	2800	124	369	493	3293
Positive opinions, variations type II	758	886	1644	223	203	426	2070
Negative opinions, variations type II	1	6	7	0	2	2	9
Extensions (Annex II applications)	53	63	116	6	5	11	127

[1] Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivatives of human blood or plasma and Directive 2001/104/EC.
[2] 23 positive opinion corresponding to 23 Orphan Medicinal Products
[3] 324 positive opinions corresponding to 253 substances
[4] In case of appeal, the opinion will not be counted twice
[5] 7 negative opinions corresponding to 6 substances (2 of these negative opinions correspond to 2 Orphan Medicinal Products)
[6] 301 marketing authorisations corresponding to 232 substances

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE SEPTEMBER 2005 CHMP MONTHLY REPORT

Invented Name	Tarceva
INN	Erlotinib
Marketing Authorisation Holder	Roche Registration Limited
Proposed ATC code	L01XX34
Indication	Tarceva is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.
CPMP Opinion date	23 June 2005
Marketing Authorisation Date	19 September 2005

Invented Name	Vasovist
INN	Gadofosveset Trisodium
Marketing Authorisation Holder	Schering AG
Proposed ATC code	V08CA
Indication	This medicinal product is for diagnostic use only. Contrast enhancement in magnetic resonance angiography (CE-MRA). VASOVIST is indicated for contrast-enhanced magnetic resonance angiography for visualization of abdominal or limb vessels in patients with suspected or known vascular disease.
CPMP Opinion date	23 June 2005
Marketing Authorisation Date	3 October 2005

OUTCOME OF THE OCTOBER 2005 CHMP MEETING IN RELATION TO CENTRALISED APPLICATIONS IN THE POST-AUTHORISATION PHASE

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
5 Extensions of indication	3 Positive opinions and 2 Negative opinions
24 SPC changes	24 Positive opinions
17 Quality changes	17 Positive opinions

Opinions for Annual Re-Assessment application		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Aldurazyme (laronidase) Genzyme B.V	Positive Opinion	The authorisation will remain under exceptional circumstances
MabCampath (alemtuzumab) Genzyme B.V	Positive Opinion	The authorisation will remain under exceptional circumstances
Velcade (bortezomib) Janssen-Cilag International N.V.	Positive Opinion	The authorisation will remain under exceptional circumstances

Opinions for Renewal applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Agenerase (amprenavir) GlaxoSmithKline	Positive Opinion	---
Infanrix hexa (Hep B-IPV HIB vaccine) GlaxoSmithKlineBiologicals S.A	Positive Opinion	---
Infanrix penta (Hep B-IPV vaccine) GlaxoSmithKline Biologicals S.A	Positive Opinion	---
Taxotere (docetaxel) Aventis	Positive Opinion	---

Overview of Designated Orphan Medicinal Products that have been the subject of a Centralised Application for Marketing Authorisation

- update since the last COMP meeting on 8-9 September 2005 -

Active substance	*Sponsor/applicant*	*EU Designation Number & Date of Orphan Designation*	*Designated Orphan Indication*
Sorafenib tosylate (Nexavar)	Bayer Healthcare AG	EU/3/04/207 29/07/2004	Treatment of renal cell carcinoma
3-(4'aminoisoindoline-1'-one)-1-piperidine-2,6-dione (Revlimid)	Celgene Europe Limited	EU/3/04/192 8/03/2004	Treatment of myelodysplastic syndromes
(Z)-N-[2-(Diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide (S)-2-hydroxysyccinate (Sutent)	Pfizer Limited	EU/3/05/267 10/03/2005	Treatment of malignant gastrointestinal stromal tumours
(Z)-N-[2-(Diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide (S)-2-hydroxysyccinate (Sutent)	Pfizer Limited	EU/3/05/268 10/03/2005	Treatment of renal cell carcinoma

OUTCOME OF THE OCTOBER 2005 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Acute myocardial infarction			X				X	
Biological	Hemophilia A	X					X	X	
Chemical	Prevention of ischaemic cardiovascular disease			X				X	
Chemical	Acute coronary syndrome	X						X	
Chemical	Acute coronary syndrome	X					X	X	
Chemical	Parkinson's disease	X						X	
Chemical	Attention Deficit Hyperactivity Disorder (ADHD)	X					X		
Chemical	Epilepsy	X				X	X	X	
Biological	Cutaneous T cell lymphoma				X			X	X
Biological	Ovarian cancer		X			X	X	X	
Chemical	Cutaneous T cell lymphoma		X				X	X	X
Biological	Squamous cell carcinoma of the Head and neck		X			X	X	X	X

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Cystic fibrosis		X			X	X	X	
Biological	Cystic fibrosis		X			X			
Chemical	Cystic fibrosis		X					X	X
Biological	Neutropenias	X				X	X		
Chemical	Age-related macular degeneration	X				X	X	X	
Chemical	Uveitis	X						X	
Chemical	Recovery from hip fracture	X						X	
Biological	Creation of posterior vitreous detachment	X				X	X	X	
Biological	Respiratory syncytial virus infection.	X						X	
Chemical	Idiopathic pulmonary fibrosis		X				X	X	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 12 Scientific Advice letters, 7 Protocol Assistance letters, 2 Follow-up Scientific Advice letters and 1 Follow-up Protocol Assistance letters were adopted at the 10-13 October 2005 CHMP meeting.

The Committee accepted 9 Initial Scientific Advice Requests, 2 Follow-up Scientific Advice Requests and 3 Initial Protocol Assistance Requests started at the meeting that took place on 27-29 September 2005.

ANNEX 6 to CHMP Monthly Report October 2005

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE OCTOBER 2005 CHMP MEETING

EFFICACY WORKING PARTY

Reference number	Document	Status
EMEA/CHMP/EWP/327 726/2005	Concept paper on the Development of a CHMP Guideline on the Preclinical and Clinical investigation of Drug-eluting Coronary Stent	Delayed for further CHMP discussion.
EMEA/CHMP/021/97 Rev.1	Guideline on clinical investigation of medicinal products for the treatment of Hormone Replacement of Oestrogen Deficiency Symptoms in Postmenopausal Women	Adopted

PAEDRIATIC WORKING PARTY

Reference number	Document	Status
CHMP/327847/2005	Assessment of the paediatric needs for Cardiovascular products	Released for 6 months consultation

SAFETY WORKING PARTY

Reference number	Document	Status
CHMP/SWP/169215/2005	Guideline on the need for non-clinical testing in juvenile animals on human pharmaceuticals for paediatric indications	Released for 6 months consultation
CPMP/SWP/799/95 rev. 1	Guideline on the Non-Clinical Documentation for Mixed Marketing Authorisation Applications (CPMP/SWP/799/95 rev.	Adopted
CHMP/SWP/258498/2005 rev. 1	Guideline on the Non-Clinical Development of Fixed Combinations of Medicinal Products	Adopted

ICH

Reference number	Document	Status
EMEA/CHMP/167235/ 2004	ICH S8 Immunotoxicity Studies for Human Pharmaceuticals; ICH step 4: Note for Guidance on Immunotoxicity Studies for Human Pharmaceuticals	Adopted

Report from the meeting held on 10th and 11th October 2005

Final meeting of the Mutual Recognition Facilitation Group

The October meeting was the final meeting of the Mutual Recognition Facilitation Group. This Group was an informal group established by the member states in March 1995 to coordinate and facilitate the operation of the mutual recognition procedure.
The new legislation sets up a formal Group, the Coordination group, for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the mutual recognition procedure or the new decentralised procedure.
The Coordination group for the mutual recognition and decentralised procedure – human, to be known as CMD(h), will start its activities in November 2005. Practical arrangements for the transition from the MRFG to the CMD(h) have been agreed at the October meeting.
The MRFG would like to thank all MRFG members, past and present, and Interested Parties for the contribution, over the last 10 years, to the success of the MRFG.

General Issues

Guideline on the processing of renewals in the mutual recognition and decentralised procedures
The MRFG has considered the comments received on the Guideline on the processing of renewals in the mutual recognition and decentralised procedures following the consultation procedure. The final Guideline will be published shortly on the website.

Decentralised procedure – Member States' Standard Operating Procedure
The MRFG has finalised the Decentralised procedure – Member States' SOP, taking account of the comments received following the consultation procedure. The final SOP for the Decentralised procedure will be published on the website.

Disagreement in procedures – referral to CMD
The MRFG has considered the comments received from Interested Parties on the CMD SOP – Disagreement in procedures – referral to CMD. The final SOP will be published on the website to coincide with the Notice to Applicants updated chapters.

Guidance document – Information to be submitted by the Member State of the European Reference Product
The MRFG has agreed a guidance document on the information to be transmitted by the Competent Authority of the Member State of the European reference product to the Competent Authority of the Member State where an application has been submitted, in accordance with Article 10(1) of Directive 2001/83/EC, as amended, when the reference medicinal product is not authorised in that Member State. The Guidance document will be published on the website for information.

Usage patent common statement in the Package Leaflet

The MRFG, having taken account of views of the EMEA/CHMP Working Group with Patient Organisations, has agreed a statement to be included in the Package Leaflet of generic medicinal products for indication(s) or dosage form(s) of the reference medicinal product covered by patent law, in accordance with Article 11 of Directive 2001/83/EC, as amended.
The MRFG has agreed to publish the proposed statement for a 4-week consultation period with Interested Parties.
Any comments or proposals on the proposed statement for the PL should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (sonia.ribeiro@emea.eu.int).

Annotated QRD template for MR/DC procedures
The MRFG, in collaboration with the QRD, has adapted the annotated QRD product information template for medicinal products for human use with guidance suitable for use in the Mutual Recognition and Decentralised procedures. The adapted MRP/DCP QRD annotated template will be published on the website.
The 'clean' version of the template for completion by applicants will be found on the EMEA website.

Standard Operating Procedure for Article 61(3) changes to patient information
The MRFG has agreed a procedure to maintain the harmonisation of labelling and package leaflet of medicinal products approved via the decentralised or mutual recognition procedure concerning changes not connected with the summary of product characteristics, in accordance with Article 61(3) of Directive 2001/83/EC, as amended.
The SOP and the notification form will be published on the website.
The intention of the Group is to review the procedure in 3 months, in light of experience and initial comments received from Interested Parties (to be sent by 10 November 2005 to the CMD(h) secretariat (**sonia.ribeiro@emea.eu.int**)).

Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure
The MRFG has agreed a Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure, to comply with the requirements set out in Article 21(4) of Directive 2001/83/EC, as amended. The Best Practice Guide will be published on the website for a 4-week consultation period with Interested Parties.
Any comments on the BPG should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (**sonia.ribeiro@emea.eu.int**).

Best Practice Guide for the Mutual Recognition Procedure & Procedure for Automatic Validation of MR Procedures for New Applications
The MRFG has agreed an updated BPG for the Mutual Recognition Procedure, to take account of the new legislation and to include a flow chart for the mutual recognition procedure.
The Procedure for Automatic Validation of MR Procedures for New Applications has also been updated.
Any comments on the draft updated documents should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (**sonia.ribeiro@emea.eu.int**).

Guidance on submission dates for Applicants of the Decentralised and Mutual Recognition Procedures
A Guidance document on submission dates for Applicants of the Decentralised procedure and an updated Guidance document on submission dates for Applicants of the Mutual Recognition Procedure, to include dates for 2006 and 2007, has been adopted by the Group and will be published on the website.

Urgent Safety Restriction – Member States' Standard Operating Procedure
The Urgent Safety Restriction – Member States' Standard Operating Procedure has been updated by the MRFG, in collaboration with the PhVWP. As a consequence the Variations Best Practice Guide has been updated and the amended version will be published on the website.

Any comments on the draft updated Urgent Safety Restriction SOP should be sent by 10 November 2005 coordinated where possible by trade associations, to the CMD(h) secretariat (**sonia.ribeiro@emea.eu.int**).

New Questions and Answers on the implementation of the new legislation

The MRFG has agreed 4 new Q&A to address applications for marketing authorisation for generic medicinal products for indications within the mandatory scope of the centralised procedure; timing in a MR/DC procedure for consultation with target patient groups for the PL; information on marketing of medicinal products; and withdrawals in MR/DC procedures. The updated Q&A document will be published on the website.

Working group meeting on harmonisation of SPCs

The working group met in October to continue the preparatory discussions on the role of the Coordination group to promote harmonisation of authorisations for medicinal products in the Community and to consider the timing and process for selection of medicinal products for SPC harmonisation.

Meeting schedule

The inaugural CMD(h) meeting will be held on 14th and 15th of November 2005.

Mutual Recognition Monitoring

The MRFG noted that **89** new mutual recognition procedures were finalised during the month of September 2005, as well as **336** type IA variations, **180** type IB variations and **186** type II variations.

The status as of 30th of September of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CHMP
2005	782	221	3006	1440	1065	2 N.A. 6 Var.

72 new procedures (regarding **136** products) started in September 2005. The categories of these procedures are as follows:

1 new active substance classified as repeat use.

17 known active substance (already authorised in at least one member state) including **4** multiple applications and **3** repeat use.

52 abridged applications including **14** multiple applications and **10** repeat use.

2 line extension applications.

The new procedures started related to **7** full dossiers, **45** generics, **10** bibliographic applications, **3** fixed combinations, and **7** for different use, route or dose.

The procedures consisted of **70** chemical substances, **1** biological-vaccine and **1** biological-other[1].

70 of these procedures were prescription-only medicinal products in the reference Member State and **2** procedures were classified as a Non-prescription (including OTC) medicinal products2.

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 2005

Reference Member State (number of products involved in the procedure)	**Number of CMSs involved in the procedure**
AT (2)	9
CZ (1)	9
CZ (4)	6
DE (1)	1
DE (1)	10
DE (1)	3
DE (2)	11
DK (1)	5
DK (1)	1
DK (2)	2
DK (3)	7
DK (3)	9
DK (2)	13
ES (1)	4
FI (5)	15
FI (5)	6
FI (5)	3
FI (1)	1
FI (1)	4
FI (2)	1
FI (2)	1
FI (2)	5

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FI (1)	13
FI (2)	8
FI (2)	1
FR (1)	2
FR (2)	22
FR (2)	20
FR (1)	3
HU (1)	6
HU (1)	7
HU (1)	2
HU (1)	9
HU (1)	4
HU (1)	1
HU (1)	1
IT (1)	2
IT (1)	3
NL (2)	10
NL (1)	8
NL (1)	5
NL (2)	2
NL (4)	1
NL (2)	9
NL (1)	4
NL (2)	2
NL (3)	3
PT (2)	6
PT (2)	9
SE (4)	6
SE (2)	15
SE (2)	6
SE (2)	5
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	13
SE (2)	12
SE (2)	1
UK (4)	12
UK (1)	5
UK (2)	11
UK (2)	2
UK (2)	12
UK (1)	4
UK (1)	16
UK (1)	6
UK (2)	7
UK (2)	2
UK (4)	1
UK (6)	12
UK (2)	16

All documents mentioned in this press release can be found at the MRFG website at the European Medicines Authorities Windows under the heading MRFG Guidance.

Information on the above mentioned issues can be obtained from the presiding chair of the MRFG:

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