European Medicines Agency
Evaluation of Medicines for Human Use

17 February 2006
EMEA/CHMP/35006/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
JANUARY 2006 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its January plenary meeting from 23-26 January 2006.

Centralised procedure

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

- The Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on an initial marketing authorisation application for **Myozyme** (recombinant human acid alpha-glucosidase), Genzyme Europe B.V. Myozyme is indicated for enzyme replacement therapy in Pompe disease. EMEA review began on 20 December 2004 with an active review time of 196 days. Myozyme is **the twenty-fourth designated orphan medicinal product** to receive a positive opinion.
- The CHMP adopted the first positive opinion for a similar biological medicinal product. The product, **Omnitrope** is manufactured by Sandoz GmbH and contains a recombinant-DNA growth hormone. It is indicated for the treatment of growth disturbance and growth hormone deficiency in children and adults. Omnitrope is similar to Genotropin, the reference medicinal product already authorised in the EU.

A separate press release has been published and is available here.

Summaries of opinion for these medicinal products are available here. 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 adopted positive opinions on the extension of indication of medicinal products that are already authorised in the European Union:

- **Lyrica** (pregabalin), Pfizer Limited, to extend its indication to include general anxiety disorder. Lyrica was first authorised in the European Union on 6 July 2004 and is currently approved for the treatment of peripheral neuropathic pain and epilepsy.
- **Remicade** (infliximab), Centocor B.V., to extend its indication to include treatment of moderately to severely active ulcerative colitis. Remicade was first authorised in the European Union on 13 August 1999 and is currently approved for the treatment of rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis and psoriasis.
- **TachoSil** (Human fibrinogen and human thrombin), Nycomed Austria GmbH, to amend the indication by deleting the following statement: *'Efficacy has only been demonstrated in liver surgery'*. TachoSil was first authorised in the European Union on 8 June 2004 and is approved for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient.
- **Bondenza/Bonviva** (ibandronic acid), Roche registration Ltd, to add the presentation 3mg/3ml solution for injection to the existing tablet presentations. This intravenous administration allow less

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frequent administration compared to the previously authorised presentations. **Bonviva/Bondenza** were first authorized in the European Union on 23 February 2004 and this new presentation is currently approved for the treatment of osteoporosis in postmenopausal women in order to reduce the risk of fractures.

Summaries of opinion for these medicinal products are available here: Further information will be included in the EPAR once the European Commission has granted final approval.

Re-examination procedure concluded

Following the re-examination of the negative opinion adopted on 13 October 2005, the Committee adopted a final positive opinion to recommend the extension of indication for **Exelon** and **Prometax**, from Novartis Europharm Ltd, to add the symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Exelon and Prometax are currently indicated for symptomatic treatment of mild to moderately severe Alzheimer's dementia.

A summary of opinion with more information about the re-examination procedure has been published and can be found here.

Safety updates

Following a preliminary review of cases of serious liver injury associated with the use of **Ketek** (telithromycin), the CHMP has asked the marketing authorisation holder (Aventis Pharma S.A.) to change the product information to include stronger warnings relating to liver disorders. This is a precautionary measure, pending the outcome of a full benefit/risk assessment of the product in the context of the ongoing renewal procedure for the marketing authorisation.

A separate press release has been published and can be found here.

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (mandatory scope) and one List of Questions on "line extensions" applications (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Detailed information on the centralised procedure

An overview of the Pre-authorisation Marketing authorisation Applications and Scientific Services since 1995 is given in **Annex 1**. An overview of the Post-authorisation procedures and the post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2.** The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in December 2005 is provided in **Annex 3**.

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 December 2005 CHMP meeting are provided in **Annex 4**.

Referral procedures

Finalised referral procedures

- The Committee concluded a referral procedure for **Nifedipine Pharmamatch retard 30 and 60 mg** (nifedipine), from Pharmamatch BV, with a recommendation to grant a marketing authorisation. The referral was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC as amended, because of differences between the summaries of product characteristics of the reference product and the generic product regarding contraindications in women capable of child bearing and nursing mothers.

- Concluding a referral procedure for **Prograf / Prograft** (tacrolimus) hard capsules and concentrate for solution for infusion from Astellas Pharma GmbH (formerly Fujisawa GmbH), the Committee recommended that the product information be harmonised across EU Member States. The procedure was initiated by the marketing authorisation holder under Article 30 of the Community code on human medicines (Directive 2001/83/EC, as amended). The products are authorised in most EU Member States for the prevention and treatment of rejection after various types of organ transplantations.

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 4-6 January 2006. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the January 2006 CHMP meeting are listed in **Annex 6**.

Invented Name Review Group (NRG)

In order to increase transparency in relation to the activities of the NRG, it was decided that statistical information on the outcome of the checking of acceptability of proposed invented names for medicinal products processed through the centralised procedure would be provided in the CHMP Monthly Report as of January 2006. For further details, please see **Annex 7.**

Upcoming meetings following the January 2006 CHMP plenary meeting:

- The 19th meeting of the CHMP will be held at the EMEA on 20-23 February 2006.
- The next Invented Name Review Group meeting will be held at the EMEA on 20 February 2006.
- The fourth 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 20-21 February 2006.
- Workshop on cell-based products will be held at the EMEA on 21-22 June 2006

Organisational matters

The main topics addressed during the January 2006 CHMP meeting related to:

- A decision on the Co-optation of eight additional Pharmacovigilance Working Party members in order to reinforce the expertise at the Pharmacovigilance Working Party further to a gap-analysis of the available expertise undertaken in 2005 in the context of the re-establishment of the Pharmacovigilance Working Party.
- The adoption of the revised mandate, objectives and rules of procedure of the Similar Biological (Biosimilar) medicinal products Working Party (BMWP) (see Annex 6).
- The adoption of the revised composition of the BMWP.

- The adoption of the revised composition of the Blood Products Working Party (BPWP).
- The adoption of the appointment of Dr Egbert Flory as Vice Chairman of the Cell-Based Products Working Party
- The adoption of the appointment of Dr Michael Donaghy as Chairman and Dr Jean-Pierre Lepine as Vice Chairman of the Scientific Advisory Group on Central Nervous System.

The compositions of Working Parties will be published on EMEA website (www.emea.eu.int) by the end of February 2006.

EMEA Implementation of the New EU Pharmaceutical Legislation

The thirteenth CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 23 January 2006.

The following documents were adopted by the CHMP and will be published for implementation on the EMEA website:

- EPAR summary for the public
- Questions and answers on notification to the EMEA of actual marketing and cessation of placing on the market for centrally authorised medicinal products.
- Questions and answers on the application of the so-called "sunset clause" centrally authorised medicinal products.

The following documents were agreed by the CHMP and will be published at the EMEA website for external consultation:

- Guideline on reporting of suspected transmission of any infectious agent via a medicinal product (released for 2 months external consultation).
- Rules of involvement of member(s) of Patients' and/or Consumers' Organisations in Committees related activities (released for 4 weeks external consultation).

PROCEDURAL ANNOUNCEMENT

- **Communication of purchase order number /customer reference to EMEA**

  As previously announced EMEA has changed the method for payment of fees for all dossiers submitted and validated on or after the 1st December 2005. An invoice will be sent to the billing address indicated by the applicant and will contain clear details of the product and procedures involved, the type of fee, the bank account to where the fee should be paid and the due date for payment. Where more than one procedure is processed in a given month a summary invoice or statement will be issued at the end of each month.

  In order for applicants to be able to process these invoices in their payment system it is necessary to include the applicant's purchase order number or customer reference on the EMEA invoice. Accordingly all applicants are requested to quote their purchase order number or similar reference in the cover letter accompanying the dossier.

  If you have any queries on this matter please do not hesitate to contact EMEA.

Mutual Recognition and Decentralised procedures-Human

The CHMP noted the report from the third CMD(h) held on 23-24 January 2006. For further details, please see **Annex 8**.

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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

ANNEX 1 TO CHMP MONTHLY REPORT JANUARY 2006

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	Dec 2005/2006[1]							1995 onwards
	Optional Scope			Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Biotech	Indications	Orphans		
Applications for MA submitted[2]	**0**	**3**	**0**	**4**	**3**	**2**	**12**	**502**
Positive opinions[3]	**2**	**0**	**0**	**0**	**0**	**1**	**3**	**329[4]**
Negative opinions[5]	**1**	**0**	**0**	**0**	**0**	**0**	**1**	**8[6]**
Withdrawals prior to opinion	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**100**
Marketing authorisation granted by the Commission	**5**	**0**	**0**	**1**	**0**	**1**	**7**	**318**

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	Dec 2005/2006	1995 onwards
Compassionate use applications	**0**	**0**
Art. 58 applications	**0**	**2**
Consultation for medical devices[7]	**0**	**4**
PMF	**1**	**9**
VAMF	**0**	**0**

[1] Starting point for operation the new eligibility criteria to the centralised procedure
[2] Number of accelerated reviews requested and number of accelerated reviews granted (3/0)
[3] Subdivided by conditional and exceptional (0/0)
[4] 329 positive Opinions corresponding to 258 substances
[5] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[6] 8 Negative Opinions corresponding to 7 substances
[7] 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 derivates of human blood or plasma and Directive 2001/104/EC

OUTCOME OF THE JANUARY 2006 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Chemical	Treatment of HIV infection		X
Chemical	Treatment of cancer		X
Chemical	Treatment of cancer		X

The above-mentioned 3 requests for accelerated assessment were submitted in December 2005 and the Committee's conclusions were adopted at the 23-26 January 2006 2005 CHMP meeting. The respective applicants were informed accordingly of the justification and details will be made available in the CHMP AR and the concerned medicinal products EPARs.

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POST-AUTHORISATION: TYPE I AND II VARIATIONS, ANNEX II, RENEWALS AND ANNUAL RE-ASSESSMENT APPLICATIONS

Activity	2006	Overall total 1995 onwards
Type I Variations (positive notifications)	46	3429
Type II Variations (positive opinions)	35	2182
Type II Variations (negative opinions)	0	7
Annex II Applications (positive opinions)	4	131
Annual Re-assessment (positive opinions)	3	N/A
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	6	N/A

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
3 Extensions of indication	3 Positive opinions
15 SPC changes	15 Positive opinions
17 Quality changes	17 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Avonex (interferon beta-1a) Biogen Idec Ltd	Positive Opinion adopted	Since all specific obligations have now been fulfilled, it was agreed that there were no remaining grounds to keep the Marketing Authorisation under Exceptional circumstances. Annex II was revised accordingly.
Cancidas (caspofungin) Merck Sharp & Dohme	Positive Opinion adopted	The Marketing Authorisation will remain under Exceptional circumstances.
Glivec (imatinib mesilate) Novartis Europharm Ltd,	Positive Opinion adopted	The Marketing Authorisation will remain under Exceptional circumstances.

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	**N/A**	**N/A**

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Opinions for 5 Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
CellCept (mycophenolate mofetil) Roche Registration Ltd	Positive Opinion adopted	-----
Kaletra (lopinavir/ritonavir) Abbott Laboratories	Positive Opinion adopted	-----
Nutropin Aq (somatropin) Ipsen Ltd	Positive Opinion adopted	-----
Prevenar (pneumococcal conjugate vaccine) Wyeth-Lederle Vaccines S.A	Positive Opinion adopted	-----
Rapamune (sirolimus) Wyeth Europe	Positive Opinion adopted	-----
Zerit (stavudine) Bristol Myers Squibb Pharma EEIG	Positive Opinion adopted	-----

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ANNEX 3 TO CHMP MONTHLY REPORT JANUARY 2006

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

Invented Name	Exubera
INN	insulin human
Marketing Authorisation Holder	Pfizer Ltd
Proposed ATC code	Not yet assigned
Indication	Treatment of adult patients with diabetes mellitus
CPMP Opinion date	13.10.2005
Marketing Authorisation Date	24.01.2006

Invented Name	Yttriga
INN	yttrium (90Y) chloride
Marketing Authorisation Holder	AEA Technology OSA GmbH
Proposed ATC code	Not yet assigned
Indication	Radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide
CPMP Opinion date	15.09.2005
Marketing Authorisation Date	19.01.2006

Invented Name	Ionsys
INN	fentanyl hydrochloride
Marketing Authorisation Holder	Janssen-Cilag International NV
Proposed ATC code	N02AB03
Indication	Management of acute moderate to severe post-operative pain for use in a hospital setting only
CPMP Opinion date	13.10.2005
Marketing Authorisation Date	24.01.2006

Invented Name	Kiovig
INN	human normal immunoglobulin (IVIg)
Marketing Authorisation Holder	Baxter AG
Proposed ATC code	J06BA02
Indication	Primary immunodeficiency syndromes, Immunomodulation and Allogeneic Bone Marrow Transplantation
CPMP Opinion date	17.11.2005
Marketing Authorisation Date	19.01.2006

Invented Name	Cubicin
INN	daptomycin
Marketing Authorisation Holder	Chiron Corporation Ltd
Proposed ATC code	Not yet assigned
Indication	Indicated for treatment of complicated skin and skin structure infections
CPMP Opinion date	17.11.2005
Marketing Authorisation Date	19.01.2006

Invented Name	Naglazyme
INN	galsulfase
Marketing Authorisation Holder	BioMarin Pharmaceutical Inc
Proposed ATC code	A16AB08
Indication	Long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis VI
CPMP Opinion date	15.09.2005
Marketing Authorisation Date	24.01.2006

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OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION:

UPDATE SINCE THE DECEMBER 2005 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number &** **Date of Orphan Designation**	**Designated Orphan Indication**
Gemtuzumab ozogamicin (Mylotarg)	Wyeth Europa Limited	EU/3/00/005 18/10/2000	Treatment of patients with acute myeloid leukaemia
Iduronate-2-sulfatase (Zipralase)	TKT UK Ltd	EU/3/01/078 11/12/2001	Treatment of mucopolysaccharidosis, type II (Hunter syndrome)
Imatinib mesilate (Glivec)	Novartis Europharm Limited	EU/3/05/305 26/08/2005	Treatment of dermatofibrosarcoma protuberans
Imatinib mesilate (Glivec)	Novartis Europharm Limited	EU/3/05/304 26/08/2005	Treatment of acute lymphoblastic leukaemia
Imatinib mesilate (Glivec)	Novartis Europharm Limited	EU/3/05/340 23/12/2005	Treatment of myelodysplastic/myeloproliferative diseases

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PRE-AUTHORISATION: SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE EMEA CENTRALISED PROCEDURES

	1995 - 2005	2006	Overall Total
Scientific Advice	558	11	569
Follow-up to Scientific Advice	94	2	96
Protocol Assistance	107	6	113
Follow-up to Protocol Assistance	26	0	26
	785	**19**	**804**

OUTCOME OF THE JANUARY 2006 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Final 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	Parkinson's disease			X				X	
Chemical	Schizophrenia	X						X	
Chemical	Non-24-hour sleep-wake disorder in blind individuals with no light perception.		X					X	
Biological	Reduction of perioperative blood loss and the need for transfusion during coronary artery bypass graft surgery	X				X	X	X	
Chemical	Essential hypertension	X					X	X	
Chemical	Hypertension and Dyslipidaemia			X			X	X	
Chemical	Neuroblastoma and misc. non-brain tumors in children	X						X	
Chemical	Squamous cell carcinoma of the head and neck	X						X	
Chemical	Acute lymphoblastic leukaemia		X			X		X	X

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Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharma ceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Chemotherapy-induced nausea and vomiting.	X					X	X	
Chemical	Glioblastoma multiforme	X					X	X	
Chemical	Cutaneous T-Cell Lymphoma		X					X	X
Chemical	Severe sepsis	X						X	
Biological	Pancreatic insufficiency caused by cystic fibrosis		X			X		X	X
Chemical	Diabetic Macular Edema (DME).	X						X	
Biological	Anal fistula		X				X		
Chemical	Postmenopausal osteoporosis	X					X	X	
Chemical	Idiopathic pulmonary fibrosis.		X			X	X	X	
Biological	Controlled ovarian stimulation to induce development of multiple follicles in patients participating in an Assisted Reproductive Technology programme.	X					X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 11 Scientific Advice letters, 6 Protocol Assistance letters and 2 Follow-up Scientific Advice letters were adopted at the 23-26 January 2006 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 21 new Requests for which the procedure started at the SAWP meeting held on 4-6 January 2006. The new requests are divided as follows: 12 Initial Scientific Advice, 4 Follow-up Scientific Advice, 3 Initial Protocol Assistance and 2 Follow-up Protocol Assistance.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE JANUARY 2006 CHMP MEETING

BIOLOGICS WORKING PARTY

Reference number	Document	Status
CPMP/BWP/3794/03	Revision of the guideline on the scientific data requirements for a Plasma Master File	Released for 3 months consultation

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

Reference number	Document	Status
CHMP/80650/2004	Revised Mandate, Objectives and Rules of Procedure for the BMWP Working Party	Adopted

WORKING PARTY ON CELL-BASED PRODUCTS

Reference number	Document	Status
EMEA/CHMP/CPWP/323774/2005	Concept paper on guideline for human cell-based products	Adopted
EMEA/CHMP/CPWP/414659/2005	Workplan for the CPWP for 2006-2007	Adopted

EFFICACY WORKING PARTY

Reference number	Document	Status
CHMP/EWP/3535/03	Guideline on clinical investigation of medicinal products indicated for the treatment of social anxiety disorder (SAD)	Adopted
CPMP/EWP/252/03 rev. 1	Revision of Guideline on clinical medicinal products intended for the treatment of neuropathic pain (paediatric section)	Released for 6 months consultation
CPMP/EWP/788/01 rev. 1	Revision of Guideline on clinical investigation of medicinal products for the treatment of migraine (paediatric section)	Released for 6 months consultation
CHMP/EWP/18446/2006	Concept paper on the revision of the CHMP Points to consider on clinical investigation of medicinal products for the management of Crohn's disease	Released for 3 months consultation
CHMP/EWP/15695/2006	Concept paper on the development of new products for the treatment of ulcerative colitis	Released for 3 months consultation
CHMP/EWP/15263/2006	Concept paper on the preparation of a guideline on the clinical development of products for specific immunotherapy for the treatment of allergic diseases	Released for 3 months consultation

ANNEX 7 TO CHMP MONTHLY REPORT JANUARY 2006

Name Review Group (NRG)

	January 2006			2006	
	Accepted	Rejected	Pending	Accepted	Rejected
Proposed invented names	7	9	19	7	9
Justification for retention of invented name *	0	3	5	0	3

*In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the EMEA website.

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

Report from the CMD(h) meeting held on 23rd and 24th January 2006

General Issues

Guidance on Oral Explanations to CMD(h)

The CMD(h) has agreed on a Guidance on Oral Explanation to CMD(h), for applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended.

The Guidance document will be published on the website as an annex to the CMD(h) SOP – Disagreement in Procedures – Referral to CMD(h).

Questions and Answers on CMD(h) SOP - Disagreement in Procedures – Referral to CMD(h)

The CMD(h) has agreed on a Q&A document summarising the main comments received from Interested Parties on the draft SOP – Disagreement in Procedures – Referral to CMD(h). The Q&A document covers mainly the comments/questions that did not result in amendments to the SOP. The Q&A document will be published on the website and further Q&As will be added as they are developed.

New Questions and Answers on the implementation of the new Legislation

The CMD(h) has agreed 4 new Q&A to address the languages to be used for applications for variations and renewals to marketing authorisations granted via the Mutual Recognition or Decentralised procedures, PSUR submission when the time of marketing differs between MS and a Q&A to replace the document 'Triggering of Mutual Recognition by Member States (Article 18 of Directive 2001/83/EC) Member States' Standard Operating Procedure. The updated Q&A document will be published on the website.

Working document – Information to be submitted by the Member State of the European Reference Medicinal Product

The CMD(h) has agreed on a working document on the information to be transmitted by the Competent Authority of the Member State of the European reference medicinal 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 working document will be published on the website for information.

The intention of the Group is to review the document within 6 months, in light of experience gained.

Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure

The CMD(h) has finalised the 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 takes account of the comments received following the consultation procedure and will be published on the website.

Recommendation on Implementation of Article 30 Decisions for Generic Products

The Recommendation on implementation of Article 30 Decisions for Generic Products has been updated, taking into account the changes following the new pharmaceutical legislation. The updated document will be published on the website.

Best Practice Guide EU Work Sharing Procedure in the Assessment of Paediatric Data

The CMD(h) has updated the Best Practice Guide for the EU Work sharing procedure in the assessment of paediatric data, mainly to give further clarification on the role of the Rapporteur and Co-Rapporteur in the procedure. The updated Best Practice Guide will be published on the website.

Sub-Group meeting on Harmonisation of SPCs

The Sub-Group on harmonisation of SPCs agreed on the criteria for selection of products for SPC harmonisation.

The proposed criteria were endorsed by the CMD(h) and will be published on the website.

List of CMD(h) Members – Professional Qualifications

An updated list of CMD(h) Members, to include a link to the respective professional qualifications, has been agreed by the CMD(h) and 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.

Summary of MRFG/CMD(h) Activities in 2005

The CMD(h) has agreed to publish on the website a summary of the main activities carried out by the former MRFG/ new CMD(h) and its sub-groups in 2005.

MRP statistics 2005

Statistics regarding new applications in the MRP in the year 2005 according to the 5-level classification will be published on the website.

Change in the EU-Presidency

The January 2006 CMD(h) meeting was the first one under the Austrian presidency. Mrs. Christa Wirthumer-Hoche is 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 20th and 21st February 2006.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **21** new Mutual Recognition Procedures were finalised during the month of December 2005. **9** Mutual Recognition Procedures for new applications were referred to CMD(h) in this period.

The status as of 31st December 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	954	137	10 N.A.	2 N.A.

44 Mutual Recognition Procedures (regarding **81** products) started in December 2005. The categories of these procedures are as follows:

1 new active substance.

11 known active substances (already authorised in at least one member state) including **3** multiple applications and **1** repeat use.

30 abridged applications including **13** multiple applications and **2** repeat use.

2 line extension applications.

The new procedures started related to **9** full dossiers, **32** generics and **3** bibliographic applications.

The procedures consisted of **41** chemical substances, **2** Biological - Blood Product and **1** Biological - Vaccine[1].

44 of these procedures were prescription-only medicinal products in the reference Member State[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 December 2005.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (1)	8
DE (1)	13
DE (1)	8
DE (1)	7
DK (3)	1
DK (1)	1
DK (3)	1
DK (2)	16
DK (1)	7
DK (1)	1
DK (1)	1
DK (1)	1
DK (1)	1
DK (2)	1
FI (1)	13
FI (1)	5
FI (1)	1
HU (2)	13

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
HU (2)	5
HU (2)	4
HU (2)	9
HU (2)	12
IT (1)	4
NL (3)	16
NL (1)	25
NL (1)	23
NL (1)	1
NL (1)	5
NL (1)	3
SE (3)	6
SE (3)	7
SE (1)	11
SE (5)	2
UK (1)	3
UK (1)	19
UK (1)	1
UK (4)	15
UK (6)	17
UK (1)	15
UK (2)	1
UK (3)	4
UK (3)	2
UK (3)	2
UK (3)	1

Decentralised Procedure

The CMD(h) noted that **9** new Decentralised Procedures (regarding **22** products) started in December 2005. The categories of these procedures are as follows:

9 abridged applications including **4** multiple applications.

The new Decentralised procedures started related to **9** generics.

The procedures consisted of **9** chemical substances[3].

7 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 products[4].

3. As considered by RMS.
4. In this category products are classified as prescription-only or Non-prescription (OTC) products as applied for in the RMS, although the legal status is not part of the Decentralised Procedure.

Number of countries involved in the new applications in Decentralised procedures started in December 2005.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (2)	9
DE (4)	5
DE (4)	3
DE (4)	1
DE (4)	1
NL (1)	9
NL (1)	1
NL (1)	6
NL (1)	3

VARIATIONS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **414** type IA variations, **166** type IB variations and **154** type II variations were finalised during the month of December 2005. **1** arbitration from variations was referred to the CHMP in this period.

The status as of 31st December 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	4044	1944	1509	7 Var.

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

YEARS	PROCEDURES FROM NEW APPLICATIONS FINALISED	PROCEDURES FROM TYPE I VARIATIONS FINALISED	PROCEDURES FROM TYPE IA VARIATIONS FINALISED	PROCEDURES FROM TYPE IB VARIATIONS FINALISED	PROCEDURES FROM TYPE II VARIATIONS FINALISED	PROCEDURES REFERRED TO CMD(H)	ARBITRATIONS REFERRED TO CPMP
1995	10	16			17		1 N.A.
1996	84	49			73		1 N.A. and 1 variation
1997	146	101			163		1 N.A. and 1 variation
1998	182	339			222		1 N.A. and 4 variations
1999	228	671			301		2 N.A. and 2 variations
2000	306	1007			320		3 N.A. and 2 variations
2001	443	1487			474		1 N.A. and 3 variations
2002	420	2104			527		2 N.A. and 7 variations
2003	529	2473	230	94	754		5 N.A. and 3 variations
2004	760	43	3240	1998	1083		9 N.A.
2005	954	N/A	4044	1944	1509	10 N.A.	2 N.A. and 7 variations
1995-2005	4062	8290	7514	4036	5443	10 N.A.	28 N.A. and 30 variations

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/

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