European Medicines Agency
Evaluation of Medicines for Human Use

16 January 2006
EMEA/CHMP/420100/2005, rev 1

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

The Committee for Medicinal Products for Human Use (CHMP) held its December plenary meeting from 12-15 December 2005.

Centralised procedure

Initial applications for marketing authorisation

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

- **Neupro** (rotigotine), Schwarz Pharma Ltd. Neupro is indicated for the treatment of idiopathic Parkinson's disease. EMEA review began on 18 October 2004 with an active review time of 202 days.
- **Rotarix** (human rotavirus, live attenuated), GlaxoSmithKline Biologicals S.A. Rotarix is indicated for active immunisation of infants from the age of 6 weeks for prevention of gastro-enteritis due to rotavirus infection. EMEA review began on 20 December 2004 with an active review time of 175 days.

In addition:

- The CHMP revised its opinion of 15 September 2005 for **Macugen** (pegaptanib sodium), following post-marketing reporting of rare cases of anaphylaxis/anaphylactoid reactions, including angioedema, in patients following intravitreous administration of pegaptanib along with various medications administered as part of the injection preparation procedure. A direct relationship to Macugen or any of the various medications administered as part of the injection preparation procedure, or to other factors has not been established in these cases. The SPC and package leaflet have been revised, requiring careful evaluation of the patient's medical history for hypersensitivity reactions prior to performing the intravitreal procedure, and introducing a specific warning and further information about undesirable effects.

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.

The CHMP adopted a negative opinion on one initial marketing authorisation application at this meeting for:

- **Zelnorm**, Novartis Europharm Limited. The indication proposed was: the repeated symptomatic short-term treatment of Irritable Bowel Syndrome in women whose predominant bowel habit is constipation. EMEA review began on 18 October 2004 with an active review time of 204 days. A question and answer document has been published and can be found on the EMEA website http://www.emea.eu.int/pdfs/human/opinion/41043505en.pdf.

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Extensions of indication and other recommendations

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

- **Invanz** (ertapenem), Merck Sharp & Dohme, to extend its indication to add diabetic foot infections of the skin and soft tissue. Invanz was first authorised in the EU on 18 April 2002 and is currently indicated for the treatment of bacterial infections.
- **Tamiflu** (oseltamivir), Roche Registration Ltd, to include children between 1 and 12 years of age in the indication prevention of influenza. Tamiflu was first authorised in the EU on 20 June 2002 and is currently indicated for the treatment of influenza in adults and children from one year of age and for prevention of influenza in adults and adolescents of 13 years and older.

Safety updates

A review by EMEA of new safety data for **Tamiflu** has concluded that there is no new safety signal relating to psychiatric disorders while taking Tamiflu and therefore no change to the product safety information of Tamiflu is needed. A separate press release has been issued and can be found here. http://www.emea.eu.int/pdfs/human/press/pr/42008705en.pdf

Rare cases of macular oedema (swelling of the back of the eye) have been reported with rosiglitazone- (**Avandia/ Avandamet**, from SmithKline Beecham) and pioglitazone- (**Actos/Glustin**, from Takeda Europe) containing medicinal products. Following discussions of these post-marketing findings, the CHMP concluded that a further review should be performed to establish whether there is a possible association between macular oedema and the use of rosiglitazone and pioglitazone.

Application for marketing authorisation for orphan medicinal product

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

Evra (norelgestromin/ethinyl estradiol) transdermal patch for hormonal contraception

The CHMP was made aware that the use of Ortho-Evra (containing 6 mg norelgestromin and 750 µg ethinyl estradiol, manufactured and marketed in the US) is associated with higher levels of estrogen exposure compared to combined oral contraceptives containing 35 µg ethinyl estradiol.

The CHMP reviewed if this could have implications for Evra (containing 6 mg norelgestromin and 600 µg ethinyl estradiol, manufactured and marketed in the EU) in terms of an increased risk of adverse events.

As Evra contains a smaller amount of ethinyl estradiol, and its exposure is equivalent to combined oral contraceptives containing 35 µg ethinyl estradiol, it was considered that there is no increased risk of serious adverse events connected with the use of EVRA.

The EMEA/CHMP CHMP will continue to monitor the situation.

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. No medicinal products have been granted marketing authorisations by the European Commission since the CHMP plenary meeting in November 2005**.** The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**.

Referral procedures

Start of referral procedures

- The Committee started a referral procedure for **atorvastatin-**containing medicinal products (Sortis and other associated names) in relation to an application submitted by Parke-Davis GmbH to extend the indication to the prevention of cardiovascular events in patients with multiple risk factors. The procedure was initiated by Spain under Article 6(12) of Commission Regulation EC No 1084/2003 because of differences between Member States with regard to the extent of the patient population likely to benefit from atorvastatin therapy in this clinical setting.

- The Committee started a referral procedure for **mifepristone**-containing medicinal products (Mifegyne). France triggered this referral following safety and efficacy concerns with regards to the use of the approved dose of 600 mg mifepristone in the indication of "medical termination of developing intra-uterine pregnancy in sequential use with prostaglandin analogue" as compared to the use of a 200 mg mifepristone dose. The procedure was initiated under Article 31 of Directive 2001/83/EC as amended.

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 29 November – 1 December 2005. For further details, please see **Annex 4**.

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

Upcoming meetings following the December 2005 CHMP plenary meeting:

- The 18th meeting of the CHMP will be held at the EMEA on 23-26 January 2006.
- The next Invented Name Review Group meeting will be held at the EMEA on 23 January 2006.
- The Workshop on Regulatory and scientific issues related to concomitant administration of vaccines will be held on 30-31 January 2006.
- The third CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures - human) replacing the former Mutual Recognition Facilitation Group, will be held at the EMEA on 23-24 January 2006.
- EMEA/EWP Information session for CHMP members and clinical assessors on methodology for benefit/risk assessment will be held at EMEA on 9 February 2006.

- EWP Training for clinical assessors on how to improve the quality of clinical assessment reports will be held at EMEA on 10 February 2006.

Organisational matters

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

- The adoption of the revised composition of the Vaccine Working Party (VWP).
- The adoption of the Work programme for 2006 of the following CHMP Working Parties (please see also Annex 5 of the CHMP Monthly Report):
  Vaccine Working Party (VWP), Pharmacogenetics Working Party (PgWP), Blood Products Working Party (BPWP), Safety Working Party (SWP), Paediatric Working Party (PEG), Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP).
  The adopted Work programmes are available on the EMEA website: http://www.emea.eu.int.

EMEA Implementation of the New EU Pharmaceutical Legislation

The eleventh CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 12 December 2005.

The following Guideline was adopted by the CHMP and is published on the EMEA website for external consultation:

- Guideline on the procedure for Accelerated Assessment pursuant to Article 14(9) of Regulation (EC) No 726/2004.
  This Guideline is released for comments by 10 February 2006:
  http://www.emea.eu.int/pdfs/human/euleg/41912705en.pdf

The following Guideline has been published by the European Commission for external consultation:

- Guideline concerning the optional scope of the centralised procedure in accordance with Article 3(2)(b) of Regulation (EC) No 726/2004.
  This Guideline is released for comments by 31 January 2006:
  http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/12-05/Optional%20scope%20publ%2021%2012%2005.pdf

The following final Guidelines were adopted by the CHMP for implementation and published at the EMEA website, as appropriate:

- Guideline on procedures for the granting of a marketing authorisation under Exceptional circumstances, pursuant to Article 14(8) of Regulation (EC) No 726/2004.
  http://www.emea.eu.int/pdfs/human/euleg/35798105en.pdf

- Guideline on Risk Management Systems for medicinal products for human use.
  http://www.emea.eu.int/pdfs/human/euleg/9626805en.pdf

- Timetable for Generics applications under Articles 10(1) of Directive 2001/83/EC via the Centralised procedure, as amended.
  http://www.emea.eu.int/pdfs/human/euleg/32789605en.pdf
  This timetable has been developed as part of more general guidance produced in support of generic applications in the Centralised procedure.

Follow-on discussions took place on the following topics:

- Criteria for the appointment of CHMP Rapporteur/Co-Rapporteur

PROCEDURAL ANNOUNCEMENT

- **New Council Regulation on fees payable to the European Medicines Agency.**

  The new "Council Regulation (EC) No 1905/2005 of 14 November 2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency" has been published:

  http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/11_05/Reg_2005_1905_EN.pdf

- **Handling of IS translation in the Centralised procedure.**

  Further to recent discussions with the Icelandic Authorities, the EMEA has been advised that Icelandic translations must be included by MAHs/applicants when submitting translations in the Centralised procedure.

  This will apply to all regulatory procedures with (amended) product information annexes for which an opinion will be adopted as of February 2006 CHMP meeting.

  For November/December 2005 and January 2006 Opinions (which did not include IS translations) companies are advised to contact Thorbjorg Kjartansdottir (thorbjorg.kjartansdottir@lyfjastofnun.is) from the Icelandic Authorities.

  The EMEA guidance document on the linguistic review process has been updated accordingly http://www.emea.eu.int/pdfs/human/regaffair/554202en.pdf

- **New clean QRD product information templates**, to be used for **referral** procedures, in all EEA languages.

  Please note the following new clean QRD templates published at the EMEA website:

  http://www.emea.eu.int/htms/human/qrd/qrdtemplate.htm

  For further guidance on how to complete the template, please refer to the CMDh Annotated QRD template and to a specific Guidance document on referral product information:

  http://heads.medagencies.org/mrfg/docs/pi/QRD_annotated_template_CMDh.pdf
  http://www.emea.eu.int/htms/human/qrd/ReferralSPC/Guidance-referralSPC.pdf

- **New pre-accession linguistic review process (PALC II)** in view of the accession of Bulgaria and Romania to the EU on 1 January 2007.

  The new pre-accession linguistic review process (PALC II) is aimed at ensuring a good standard of quality for the translation of product information for centrally authorised medicinal products, and will help pharmaceutical companies to market their products in these countries following completion of their accession.
  PALC II will be fully co-coordinated by the QRD Secretariat:
  http://www.emea.eu.int/pdfs/euenlargement/55075705en.pdf

  As with the previous accession, the enlargement-specific webpage has been re-created and will contain various enlargement-related guidance documents in due time (for instance, guidance on the phasing-in of Bulgaria/Romania in regulatory procedures as of September/October 2006 will be published 1/2Q 2006):
  http://www.emea.eu.int/euenlargement.htm

Mutual Recognition and Decentralised procedures-Human

The CHMP noted the report from the second CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures held on 12-13 December 2005. For further details, please see **Annex 6**.

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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	113	546
Follow-up to Scientific Advice	71	22	93
Protocol Assistance	59	43	102
Follow-up to Protocol Assistance	12	13	25

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Applications submitted	153	303	456	6	35	41	497
Consultation for Medical Device[1]	0	1	1	0	3	3	4
Withdrawals	22	62	84	0	11	11	95
Positive opinions[2]	107	197	304	4	20	24	328[3]
Negative opinions[4]	2	5	7	0	1	1	8[5]
Marketing authorisations granted by the Commission	98	190	288	6	17	23	311[6]

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Variations type I	863	1937	2800	152	485	637	3437
Positive opinions, variations type II	758	886	1644	260	243	503	2147
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] 328 positive opinions corresponding to 257 substances
[4] In case of appeal, the opinion will not be counted twice
[5] 8 negative opinions corresponding to 7 substances (2 of these negative opinions correspond to 2 Orphan Medicinal Products)
[6] 311 marketing authorisations corresponding to 240 substances

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

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
2 Extensions of indication	2 Positive opinions
14 SPC changes	14 Positive opinions
24 Quality changes	24 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Fabrazyme (agalsidase beta) Genzyme B.V.,	Positive Opinion	The authorisation will remain under exceptional circumstances
Replagal (agalsidase alfa) TKT Europe-5S AB	Positive Opinion	The authorisation will remain under exceptional circumstances

Opinions for Renewal applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Azomyr (desloratadine) SP Europe	Positive Opinion	---
Aerius (desloratadine) SP Europe	Positive Opinion	---
Neoclarityn (desloratadine) SP Europe	Positive Opinion	---
Fasturtec (rasburicase) Sanofi	Positive Opinion	---
Humalog (insulin lispro) Eli Lilly Nederlands B.V	Positive Opinion	---
Liprolog (insulin lispro) Eli Lilly Nederland B.V	Positive Opinion	---

Opinions for Renewal applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Metalyse (tenecteplase) Boehringer Ingelheim International GmbH	Positive Opinion	---
Neurobloc (botulinum toxin type B) Elan Pharma International Ltd,	Positive Opinion	---
NovoSeven (eptacog alfa (activated)) Novo Nordisk	Positive Opinion	---
Xeloda (capecitabine) Roche Registration Ltd	Positive Opinion	---

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

Active substance	Human *Staphylococcus aureus* immunoglobulin
Sponsor	Nabi Biopharmaceuticals Europe Ltd
Orphan Indication	Treatment of *Staphylococcus aureus* bacteraemia
Opinion receipt date	22/09/2005
Date of Commission Decision	03/11/2005

Active substance	Imatinib mesilate
Sponsor	Novartis Europharm Limited
Orphan Indication	Treatment of chronic eosinophilic leukaemia and the hypereosinophilic syndrome
Opinion receipt date	22/09/2005
Date of Commission Decision	28/10/2005

Active substance	Recombinant modified vaccinia virus Ankara expressing tuberculosis antigen 85A
Sponsor	University of Oxford
Orphan Indication	Prevention of tuberculosis disease in BCG vaccinated individuals
Opinion receipt date	22/09/2005
Date of Commission Decision	28/10/2005

Active substance	Peptide 144 TGF-beta1-inhibitor (TSLDASIIWAMMQN)
Sponsor	Digna Biotech S.L.
Orphan Indication	Treatment of systemic sclerosis
Opinion receipt date	22/09/2005
Date of Commission Decision	28/10/2005

OUTCOME OF THE DECEMBER 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				
Chemical	Chronic low back pain	X						X	
Chemical	Attention deficit hyperactivity disorder	X						X	
Chemical	Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension		X			X		X	X
Biological	Idiopathic thrombocytopenic purpura		X					X	X
Chemical	Prevention and treatment of thromboembolic events	X					X	X	
Chemical	Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension		X			X	X	X	X
Biological	Peripheral arterial disease	X				X	X		
Chemical	Pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension		X			X		X	
Biological	Acute myeloid leukemia	X					X		
Biological	Prevention and treatment of bone metastases in advanced malignancies.	X						X	
Chemical	Breast cancer	X						X	

Chemical	Small cell lung cancer				X			X	X
Chemical	Prevention of radiation proctitis in prostate cancer		X					X	
Biological	Influenza vaccine			X		X			
Biological	Pandemic influenza vaccine	X				X	X	X	
Chemical	Erosive gastro-oesophageal reflux disease	X				X		X	
Chemical	Cirrhotic ascites	X						X	
Chemical	Iron overload in thalassemia major	X						X	
Chemical	Ocular hypertension and open-angle glaucoma	X					X		

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 12 Scientific Advice letters, 5 Protocol Assistance letters, 1 Follow-up Scientific Advice letters and 1 Follow-up Protocol Assistance letters were adopted at the 12-14 December 2005 CHMP meeting.

The Committee accepted 17 Initial Scientific Advice Requests, 1 Follow-up Scientific Advice Requests and 7 Initial Protocol Assistance Requests, which started at the SAWP meeting that took place on 29 November – 1 December 2005.

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

BIOLOGICS WORKING PARTY

Reference number	Document	Status
EMEA/CHMP/CPWP/323774/2005	Concept paper on guideline for human cell-based medicinal products	**Adopted**

BLOOD PRODUCTS WORKING PARTY

Reference number	Document	Status
EMEA/CHMP/BPWP/371017/2005	Concept Paper on Revision of Core SPC For Human Plasma Fibrinogen Products	Adopted
EMEA/CHMP/BPWP/322952/2005	BPWP Workprogramme 2006	Adopted

WORKING PARTY ON CELL-BASED PRODUCTS

Reference number	Document	Status
EMEA/CHMP/CPWP/323774/2005	Concept paper on guideline for human cell-based medicinal products	Adopted

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/552/95 Rev. 2	Guideline on the evaluation of new medicinal products in the treatment of Primary Osteoporosis	Released for 6 months consultation
CPMP/EWP/205/95/Rev. 3	Guideline on the evaluation of anticancer medicinal products in man	Adopted

PAEDIATRIC WORKING PARTY

Reference number	Document	Status
EMEA/405911/2005	Assessment of the paediatric needs for epilepsy	Released for 6 months consultation
EMEA/405911/2005	Assessment of the paediatric needs for epilepsy	Released for 6 months consultation
EMEA/CHMP/406990/2	PEG Workprogramme for 2006	Adopted

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PHARMACOGENETICS WORKING PARTY (PgWP)

Reference number	Document	Status
CHMP/PGxWP/391116/2005	PgWP Workprogramme for 2006	Adopted

SAFETY WORKING PARTY (SWP)

Reference number	Document	Status
EMEA/276635/2005	SWP Workprogramme 2006 - 2007	Adopted

VACCINE WORKING PARTY (VWP)

Reference number	Document	Status
EMEA/CHMP/VWP/355252/2005	VWP Workprogramme for 2006	Adopted

Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

Report from the CMD(h) meeting held on 12th and 13th December 2005

General Issues

Interested Parties comments on CMD(h) draft Guidance

The CMD(h) would like to thank Interested Parties for the comments received on the Best Practice Guide on Break-out sessions, Usage patent common statement in the PL, Standard Operating Procedure for Article 61(3) changes to patient information, Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure and Urgent Safety Restriction – Member States' Standard Operating Procedure.
The comments received will be considered carefully when finalising the documents.

List of MRFG Guidance documents in the Mutual Recognition Procedure under revision

In the interest of transparency, the CMD(h) would like to inform Interested Parties of the guidance documents in the Mutual Recognition Procedure, under revision by the Group. This list will be published on the website.

New Questions and Answers on the implementation of the new Legislation

The CMD(h) has agreed 2 new Q&A to address the languages to be used for applications for marketing authorisation in the decentralised or mutual recognition procedures and the PSUR cycle for medicinal products authorised before 30 October 2005.

Annotated QRD Template for MR/DC procedures

The CMD(h) annotated QRD template for MR/DC procedures has been updated to include a link to the 'clean' QRD template for use in a MRP, DCP or referral procedure, published in all languages on the website of the EMEA.

Best Practice Guide for the Mutual Recognition Procedure

The CMD(h) has considered the comments received from Interested Parties on the Best Practice Guide for Mutual Recognition Procedure. The updated BPG will be published on the website.

Procedure for Automatic Validation of MR Procedures for New Applications

The CMD(h) has updated the Procedure for Automatic Validation of MR Procedures for new Applications, taking account of the comments received from Interested Parties. The updated Procedure for Automatic Validation of MR Procedures for new Applications will be published on the website.

Sub-Group meeting on Harmonisation of SPCs

The Sub-Group on harmonisation of SPCs met in December to continue the discussions on the criteria for selection of products for SPC harmonisation and to consider the comments received from Interested Parties on this regard.
A meeting with Interested Parties will be arranged during the first quarter of 2006.

List of CMD(h) Members

An updated list of CMD(h) Members will be published on the website.

Contact Points for advice on Mutual Recognition and Decentralised Procedures

An updated list of Contact Points for advice on Mutual Recognition and Decentralised Procedures has been agreed by the CMD(h) and will be published on the website.

Change in the EU-Presidency

The December 2005 CMD(h) meeting was the last one under the United Kingdom presidency. Austria will take over the presidency in January 2006. Mrs. Christa Wirthumer-Hoche will be the Vice-Chairperson of CMD(h), for the Austrian presidency of the Council of the European Union.

Meeting schedule

The next CMD(h) meeting will be held on 23 and 24 January 2006.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **38** new Mutual Recognition Procedures were finalised during the month of November 2005. **1** Mutual Recognition Procedure for a new application was referred to CMD(h) in this period.

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

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures referred to CMD(h)	Arbitrations referred to CHMP
2005	933	148	1 N.A.	2 N.A.

39 Mutual Recognition Procedures (regarding **63** products) started in November 2005. The categories of these procedures are as follows:

3 known active substance (already authorised in at least one member state) including **2** repeat use.

35 abridged applications including **8** multiple applications and **4** repeat use.

1 line extension application.

The new procedures started related to **33** generics, **3** bibliographic applications and **3** for different use, route or dose.

The procedures consisted of **39** chemical substances[1].

38 of these procedures were prescription-only medicinal products in the reference Member State and **1** procedure was classified as a 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 in Mutual Recognition procedure started in November 2005.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (2)	16
DE (2)	5
DE (1)	2
DE (1)	8
DE (1)	10
DE (2)	8
DE (2)	6
DE (2)	4
DE (2)	1
DK (1)	4
DK (1)	1
DK (4)	1
DK (1)	1
DK (1)	1
DK (1)	1
DK (2)	2
DK (1)	1
DK (1)	1
DK (1)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (1)	3
DK (4)	2
FI (1)	4
FI (1)	1
FI (1)	13
FI (1)	1
FR (2)	7
NL (1)	10
NL (1)	8
NL (1)	3
NL (1)	1
NL (3)	19
NL (4)	1
SE (4)	12
SE (1)	1
SE (1)	3
UK (1)	3
UK (1)	5
UK (3)	12
UK (1)	14

Decentralised Procedure

The CMD(h) noted that **no** new Decentralised Procedures were started during the month of November 2005.

VARIATIONS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **330** type IA variations, **170** type IB variations and **167** type II variations were finalised during the month of November 2005. **1** arbitration from variations was referred to the CHMP in this period.

The status as of 30th November of variations under mutual recognition is as follows:

Year	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CHMP
2005	3630	1778	1355	6 Var.

All documents mentioned in this press release can be found at the CMD(h) website at the European Medicines Authorities Windows under the heading *Press Releases.*

Information on the above mentioned issues can be obtained from the chair of the CMD(h):

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*Or you could visit the **CMD(h) web site** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

http://heads.medagencies.org/