European Medicines Agency

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

The Committee for Medicinal Products for Human Use (CHMP) held its May plenary meeting from 23 – 26 May 2005.

The Chairman on behalf of the Committee welcomed Dr Tapio Kuitunen, as the new CHMP member from Finland replacing Dr Markku Toivonen. Furthermore, Dr Bengt Ljungberg was welcomed in the post of CHMP alternate from Sweden, replacing Dr Per Nilsson.

Centralised procedure

Initial applications for marketing authorisation

The CHMP adopted a positive opinion on an initial marketing authorisation application for:

- **Fosavance** (alendronic acid and colecalciferol) from Merck Sharp & Dohme Ltd.
  Fosavance is indicated for the treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. The EMEA review began on 18 October 2004 with an active review time of 182 days.
  A summary of opinion including the full indication for this product is available on the EMEA website: http://www.emea.eu.int

Extensions of indication and other recommendations

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

- **Arixtra** (fondaparinux) and **Quixidar** (fondaparinux), Glaxo Group Ltd, to include the prevention of venous thromboembolism (VTE) in patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery. Arixtra was first authorised in the EU on 21 May 2002.

- **Cymbalta** (duloxetine), Eli Lilly Nederland B.V., and **Xeristar** (duloxetine), Boehringer Ingelheim International GmbH, to extend their use to the treatment of diabetic peripheral neuropathic pain. Cymbalta and Xeristar were first authorised in the EU on 17 December 2004.

- **Invanz** (ertapenem), Merck Sharp & Dohme, to extend its use to include children from 3 months to 17 years of age. Invanz is currently indicated for the treatment of the following bacterial infections in adults: intra-abdominal infections, community acquired pneumonia and acute gynaecological infections. The product was first authorised in the EU on 18 April 2002.

The CHMP also adopted an opinion to recommend the update of the contraindications for **Invirase** (saquinavir mesylate) and **Fortovase** (saquinavir) from Roche Registration Ltd.

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.

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Other issues

Following the publication of two clinical studies showing an increased mortality in cancer patients that were administered epoetin alfa and epoetin beta, the Pharmacovigilance Working Party (PhVWP) has looked at the risk of tumour growth progression and thromboembolism in patients with cancer who have been treated with epoetins. Based on this review, the CHMP agreed with the PhVWP recommendations that the product information of all epoetins indicated in the treatment of anaemic cancer patients receiving chemotherapy should be updated to reflect the new information. Harmonised changes for the product information of centrally authorised epoetins in this indication (Aranesp, Nespo and NeoRecormon) were adopted by the CHMP at its May 2005 meeting. Harmonisation of the product information of nationally authorised epoetins will be done in accordance with the relevant legal framework.

Lists of Questions

The Committee adopted two Lists of Questions on initial applications (one Part A and one Part B).

Plasma Master File Certification

The CHMP at its May 2005 meeting adopted the Plasma Master File (PMF) Evaluation Report recommending the Baxter PMF certification.

It is noted that the CHMP at its *April 2005* CHMP meeting adopted PMF Evaluation Reports recommending the following PMF certifications: Plasma Master File by ZLB Behring ZPS, Plasma Master File by Sanquin and Plasma Master File by ZLB Behring AG – BTS GRC. A PMF Evaluation report recommending the PMF re-certification for ZLB Behring was also adopted as a result of a variation to the PMF dossier.

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2.** No Commission Decision was granted since the CHMP meeting in April 2005.

Applications for marketing authorisation for orphan medicinal products

Details of those Orphan medicinal products that have been subject of a centralised application for marketing authorisation since the April 2005 CHMP are provided in **Annex 3**.

Arbitration and Referral procedure

- The CHMP began an arbitration review for **Prozac** (fluoxetine) and associated trade names, following an application by Eli Lilly to extend the indication to include the treatment of major depressive episodes in children and adolescents. France initiated the review on the basis of safety and efficacy concerns raised by a number of Member States concerning the use of Prozac in this age group. The arbitration is made under Article 6(12) of Commission Regulation (EC) No 1084/2003.
  Prozac is authorised in most EU Member States for the treatment of major depressive episodes, obsessive-compulsive disorder and bulimia nervosa in adults. The CHMP advised in April 2005 that the class of serotonin selective re-uptake inhibitors (SSRI) medicines, including fluoxetine, should not be used in children and adolescents except in their approved indications. The April 2005 statement, including advice for prescribers, patients and parents, is available on the EMEA website (http://www.emea.eu.int/pdfs/human/press/pr/12891805en.pdf).

CHMP Working Parties

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Group (SAWP) meeting, which was held on 27-29 April 2005. For further details, please see **Annex 4**.

Documents prepared by the CHMP Working Parties adopted during the May 2005 CHMP meeting are listed in **Annex 5**.

Upcoming meetings following the May 2005 CHMP plenary meeting:

- The 12th meeting of the CHMP will be held at the EMEA on 20 – 23 June 2005.
- The next Invented Name Review Group meeting will be held at the EMEA on 20 June 2005.
- The next Mutual Recognition Facilitation Group Meeting will be held at the EMEA on 20 – 21 June 2005.
- A Workshop on regulatory and scientific issues related to concomitant administration of vaccines will be held at the EMEA on 30 – 31 January 2006.
- An extra plenary meeting of the Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP) will be held at the EMEA on 15 – 16 June 2005.

Interested Parties meetings:

- An EMEA/DIA Workshop "EMEA New Guidelines for Development and Approval of similar biological medicinal products" will take place on 8-9th December 2005, in Paris, France.

Organisational matters

The main topics addressed during the May 2005 CHMP related to:

- The adoption of the revised Composition of the Blood Products Working Party (BPWP).
- The election of the Vice Chairperson for the Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP): Dr Matina Weise was elected Vice Chairperson.

  The following Guideline/Annexes on similar biological medicinal products containing biotechnology-derived proteins as active substance were adopted and released for 5 months consultation on the EMEA website: http://www.emea.eu.int (please see also **Annex 5**):

  - "Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues"
  - "Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing recombinant human insulin"
  - "Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing somatropin"

  In addition "Summaries of activities relating to similar biological medicinal products, Summary Overview" is outlined in **Annex 6** of this Monthly Report.

- The Procedure for European Union Guidelines and related documents within the pharmaceutical legislative framework. This procedure will be finalised and released on the EMEA website in the near future.
- A presentation by DG Research on "Innovative Medicines Initiative 7th Framework Programme DG Research Private Public Partnership Platform for innovation". A document on this issue will be finalised by DG Research by end of November 2005.
- A presentation by Ms Lesley Greene (member of Climb, Children Living with Inherited Metabolic Diseases) on "Living with an orphan disease, the experience with an orphan drug".
- The release for consultation of the European Commission Proposal for Regulatory Framework on Human tissue engineered products and other cell / tissue based products:
    - Consultation paper - Human Tissue engineering and beyond - proposal for a Community regulatory framework on advanced therapies (please see: http://pharmacos.eudra.org/F2/advtherapies/docs/ConsultationPaper-AdvancedTherapies-2005-May-04.pdf)
    - Draft Regulation - Human Tissue engineering and beyond - proposal for a Community regulatory framework on advanced therapies (please see: http://pharmacos.eudra.org/F2/advtherapies/docs/DraftRegulation-Advanced%20Therapies-2005-May-04.pdf).

      The consultation period of the European Commission will close on 20th June 2005.
- An Audit on the CHMP composition and scientific competence.

EMEA implementation of the New EU Pharmaceutical Legislation

The fourth CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 23 May 2005.

The main topics addressed during this meeting related to:

- "Re-examination of opinions".
  A document was adopted by the CHMP and will be transmitted to the European Commission.
- "CHMP opinion in collaboration with the WHO".
  Following the end of the consultation period, a document was adopted by the CHMP and is available on the EMEA website:
  http://www.emea.eu.int/htms/general/direct/legislation/legislationhuman.htm
- "Scope mandatory indications".
  A document is released for 4 weeks external consultation until 8 July 2005 and is available on the EMEA website:
  http://www.emea.eu.int/htms/general/direct/legislation/legislationhuman.htm.

Initial discussions took place on the following review implementation topics: Pharmacovigilance Risk Management System evaluation/procedure, Infectious agents, Publication of withdrawal opinions and Conflict of Scientific Opinions between EU Institutions.

Mutual Recognition procedure

The CHMP noted the report from the Mutual Recognition Facilitation Group (MRFG) meeting held on 23 – 24 May 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	51	484
Follow-up to Scientific Advice	71	4	75
Protocol Assistance	59	19	78

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Applications submitted	153	303	456	3	13	16	472
Consultation for Medical Device[1]	0	1	1	0	1	1	2
Withdrawals	22	62	84	0	3	3	87
Positive opinions[2]	107	197	304	0	3	3	307[3]
Negative opinions[4]	2	5	7	0	0	0	7[5]
Marketing authorisations granted by the Commission	98	190	288	3	7	10	298[6]

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Variations type I	863	1937	2800	61	173	234	3034
Positive opinions, variations type II	758	886	1644	100	89	189	1833
Negative opinions, variations type II	1	6	7	0	0	0	7
Extensions (Annex II applications)	53	63	116	1	2	3	119

[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] 19 positive opinion corresponding to 19 Orphan Medicinal Products
[3] 307 positive opinions corresponding to 238 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] 298 marketing authorisations corresponding to 229 substances

OUTCOME OF THE MAY 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	5 Positive opinions
23 SPC changes	23 Positive opinions
28 Quality changes	28 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
N/A	**N/A**	**N/A**

Opinions for Renewal applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
N/A	**N/A**	**N/A**

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE APRIL 2005 CHMP MEETING

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
Stiripentol (Diacomit)	Laboratoires BIOCODEX	EU/3/01/071 05/12/2001	Treatment of severe myoclonic epilepsy in infancy
4-(3,5-bis-(hydroxy-phenyl)-1,2,4) triazol-1-yl)-benzoic acid (Exjade)	Novartis Europharm Limited	EU/3/02/092 13/03/2002	Treatment of chronic iron overload requiring chelation therapy

OUTCOME OF THE MAY 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	Treatment of partial dermal and full thickness burns		X					X	X
Biological	Treatment of Diffuse Large B-cell Lymphoma	X					X	X	
Chemical	Treatment of relapsing forms of Multiple Sclerosis.	X						X	
Biological	Active immunisation against Japanese Encephalitis Virus	X				X	X	X	
Chemical	Treatment of breast cancer	X						X	
Chemical	Control of serum phosphorus in patients with chronic kidney disease.	X						X	
Chemical	Treatment of phenylketonuria		X				X	X	X
Biological	Treatment of anemia			X		X	X	X	
Biological	Treatment of Urinary Incontinence	X					X	X	
Chemical	Treatment of depression	X						X	
Chemical	Treatment of post-operative nausea and vomiting			X				X	
Biological	Treatment of diabetes	X						X	
Biological	Treatment of dermatomyositis				X			X	X
Chemical	Treatment of hormone refractory prostate cancer	X						X	

Chemical	Treatment of manic episodes in bipolar I disorder			X			X	X	
Chemical	Use with MRI in patients with abnormal brain barrier or abnormal vascularity in brain, spine or associated tissues.	X						X	
Chemical	Treatment of postmenopausal osteoporosis	X						X	
Chemical	Treatment of HIV-1 infection	X				X			
Chemical	Treatment of Major Depressive Disorder and General Anxiety Disorder	X					X	X	
Chemical	Treatment of Diabetes	X						X	
Biological	Treatment of psoriasis	X						X	
Chemical	Treatment of Glioblastoma Multiforme	X						X	
Chemical	Treatment of endometriosis	X						X	
Chemical	Treatment of Friedreich's Ataxia.		X				X	X	
Biological	Treatment of Acute lymphoblastic leukaemia		X			X	X	X	X
Biological	Treatment of diabetes	X						X	
Chemical	Treatment of relapse refractory Multiple Myeloma		X					X	X

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 18 Scientific Advice letters, 3 Follow-up Scientific Advice letters, 5 Protocol Assistance letters and 1 Follow-up Protocol Assistance letter were adopted at the 23-25 May CHMP meeting.

The Committee accepted 5 Initial Scientific Advice Requests, 2 Initial Protocol Assistance Requests, 3 Follow-up Scientific Advice Requests and 1 Follow-up Protocol Assistance Requests.

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

BIOLOGICS WORKING PARTY

Reference number	Document	Status
EMEA/CHMP/BWP/ 2458/03	Guideline on the development and manufacture of lentiviral vectors	Adopted

WORKING PARTY ON BIOLOGICAL (BIOSIMILAR) MEDICINAL PRODUCTS (BMWP)

Reference number	Document	Status
CHMP/42832/2005	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues	Released for 5 months consultation
CHMP/32775/2005	Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues- guidance on biosimilar medicinal products containing recombinant human insulin	Released for 5 months consultation
CHMP/94528/2005	Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues- guidance on biosimilar medicinal products containing somatropin	Released for 5 months consultation
EMEA/CHMP/BWP/ 133252/2005	Summaries of activities relating to similar biological medicinal products, Summary Overview	Please see **Annex 6** of this Monthly Report

EFFICACY WORKING PARTY

Reference number	Document	Status
CHMP/EWP/4713/03	Guideline on clinical investigation of medicinal products for the treatment of sepsis	Released for 6 months consultation
CHMP/EWP/6235/04	Guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolic risk in non-surgical patients	Released for 6 months consultation
CPMP/EWP/1080/00	CHMP Guideline on medicinal products in the treatment of diabetes mellitus	The CHMP considered the need for revision of this Guideline and was of the opinion that the Guideline is still valid as it is

QUALITY WORKING PARTY

Reference number	Document	Status
CPMP/QWP/2820/00 rev. 1 EMEA/CVMP/815/00 rev. 1	Guideline on specifications test procedures and acceptance criteria for herbal substances: Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products	Adopted by the CHMP. Publication subject to adoption by the CVMP.

VACCINE WORKING PARTY

Reference number	Document	Status
CHMP/VWP/164653/05	Note for Guidance on the clinical evaluation of vaccines	Released for 6 months consultation

ICH

Reference number	Document	Status
CHMP/ICH/2/2004	E14 Step 4: Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential of non-antiarrhthmic drugs	Adopted
CHMP/ICH/423/2002	S7B Step 4: Non-clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	Adopted
CHMP/ICH/168535/2005	M5 EWG Step 2: Data elements and standards for drug dictionaries ▪ Routes of Administration Controlled Vocabulary: released for information ▪ Units and Measurements Controlled Vocabulary: released for information	Released for 4 months consultation
CHMP/ICH/166783/2005	E2B(R) Step 2: Data elements for transmission of individual case safety reports	Released for 4 months consultation

Summary of activities relating to Similar Biological Medicinal Products.

An overview of the activities ongoing and anticipated with regard to Similar Biological Medicinal Products is provided and illustrated in the attached Figure.

It is intended that comments on all guidelines will be received through the normal consultation procedure and addressed by the appropriate CHMP Working Parties. Written comments should be provided as appropriate during the external consultation period.

Since the guidelines form a natural hierarchy, the release of the overarching (general) guideline will be followed by progressively more specific and detailed guidelines, including product-class specific guidelines on (non)clinical issues.

To date, the CHMP has released the following draft guidelines for consultation:

Guideline on similar biological medicinal products (CHMP/437/04). Consultation period from November 2004 to February 2005.

Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Quality issues (EMEA/CHMP/BWP/49348/2005). Consultation period from March 2005 to 30 June 2005.

The CHMP released for consultation at their meeting in May 2005 the following draft guidelines:

Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (CHMP/42832/2005).

Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing recombinant human insulin (CHMP/32775/2005).

Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing somatropin (CHMP/94528/2005).

The consultation period for these documents will be closed by 31 October 2005.

Additional product class specific guidance annexes will be released during the course of 2005 (see attached Figure).

After the release of the majority of the guidelines, it is envisaged to hold a stakeholder workshop to discuss the issues and any outstanding areas of major concern.

The CHMP agreed to contribute to a DIA co-sponsored workshop on Similar Biological Medicinal Products to be held on 8-9 December 2005 in Paris.

Similar Biological Medicinal Products Guidelines – Summary Overview

User guide - Consultation (Nov-04 to Feb-05)

Overarching Guideline (CHMP/437/04).
"Guideline on Similar Biological Medicinal Products"
Defines key concepts / principles (information reference)

Biotechnology- derived proteins

Quality Issues - Consultation (Mar 05 to Jun 05)

Quality

Non-clinical, General Issues – Consultation (May 05 to Oct 05)

Non-clinical

Clinical

Class specific, (Non)clinical - Stage:

Concept Papers Consultation (Nov-04 to Feb-05)

Guidelines: roll-out beginning May-05, also drafting ongoing

Insulin	Somatropin	GCSF	Epoetin	Others…
Non-clinical	Non-clinical	Non-clinical	Non-clinical	Non-clinical
Clinical	Clinical	Clinical	Clinical	Clinical

Report from the meeting held on 23 and 24 May 2005

General Issues

Applicant's response document in Mutual Recognition – Recommended (CTD) format

Updated versions of the documents, to include the possibility for Applicants to send the responses to National Competent Authorities via eudralink, in addition to the paper versions, has been adopted by the group and will be published on the Heads of Agencies website.

The rules to be followed for the standardization of the heading of the e-mail and for the sending of the responses have been included in the updated documents.

Applicants are informed that e-mail addresses to be used for sending the responses will be published in Chapter 7 of the Notice to Applicants.

Best Practice Guide on Break-out session

The MRFG has agreed on a template for the minutes of Break-out sessions, included as an appendix to the Best Practice Guide. The minutes of Break-out sessions should focus on the main issues for discussion and outcome of the discussion.

MRFG Position on changing the Reference Member State

An updated version of the MRFG Position on changing the Reference Member State has been adopted by the group and will be published on the website.

The document has been updated to include that in case of withdrawal of a marketing authorisation in the RMS when only one CMS remains in the MR procedure, the CMS will automatically become the new RMS. The MRFG has also agreed that MR rules still apply for variations and renewals where only one MS remain in the MRP.

Contact points for advice on Mutual Recognition Procedure

The MRFG has updated the list of contact points for advice on Mutual Recognition Procedure. The updated list of contact points will be published on the website.

Timing for submission of renewal applications

The MRFG has agreed that the six-month period for the submission of the renewal application, referred to in Article 24(2) of Directive 2001/83/EC, as amended, is only applicable for marketing authorisations with a renewal date after 1 May 2006.

For marketing authorisations with a renewal date before 1 May 2006, the renewal application should be submitted at least 3 months before the renewal date. The MRFG Best Practice Guide for handling Renewals in the Mutual Recognition Procedure, available on the Heads of Agencies website http://heads.medagencies.org/mrfg/docs/bpg/renewal.pdf, strongly recommends the submission of the renewal application 4 months ahead of the renewal date.

Proposal for the Decentralised procedure Member States' SOP- Consultation procedure

The MRFG has noted the comments received on the SOP for the Decentralised procedure and will take account of it on the discussions regarding the Decentralised procedure.

Information on MR procedures for new active substances

The MRFG has agreed to start publishing information on the MR procedures finalised for medicinal products containing new active substances.

Three parallel Mutual Recognition Procedures for medicinal products containing prulifloxacin have been finalised on 03 April 2005. Please find below information on the Invented names, INN, MAH, Indication, Procedure number and Day 90.

Invented Name (RMS)	Unidrox/Chinoplus/Keraflox
INN	prulifloxacin
Marketing Authorisation Holder	Aziende Chiniche Riunite Angelini Francesco ACRAF SpA
Indication	Treatment of infections caused by susceptible strains, in the following conditions: • Acute uncomplicated lower urinary tract infections (simple cystitis); • Complicated lower urinary tract infections; • Acute exacerbation of chronic bronchitis. Local antibiotic susceptibility pattern should be considered in the treatment of patients with infective diseases.
Procedure number	IT/H/0117/001;IT/H/0118/001;IT/H/0119/001
Day 90	03.04.2005

Meeting schedule

The next MRFG meeting will be held on 20 and 21 June 2005.

Mutual Recognition Monitoring

The MRFG noted that **54** new mutual recognition procedures were finalised during the month of April 2005, as well as **355** type IA variations, **114** type IB variations and **83** type II variations.

The status as of 30th April of procedures and for the whole year 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	256	311	1197	508	323	1 Var.

133 new procedures (regarding **256** products) started in April 2005. The categories of these procedures are as follows:
3 new active substances classified as repeat use.
42 known active substances (already authorised in at least one member state), including **2** multiple applications and **18** repeat use.
80 abridged applications including **16** multiple applications and **14** repeat use.
8 line extension applications including **5** repeat use.

The new procedures started related to **29** full dossiers, **67** generics, **20** bibliographic applications, **1** informed consent and **16** for different use, route or dose.

The procedures consisted of **127** chemical substances, **1** biological-other, **3** biological-vaccines and **1** biological-blood product[1].

118 of these procedures were prescription-only medicinal products in the reference Member State and **15** procedures was classified as a Non-prescription (including OTC) medicinal product[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 April 2005

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	2
AT (4)	12
AT (1)	11
AT (1)	1
AT (1)	1
CZ (3)	6
DE (1)	4
DE (1)	10
DE (1)	10
DE (4)	12
DE (3)	16
DE (3)	7
DE (2)	1
DE (4)	12
DE (1)	2
DE (1)	2
DE (1)	1
DK (2)	5
DK (1)	8
DK (1)	3
DK (2)	3
DK (4)	1
DK (3)	9

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (1)	1
DK (1)	20
DK (2)	10
DK (2)	7
DK (3)	6
DK (2)	2
DK (2)	1
DK (2)	1
DK (2)	3
DK (2)	4
DK (1)	5
DK (5)	6
DK (5)	3
DK (5)	7
DK (3)	3
DK (2)	2
DK (1)	3
DK (1)	9
EE (1)	2
FI (3)	4
FI (2)	3
FI (3)	7
FI (2)	1
FI (4)	4
FI (1)	16
FI (2)	5
FI (2)	8
FI (2)	7
FI (2)	4
FI (2)	6
FI (2)	6
FI (2)	1
FI (2)	11
FI (2)	10
FI (2)	2
FI (2)	1
FR (1)	12
FR (2)	10
FR (2)	8
FR (1)	6
FR (1)	19
FR (3)	11
FR (2)	10
FR (1)	11
FR (1)	2
FR (3)	7
FR (2)	1
FR (1)	6
FR (3)	11
FR (1)	17
FR (1)	9
FR (1)	7
IE (1)	3
IE (1)	2
IE (1)	7
IE (1)	11
IE (1)	15
IE (1)	10
IE (1)	1
IE (2)	3
IE (2)	2
IE (1)	2
IT (2)	2

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
IT (1)	9
NL (2)	8
NL (2)	1
NL (1)	1
NL (1)	7
NL (2)	1
NL (3)	3
NL (3)	1
NL (2)	20
NL (2)	1
NL (2)	1
NL (2)	6
NL (2)	11
NL (1)	1
NL (2)	1
NL (3)	8
NL (4)	7
NL (1)	1
NL (4)	4
NL (1)	2
NL (2)	1
NL (1)	2
SE (3)	5
SE (2)	1
SE (4)	3
SE (1)	6
SE (5)	3
SE (1)	4
SE (3)	1
UK (3)	12
UK (2)	6
UK (1)	6
UK (1)	6
UK (1)	18
UK (1)	11
UK (1)	10
UK (1)	10
UK (1)	3
UK (1)	1
UK (1)	6
UK (1)	9
UK (3)	7
UK (1)	2
UK (1)	2
UK (2)	5
UK (2)	14
UK (2)	9

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 chair of the MRFG on behalf of the Luxembourg Presidency:

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Or you could visit the ***MRFG web site*** *at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*
http://heads.medagencies.org/