European Medicines Agency
Evaluation of Medicines for Human Use

London, 14 June 2006
EMEA/209537/2006

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

The Committee for Medicinal Products for Human Use (CHMP) held its May plenary meeting from 29 May-01 June 2006.

The CHMP Chairman welcomed on behalf of the Committee Dr. Laitinen-Parkkonen, as the new CHMP alternate from Finland (from June 1st 2006), replacing Dr. Tokola. In addition, Dr. Kuitunen, the Finnish CHMP Member left the Committee. The Chairman, on behalf of the Committee, expressed its thanks and appreciation to both Dr. Kuitunen and Dr. Tokola, for their work in the CHMP.

Centralised procedure

Initial marketing authorisation applications

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

- **Competact** (pioglitazone/metformin), from Takeda Global R & D Centre (Europe) Ltd, for the treatment of type II diabetes. EMEA review began on 14 March 2005 with an active review time of 204 days.

- **Intrinsa** (testosterone) and **Livensa** (testosterone), from Procter and Gamble Pharmaceuticals UK, for the treatment of hypoactive sexual desire disorder in women who have uterus and both ovaries removed. EMEA review for both products began on 15 November 2004 with an active review time of 210 days.

- **Savene** (dexrazoxane), from TopoTarget A/S, for the treatment of anthracycline extravasation (accidental leakage of intravenously administered chemotherapeutics into the surrounding tissue). EMEA review began on 17 August 2005 with an active review time of 204 days. Savene is the twenty-eighth orphan medicinal product to receive a positive CHMP opinion.

- **Thelin** (sitaxentan sodium), from Encysive (UK) Ltd, for the treatment of pulmonary arterial hypertension. EMEA review began on 17 August 2005 with an active review time of 196 days. Sitaxentan sodium is the twenty-ninth orphan medicinal product to receive a positive CHMP opinion.

Re-examination procedure concluded

The CHMP has adopted a final positive opinion for **ATryn**, from Genzyme Europe. ATryn, which contains antithrombin alfa, a recombinant-DNA human anti-clotting blood protein, is the first medicinal product derived from transgenic biotechnology to receive a positive opinion from the Committee. Antithrombin alfa is extracted from the milk of goats which have the human antithrombin gene inserted, that enables them to produce the human protein in their milk.
Following re-examination of its negative opinion, adopted in February 2006, the CHMP has now adopted a final positive opinion, recommending that ATryn should be authorised for use in patients with congenital antithrombin deficiency (inherited reduction of antithrombin) undergoing surgery, to prevent deep-vein thrombosis (formation of clots in the vessels of the legs) and thromboembolism (formation of clots in other vessels of the body).
A separate press release and question and answer document are available.

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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:

- **Mabthera** (rituximab), from Roche Registration Ltd, to extend its indications to add:
  - maintenance therapy indicated for patients with relapsed/refractory follicular lymphoma responding to induction therapy with chemotherapy with or without Mabthera.
  - use in combination with methotrexate for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease- anti-rheumatic drugs including one or more tumour necrosis factor (TNF) inhibitor therapies.

  Mabthera was first authorised in the European Union on 2 June 1998 and is currently indicated for treatment of follicular lymphoma.

- **Remicade** (infliximab), from Centocor B.V., to extend its indication to include use of infliximab alone or in combination with methotrexate in the treatment of psoriatic arthritis patients. 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, psoriasis and ulcerative colitis.

Summaries of opinions for all these products are available and can be found here.

Adoption of extension application

The Committee also adopted a positive opinion by consensus on a "line extension" application (under the optional scope) (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (under the mandatory scope).

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**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in April 2006 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 April 2006 meeting are provided in **Annex 4**.

Referral procedures

Finalised Referral procedures

- The Committee finalised an arbitration procedure for the generic product **Ceftriaxone Tyrol 1g and 2g** (ceftriaxone) from Sandoz Ltd, recommending harmonisation of the product information of the reference product and of the generic product, in particular concerning the dosing of newborn infants. The procedure was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC, as amended.

- The Committee finalised a harmonisation referral for **Neurontin** (gabapentin) and associated names, from Pfizer recommending harmonisation of the summaries of product characteristics across the European Union, in particular with regard to indications, posology, contra-indications and undesirable effects. The referral was initiated by Italy under Article 30 of Directive 2001/83/EC as amended.

- The Committee finalised referral procedures under Article 36 of Directive 2001/83/EC as amended, for a number of generic medicines containing **cetirizine dihydrochloride 10 mg** (film coated tablets), recommending their suspension because of concerns regarding good clinical practices (GCP) and good laboratory practices (GLP) compliance that impact on the quality and reliability of bioequivalence studies supporting the marketing authorisations.

- The Committee finalised a referral procedure under Article 6(12) of Commission Regulation (EC) No 1084/2003 for **Prozac** (fluoxetine) and associated names from Eli Lilly UK Ltd. The Committee recommended to extend the indication of Prozac to include the treatment of children and adolescents 8 years of age or older who suffer from moderate to severe depression and who do not respond to psychological therapy. Please see Press Release: http://www.emea.eu.int/pdfs/human/press/pr/20255406en.pdf and "Questions and Answers on the review of Prozac for use in children and adolescents" http://www.emea.eu.int/pdfs/human/press/pr/19832306en.pdf.

Start of Referral procedures

The Committee started a large number of arbitration and referral procedures for medicinal products authorised through the Mutual Recognition Procedure:

- Arbitrations under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure. Procedures were started for the following products:
  - **Felodipine/metoprolol tartrate** and associated names (felodipine metoprolol tartrate), from Yes Pharmaceuticals Development Services GmbH
  - **Ciprofloxacin 2mg/ml solution for infusion** (ciprofloxacin), from Nycomed Danmark APS.

- A harmonisation referral under Article 30 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) was started for **Lornoxicam** (lornoxicam) at the request of the Marketing Authorisation Holder, Nycomed. Article 30 referrals are initiated with a view to harmonising product information for medicinal products authorised at Member State level.

- Referral procedures under Article 36 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) were begun for **Gadovist** and **Gadograf**, from Schering España. Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action. The referrals were made by Spain with a view to restricting the indication of the products.

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 2-4 May 2006. For further details, please see **Annex 5**.

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

Invented Name Review Group (NRG)

Statistical information on the outcome of the checking of acceptability of proposed invented names for medicinal products processed through the centralised procedure are provided in **Annex 7.**

Upcoming meetings following the March 2006 CHMP plenary meeting:

- The 23rd meeting of the CHMP will be held at the EMEA on 26-29 June 2006.
- The next Invented Name Review Group meeting will be held at the EMEA on 26 June 2006.
- The eighth CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 26-27 June 2006.

Organisational matters

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

- Nomination of the Chair and Vice Chair of the SAG-Diagnostic:
  Chairman was nominated Prof. Jean-Nöel Talbot and Vice-Chairman was nominated Prof. Lars Friberg.
- Adoption of the revised Mandate, Objectives and Rules of Procedure of the SAWP to accommodate the appointment of 4 additional members.
- Adoption of the revised Mandate, Objectives and Rules of Procedure for the CHMP Safety Working Party.
- Discussion on a Report from the PhVWP on the Assessment of the Community System of Pharmacovigilance.
- Discussion on the Utilisation of Co-opted PhVWP Members' Expertise in the EU Regulatory System.

EMEA Implementation of the New EU Pharmaceutical Legislation

The seventeenth CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 29 May 2006.

The following Guidelines were adopted by the CHMP and will be published on the EMEA website:

- Publication of withdrawals of Marketing authorisation Applications for human medicinal products
- Rules of involvement of Members of patients' and/or consumers' organisations in Committees related activities

The following document was agreed by the CHMP and will be transmitted to the European Commission:

- Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorization for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004.

Follow-on discussion took place on the following topic:

- Criteria for Rapporteur /Co-Rapporteur appointment
  The Committee finalised its discussions on the Review Implementation topic "Criteria for Rapporteur /Co-Rapporteur appointment". A "Reflection Paper on CHMP Rapporteur /Co-Rapporteur appointment: Principles, objective criteria and methodology" was subsequently adopted by the CHMP (please see Procedural Announcement below).

PROCEDURAL ANNOUNCEMENTS

- **Criteria for Rapporteur /Co-Rapporteur appointment**

The Committee finalised its discussions on the Review Implementation topic "Criteria for Rapporteur /Co-Rapporteur appointment".

The new Pharmaceutical legislation (Regulation (EC) No 726/2004) provides the legal framework for the Rapporteur /Co-Rapporteur appointment. In addition, the CHMP Rules of Procedure (EMEA/CHMP/111481/2004) and the Notice to Applicants (Chapter 4.1) outline the following key point in the future practice for the appointment of CHMP Rapporteurs and Co-Rapporteurs:

- The appointment of the Rapporteur /Co-Rapporteur should be on the basis of objective criteria, which will ensure the provision of objective scientific opinions and allow the use of the best and available expertise in the European Economic Area on the relevant scientific area.

Based on the above, the Committee adopted a Reflection Paper on the principles, objective criteria and the methodology on the appointment procedure for the CHMP Rapporteur/Co-Rapporteur and their assessment teams.
These principles and objective criteria shall apply to several application types (e.g. centralised applications, application on Article 58 of Regulation (EC) No 726/2004, compassionate use).

Additional principles were finalised by the Committee for the Rapporteur /Co-Rapporteur appointment for other types of application procedures such as:

- Generics/Hybrids
- Similar Biological medicinal products
- Referrals and
- Re-examination of a CHMP opinion

The adopted "Reflection Paper on CHMP Rapporteur /Co-Rapporteur appointment: Principles, objective criteria and methodology" will be published at the EMEA website by the beginning of July 2006.

The new Rapporteur /Co-Rapporteur appointment procedure will be implemented as of September 2006 and shall apply as of that date. The new appointment procedure for Rapporteur/Co-Rapporteur and their assessment teams shall take place 7 months prior to the Marketing Authorisation Application (MAA) submission intended date, to allow Rapporteur /Co-Rapporteur appointment 6 months prior to the MAA intended submission date.

- **Need for an EU-Risk Management Plan in the post authorisation phase for centralised applications**

This month saw the start of the new procedure whereby the CHMP indicates whether an EU Risk Management Plan should be submitted by the Marketing Authorisation Holder (MAH) when seeking a "significant change" to the Marketing Authorisation in the post authorisation phase. MAHs are strongly encouraged to inform their EMEA Product Team Leader well in advance of any planned submissions so that appropriate guidance can be given.
Please see the "Guideline on EU Risk Management Systems for medicinal products for human use": http://www.emea.eu.int/pdfs/human/euleg/9626805en.pdf.

- **Information for Delegates and Visitors to European Medicines Agency**

The EMEA is renewing the access control system to provide an even safer environment for staff and visitors to the Agency. The managing agents of 7 Westferry Circus have installed turnstiles on the ground floor and the Agency's access control system and the turnstiles will work in conjunction.

There will be an EMEA ground floor reception and this will be the first point of contact for all staff, delegates and visitors to the Agency. For those delegates and visitors who do not have permanent access cards they will be asked for identification, once this has been verified, they will be issued with a visitor's pass which will include a photograph of the person and an access card for the specific areas required. The pass will be valid for the duration of the delegate's visit.

As the new access control system will be integrated with the meetings management database, it is important that delegates respond to meeting invitations to enable EMEA to have the badges ready for collection. If Reception is not aware that a delegate is coming to a meeting, this can lead to a delay whilst Security verifies your attendance at the Agency.

Delegates with permanent passes will be able to pass through the turnstiles. Presenting the pass/access card to the reader on the turnstile opens the barrier and activates the access card so that it operates on the readers on EMEA's doors. It also registers the person for Health & Safety purposes. For example, if there is a fire evacuation, fire marshals will have an accurate record of everyone in the EMEA demised area.

To exit the building, a person must pass through the turnstile barrier on the ground floor. Presenting the pass/access card to the reader opens the barrier, and deactivates the card from operating within EMEA demised area.

If the pass/access control card is not presented on exit, or the person leaves by an unauthorised route, the system will think the card and cardholder are still within the demised area, and will not authorise re-entry.
A member of the ground floor security team will be available to assist visitors if required.

Work on the new access control system has already begun and it is anticipated the system will become operational by June/July 2006.

Please arrive 30 minutes before the start of your meeting to allow reception time to complete the new visitors registration procedure and to issue your pass.

EMEA thanks you for your cooperation and patience during this initial period.

Mutual Recognition procedure and Decentralised procedures-Human

The CHMP noted the report from the seventh CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 29-30 May 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

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]	**12**	**4**	**0**	**12**	**3**	**4**	**35**	**525**
Positive opinions[3]	**12**	**2**	**0**	**4**	**0**	**6**	**24**	**350[4]**
Negative opinions[5]	**1**	**0**	**0**	**1**	**0**	**0**	**2**	**9[6]**
Withdrawals prior to opinion	**2**	**1**	**0**	**1**	**0**	**2**	**6**	**105**
Marketing Authorisations granted by the Commission	**12**	**0**	**0**	**6**	**0**	**2**	**20**	**331**

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[6]	**0**	**4**
PMF	**1**	**8**
VAMF	**0**	**0**

[1] Starting point for operation of 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] [4] 350 positive Opinions corresponding to 277 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] 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

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

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
N/A	N/A	N/A	N/A

ANNEX 2 TO CHMP MONTHLY REPORT MAY 2006

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)	257	3697
Type II Variations (positive opinions)	259	2441
Type II Variations (negative opinions)	0	7
Annex II Applications (positive opinions)	8	135
Annual Re-assessment (positive opinions)	14	N/A
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	32	N/A

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
3 Extensions of indication	3 Positive opinions
22 SPC changes	22 Positive opinions
21 Quality changes	21 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Prialt (ziconotide), Elan Pharma International Ltd	Positive Opinion adopted	The Marketing Authorisation will remain under Exceptional Circumstances
Reyataz (atazanavir sulphate) Bristol Myers Squibb Pharma EEIG	Positive Opinion adopted	The Marketing Authorisation will remain under Exceptional Circumstances
Trisenox (arsenic trioxide) Cell Therapeutics (UK) Ltd	Positive Opinion adopted	The Marketing Authorisation will remain under Exceptional Circumstances
Ventavis (iloprost) Schering AG,	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**

Opinions for 5 Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Ceprotin (protein C) Baxter AG	Positive Opinion adopted	Unlimited validity
MabCampath (alemtuzumab) Genzyme B.V	Positive Opinion adopted	Additional 5-year renewal
Nonafact (human coagulation factor IX), Sanquin CLB	Positive Opinion adopted	Unlimited validity
Rapilysin (reteplase) Roche Registration Ltd	Positive Opinion adopted	Unlimited validity
Fabrazyme (agalsidase beta) Genzyme B.V.,	Positive Opinion adopted	Unlimited validity
INOmax (nitric oxide) INO Therapeutics AB	Positive Opinion adopted	Unlimited validity
Replagal (agalsidase alfa) TKT Europe-5S AB	Positive Opinion adopted	Unlimited validity
Tritanrix-HepB (comb Vaccine DTPw-Hep B) GlaxoSmithKline Biologicals S.A.	Positive Opinion adopted	Unlimited validity
Zyprexa (olanzapine) Eli Lilly Nederland B.V	Positive Opinion adopted	Unlimited validity
Zyprexa velotab (olanzapine) Eli Lilly Nederland B.V	Positive Opinion adopted	Unlimited validity
Rilutek (riluzole) Aventis Phrma S.A.	Positive Opinion adopted	Unlimited validity
Epivir (lamivudine) GlaxoSmithKline	Positive Opinion adopted	Unlimited validity

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MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE APRIL 2006 CHMP MONTHLY REPORT

Invented Name	M-M-RVAXPRO
INN	Measles, Mumps and Rubella Vaccine (Live)
Marketing Authorisation Holder	Sanofi Pasteur MSD
Proposed ATC code	J07BD52
Indication	M-M-RVAXPRO is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months or older
CPMP Opinion date	23.02.2006
Marketing Authorisation Date	05.05.2006

Invented Name	Ganfort
INN	bimatoprost/timolol
Marketing Authorisation Holder	Allergan Pharmaceuticals Ireland
Proposed ATC code	SO1ED51
Indication	Reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.
CPMP Opinion date	23.03.2006
Marketing Authorisation Date	19.05.2006

Invented Name	Zostavax
INN	Zoster vaccine
Marketing Authorisation Holder	Sanofi Pasteur MSD, SNC
Proposed ATC code	Not yet assigned
Indication	ZOSTAVAX is indicated for prevention of herpes zoster (“zoster” or shingles) and herpes zoster-related post-herpetic neuralgia (PHN). ZOSTAVAX is indicated for immunization of individuals 60 years of age or older.
CPMP Opinion date	23.03.2006
Marketing Authorisation Date	23.05.2006

ANNEX 4 TO CHMP MONTHLY REPORT MAY 2006

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING UTHORISATION: UPDATE SINCE THE APRIL 2006 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
5-Aminolevulinic acid hydrochloride (Gliolan)	Medac Gesellschaft für klinische Spezialpräparate mbH	EU/3/02/121 13/11/2002	Intra-operative photodynamic diagnosis of residual glioma

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

	1995 - 2005	2006	Overall Total
Scientific Advice	558	64	622
Follow-up to Scientific Advice	94	8	102
Protocol Assistance	107	23	130
Follow-up to Protocol Assistance	26	3	29
	785	**98**	**883**

OUTCOME OF THE MAY 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	Huntington's disease		X			X	X	X	
Chemical	Muckle-Wells Syndrome, Familial Cold-associated Auto-inflammatory Syndrome, Polyarticular Juvenile Idiopathic Arthritis, Systemic-onset Juvenile Idiopathic Arthritis, and adult Rheumatoid Arthritis			X		X		X	
Chemical	Myelodysplastic Syndromes		X			X	X	X	
Chemical	non small cell lung cancer	X						X	
Chemical	early stage breast cancer	X				X		X	
Chemical	Acute Myeloid Leukaemia		X			X	X	X	X
Chemical	Multiple myeloma		X					X	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Acute Graft-Versus-Host-Disease		X			X	X	X	X
Biological	Bladder cancer	X				X	X	X	
Chemical	Non-small cell lung cancer	X						X	
Chemical	Medullary thyroid carcinoma				X			X	
Biological	Non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease	X				X	X	X	
Chemical	QD combination therapy for the treatment of type 2 diabetes mellitus	X					X	X	
Biological	prevention of Pseudomonas aeruginosa colonisation in non-colonised cystic fibrosis patients		X					X	
Chemical	HIV-1 infection	X					X	X	
Biological	Glabellar lines	X						X	
Chemical	HIV/AIDS	X						X	
Biological	Pandemic Vaccine	X					X	X	
Chemical	anemias in patients with chronic kidney disease and chemotherapy induced anemias	X					X	X	
Chemical	Osteoporosis			X			X		
Chemical	Clostridium difficile-associated diarrhoea	X						X	
Biological	ulcerative colitis and Crohn's disease	X				X	X		
	Total	**13**	**6**	**2**	**1**				

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 13 Scientific Advice letters, 6 Protocol Assistance letters, 2 Follow-up Scientific Advice letters and 1 Follow-up Protocol Assistance letters were adopted at the 29 May - 1 June 2006 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 30 new Requests for which the procedure started at the SAWP meeting held on 2-4 May 2006. The new requests are divided as follows: 22 Initial Scientific Advice, 5 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

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

BIOLOGICS WORKING PARTY

Reference number	Document	Status[7]
CHMP/BWP/123643 2006	Revised EU recommendations dated 29 May 2006 for the seasonal influenza vaccine composition for the season 2006-2007	Adopted
CHMP/BWP/42208/ 2006	Comments during consultation on Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Quality Issues	Adopted
CHMP/BWP/124446/ 2005	Guideline on potency labelling for insulin analogue containing products with particular reference to the use of "International Units" or "Units"	Adopted

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

Reference number	Document	Status
CHMP/94528/05	Overview of Comments on Guideline on Similar Biological Medicinal Products containing biotechnology derived products as active substance: non-clinical and clinical issues Annex: Somatropin	Adopted

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/281/96 Rev.1	Draft Guideline on Clinical Investigation of Medicinal Products used in Weight Control	Released for 6 months consultation
CHMP/EWP/4713/03	Draft Guideline on Clinical Investigation of Medicinal Products for the Treatment of Sepsis	Adopted
CPMP/EWP/6235/04	Draft Guideline on Clinical Investigation of Medicinal Products for the Prophylaxis of Venous Thromboembolic Risk in Non-Surgical Patients	Adopted
CPMP/EWP/234/95/rev. 1	Draft Guideline on the Clinical Investigation of Anti-Anginal Medicinal Products in Stable Angina Pectoris	Adopted

[7] Adopted or release for consultation documents can be found at the EMEA website (under "What's new-recent publications" or under Human Medicines-Guidance documents").

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SAFETY WORKING PARTY

Reference number	Document	Status
EMEA/CHMP/SWP/ 4447/00	Draft Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status
EMEA/HMPC/287539/ 2005	Draft Guideline on Declaration of Herbal Substances and herbal Preparations8 in Herbal Medicinal Products/Traditional Herbal Medicinal Products IN THE SPC	Released for 6 months consultation
EMEA/209537/2006	Concept Paper on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products	Released for 3 months consultation
EMEA/209537/2006	Draft Concept Paper on Revision of the Note for Guidance on the Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations	Released for 3 months consultation

VACCINE WORKING PARTY (VWP)

Reference number	Document	Status
EMEA/VWP/171037/2006	Concept paper on guideline on dossier structure and content for marketing authorisation for influenza vaccines with avian strains with a pandemic potential for use outside of the core dossier context	Released for 1 month consultation

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Name Review Group (NRG)

	May 2006			2006	
	Accepted	Rejected	Pending	Accepted	Rejected
Proposed invented names	22	23	29[1]	47	74
Justification for retention of invented name *	3	0	11[2]	5	13

*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.

[1] Two proposed invented names requests have been postponed from the May NRG meeting.
[2] One justification request has been postponed from the May NRG meeting.

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

Report from the CMD(h) meeting held on 29th and 30th May 2006

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-Group on harmonisation of SPCs, to discuss the proposals from Member States for products for which a harmonised SPC should be drawn up.

The Group agreed to prepare the rationale for selection of the products to be included in the list for SPC harmonisation, addressing each of the agreed criteria, for discussion at the July sub-group meeting.

The CMD(h) Sub-Group on harmonisation of SPCs will continue its work with a view to laying down a list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended.

Interpretation and Member States Recommendation for Applications submitted according to Article 10 when the strength and/or pharmaceutical form of the Reference medicinal product differs between RMS/CMS(s)

The CMD(h) has updated the above mentioned Recommendation, in line with the new legal references in the revised pharmaceutical legislation and to consider generic/hybrid applications submitted via the decentralised procedure.

The legal basis for the applications where the strength and/or pharmaceutical form of the Reference medicinal product differs between RMS/CMS(s) should be Article 10 of Directive 2001/83/EC, as amended. The Applicant should tick in the application form either Article 10.1 or 10.3, depending on whether the strength and/or pharmaceutical form of the reference medicinal product is or not authorised in the MS where the application is made.

Applicants are reminded to inform the RMS in due time if different sections of Article 10 will be used.

Applicant's response document in Mutual Recognition and Decentralised Procedures

The CMD(h) has updated the above mentioned document, to consider the response documents to be submitted in the mutual recognition procedure and decentralised procedure, including the referral to the CMD(h) for the 60 days procedure and to address the submission of new proposals for the labelling and package leaflet.

Harmonisation of labelling and package leaflet in parallel to a repeat-use MRP – End of transitional period

The CMD(h) has agreed that from the 1st November 2006 separate applications will not be accepted for the harmonisation of the labelling and package leaflet of a medicinal product in parallel to a repeat-use MRP. After this date the revised pharmaceutical legislation must be applied and the harmonisation of the labelling and package leaflet of a medicinal product should be achieved before the start of the repeat-use MRP.

Consultation with target patients groups for the package leaflet

Applicants are reminded that the submission of the results of consultation with target patient groups, in accordance with Article 59(3) of Directive 2001/83/EC, as amended, or justification for its absence is required with the submission of applications for marketing authorisation via the mutual recognition procedure. Failure to address the matter may result in Member States deeming the application invalid.

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For applications submitted via the decentralised procedure this is also a requirement and failure to comply could lead to invalidation of the application; however, within the decentralised procedure there is an additional possibility that applicants may make use of the 'clock stop' period to undertake consultation with target patients groups and therefore it may be possible for the matter to be addressed within the procedural timeframe.

For further information on the timing of user consultation, submission and assessment within the evaluation procedure in the mutual recognition or decentralised procedure, please refer, respectively, to the Best Practice Guide for the Mutual Recognition Procedure and to the Decentralised procedure – Member States SOP, available on the Heads of Medicines Agencies website.

Information on MR procedures for new active substances

A mutual recognition procedure for a medicinal product containing treprostinil has been finalised on 8 March 2006. Please find below information on the Invented name, INN, MAH, Indication, Procedure number and Day 90.

Invented Name (RMS)	Pabal solution for injection 100 micrograms in 1 ml
INN	Carbetocin
Marketing Authorisation Holder	Ferring Pharmaceuticals Ltd
Indication	Prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anaesthesia.
Procedure number	UK/H/0838/001/MR
Day 90	08.03.2006

Information on applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

Please find below information on the Name of the products in the RMS, active substances, pharmaceutical forms, procedure numbers, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedures, for the referrals to the CMD(h) finalised on 2 May 2006.

Name of the product in the RMS	TerbiLich 250mg
Active substance	terbinafine
Pharmaceutical form	tablet
Procedure number	DE/H/0555/01
CMS	BE, PT
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	Different interpretation of the available clinical and toxicological data with regard to the inclusion of paediatric indications to the product information.
Day 60	02.05.06
Outcome	Agreement reached not to extend the current product information and to await the outcome of the evaluation of paediatric data for terbinafine in the current ongoing Paediatric Worksharing Project of the HMA. Further regulatory actions – if deemed necessary – will include all medicinal products with terbinafine as active substance.

Name of the product in the RMS	Ciprofloxacin 2 mg/ml solution for infusion
Active substance	ciprofloxacin
Pharmaceutical form	Solution for infusion
Procedure number	UK/H/848/01
CMS	FI, NO, SE
Legal basis	Art 10.1, Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	The procedure highlighted differences in approved posology between national 'brand leader' SPCs. Specifically, the referring CMS objected to the RMS approved posology for urinary tract infections, UTI (100mg twice daily) and considered that the maximum recommended daily dose (800mg) should be increased up to 1200mg daily. Referring CMS consider that the experience of UTI posology of 200-400mg twice daily in a number of EU Member States, together with available published data from open post marketing studies, would justify amendment to the RMS approved posology (UTI). Furthermore, referring CMS were concerned that the SPC should include an optimal dosage regimen because, in their view, the RMS approved posology may risk sub-therapeutic dosing and lead to development of resistance. The RMS considered that the available information was insufficient to justify amendment to the posology and in the absence of data in favour or against the different options under discussion a consensus could not be reached.
Day 60	02.05.06
Outcome	Referred to CHMP for arbitration.

Name of the product in the RMS	Estradiol 2mg film-coated tablets	
Active substance	estradiol	
Pharmaceutical form	Film-coated tablet	
Procedure number	NL/H/685/01	NL/H/686/01
CMS	DE, DK, EE, FI, FR, LT, LU, LV, SI, SK	CZ, DE, DK, EE, FI, LT, LV, SK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic	
Grounds for referral to CMD(h)	The indication "*Prevention of osteoporosis in postmenopausal women at high risk of fractures who are intolerant or contraindicated for other medicinal products approved for the prevention of osteoporosis"* is beyond the indications approved for the reference product in one CMS.	
Day 60	02.05.06	
Outcome	Agreement reached. The procedure is finalised without the osteoporosis indication. The applicant commits to submit a type II variation to introduce this indication.	

Name of the product in the RMS	Modafinil 100mg Tablets
Active substance	modafinil
Pharmaceutical form	Tablet
Procedure number	UK/H/834/01
CMS	AT, BE, CZ, DE, DK, ES, IE, IT, NL, NO, PL, PT, SE, SK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	Concerns were raised on the GCP documentation for the bioequivalence study. Concerns were raised that the deletion of the indication for Obstructive sleep apnoea, which is authorised in some CMS, might result in inadequate information being provided to some patients. The applicant addressed all the concerns. Some changes were made to the Patient Information Leaflet.
Day 60	02.05.06
Outcome	Agreement reached

Name of the product in the RMS	Equasym 10, 20 and 30mg Capsules
Active substance	Methylphenidate hydrochloride
Pharmaceutical form	Capsule
Procedure number	UK/H/819/01-03
CMS	AT, BE, DK, FR, DE, EL, IS, IE, LU, MT, NO, NL
Legal basis	Article 10.1(a)(iii), last paragraph, Directive 2001/83/EC
Grounds for referral to CMD(h)	There were concerns that the once daily treatment with Equasym XL would not give sufficient therapeutic cover relative to the immediate release (IR) formulations. There were concerns that treatment with Equasym XL would provide less control of symptoms after the school day than a conventional twice daily regimen of IR methylphenidate and hence that patients using Equasym XL would be more likely to require additional IR methylphenidate to control ADHD, resulting in increased overall exposure to methylphenidate. There were concerns regarding initiating methylphenidate treatment with Equasym XL in the treatment of naive patients. Finally the applicant was requested to provide a risk management plan (RMP). The applicant addressed all the concerns. Some alterations were made to the Summary of Product Characteristics to clarify some of the above issues and a RMP has been agreed.
Day 60	02.05.06
Outcome	Agreement reached

Name of the product in the RMS	Metoprolol/Felodipin Yes	Metofelosan, Mefelor, Mefesan, Mefecur	Mefecomb
Active substance	felodipine/metoprolol tartrate		
Pharmaceutical form	Prolonged release tablet		
Procedure number	DK/H/853/01	DK/H/854, 884-6/01	DK/H/887/01
CMS	BE, DE, FI, LU	DE	DE, FI, LU
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic		
Grounds for referral to CMD(h)	Different interpretation of the submitted study to establish therapeutic equivalence.		
Day 60	02.05.06		
Outcome	Referred to CHMP for arbitration		

Name of the product in the RMS	Yasminelle	Belanette	Yasminelle 28
Active substance	Drospirenone, ethinyl estradiol		
Pharmaceutical form	Film-coated tablet		
Procedure number	NL/H/701/01	NL/H/702/01	NL/H/704/01
CMS	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LV, LT, MT, NO, PL, PT, SK, SI, SE, UK	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, LT, MT, NO, PL, PT, SK, SI, SE, UK	DK, ES, FR, NO, SE
Legal basis	Art 8.3 Dir 2001/83/EC - Full Dossier		
Grounds for referral to CMD(h)	The proposed package leaflet (PL) is not in accordance with the Directive 2001/83/EC, which states that "the package leaflet must be written and designed to be clear and understandable, enabling the user to act appropriately". The proposed PL is too long, repetitive and alarming for women, with too many details, which are not relevant and not always understandable for women. The text in the paragraph on liver tumours under section *Yasminelle and cancer* is not agreed, like the recommendations on the shift/delay of menstrual period.		
Day 60	02.05.06		
Outcome	Agreement reached. The MAH commits to perform user consultation in two Member States, amongst France.		

Name of the product in the RMS	Paroxetine Ranbaxy 20mg
Active substance	paroxetine
Pharmaceutical form	Film-coated tablet
Procedure number	DE/H/0574/01
CMS	BE, DK, ES, FI, IS, NL, NO, PT, SE, UK
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic
Grounds for referral to CMD(h)	The bioequivalence data submitted with the application have been regarded by CMS as not in agreement with the criteria given in the 'Note for Guidance on the Investigation of Bioavailability and Bioequivalence'.
Day 60	02.05.06
Outcome	Agreement reached following a scientific discussion at the CMD(h)-Meeting.
	The CMD(h) and the MS concerned have noted, that not all criteria mentioned in the 'Note for Guidance on the Investigation of Bioavailability and Bioequivalence' are fulfilled. However, due to the nature of the medicinal product, these deviations are not of clinical relevance and therefore not a risk to public health. The CMD(h) has agreed to forward questions with regard to the scientific methodology to the PK Study Group of the Efficacy Working Party of the CHMP for further discussion.

Name of the product in the RMS	Sumatriptan Basics 50/100 mg	Sumatriptan Basics F 50/100 mg	Sumatriptan Basics A 50/100 mg	Sumatriptan Basics B 50/100 mg
Active substance	Sumatriptan succinate			
Pharmaceutical form	tablet			
Procedure number	DE/H/0530/001-2	DE/H/0545/001-2	DE/H/0591/001-2	DE/H/0592/001-2
CMS	AT, BE, CZ, EE, EL, ES, IS, IT, LT, LU, LV, NL, PL, SI, SK, UK	DK, FI, NO, SE	AT, BE, ES, LU, NL, UK	DK, FI, NO, SE
Legal basis	Article 10.1(a)(iii), Directive 2001/83/EC - Generic			
Grounds for referral to CMD(h)	Non-GCP compliance of the submitted bioequivalence study.			
Day 60	02.05.06			
Outcome	Withdrawal of the marketing authorisation and applications in the RMS and CMS. No further actions were deemed to be necessary by the CMD(h), as the potential serious risk to public health raised was not related to the active substance, but to the specific medicinal products.			

INFORMAL CMD(h) MEETING HELD ON 18 AND 19 MAY 2006, VIENNA, AUSTRIA

The CMD(h) convened for an Informal Meeting on 18th and 19th May 2006 in Vienna, Austria, chaired by the CMD(h) Vice-Chair Christa Wirthumer-Hoche.
The Meeting was held as part of a programme of events organised under the Austrian Presidency of the EU, in parallel to the Informal CHMP and COMP.

- Joint meeting CHMP – CMD(h)
  A joint meeting between the CHMP and CMD(h) took place in order to discuss the experience with CMD(h) referrals. A closer cooperation was agreed with regard to the update and interpretation of guidelines, in particular the Note for Guidance on the Investigation of Bioavailability and Bioequivalence.

- European Pharmacopoeia (EP) requirement for Influenza vaccines
  Based on new requirements in the EP 5.3, the maximum amount of ovalbumin has to be stated in the labelling of the Influenza vaccines. This should be done until the end of June 2006 or if Companies are not ready with the new labelling, in order not to jeopardize seasonal flu vaccination, the national competent authorities will accept a change in the labelling later via a variation application. This approach was confirmed at the May CMD(h) meeting.

- Experience with DCP
  The discussions on the decentralised procedure were mainly focussed on MS experience until day 105 of the procedure, in particular on communication between day 100 and 105, as there are no applications in the DCP finalised yet.

- Potential serious risk to public health
  The Commission presented the final Guideline on "Potential serious risk to public health" which will be published on 5 June 2006 on the Commission website in Eudralex, Vol.1. The guideline will be translated into all national EU-languages. Annexed separately to the guideline there will be a list of examples of issues, which normally would not be considered as grounds for a 'potential serious risk to public health' and will be updated as experience is gained. This annex will be published in Eudralex, Vol.2C.

- Readability/ User testing
  Different methods for user testing were discussed and MSs agreed to be flexible in accepting different testing methods. A valid interpretation and justification on the methods used, language tested, etc., should be provided by the Applicant.
  The need for readability/user testing for already authorised medicinal products where significant changes are made to the package leaflet was also discussed and would be further considered by the CMD(h).

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that 9 new Mutual Recognition Procedures were finalised during the month of April 2006. 2 Mutual Recognition Procedures for new applications were referred to CMD(h) in this period. There has not been any Mutual Recognition Procedures for new applications referred to CHMP in this period.

The status as of 30th April 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)	Agreement reached in the CMD(h)	Arbitrations referred to CHMP
2006	161	153	34 N.A.	11	7

48 Mutual Recognition Procedures (regarding **90** products) started in April 2006. The categories of these procedures are as follows:

1 new active substance, which is a repeat use.

8 known active substances (already authorised in at least one member state), including **1** repeat use.

37 abridged applications including **14** multiple applications and **3** repeat use.

2 line extension application, including **1** repeat use.

The new procedures started in April related to **8** full dossiers, **32** generics, **6** hybrid applications, **1** similar-biological application and **1** bibliographic application.

The procedures consisted of **46** chemical substances and **1** biological blood product and **1** biological vaccine product.

All 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 April 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
CZ (2)	4
CZ (4)	5
CZ (3)	5
DE (1)	6
DE (2)	1
DE (1)	5
DE (1)	9
DE (4)	6
DK (1)	7
DK (4)	7
FI (2)	2
FI (1)	7
FI (1)	3
FI (1)	5
FI (1)	1
FI (1)	1
FI (1)	1
FI (1)	1
FI (1)	1
FI (2)	17
FI (2)	4
FI (2)	10
FI (2)	4
FI (2)	12
FI (1)	6
FR (1)	11
FR (1)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
IT (1)	6
IT (4)	3
IT (1)	13
IT (1)	5
NL (1)	20
NL (3)	2
NL (3)	2
NL (2)	1
NL (2)	8
NL (2)	3
NL (3)	1
NL (3)	3
NL (2)	1
NL (2)	1
SE (4)	11
SE (1)	27
SE (1)	4
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1

I Decentralised Procedure

The status as of 30th April of procedures under Decentralised Procedure is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures referred to CMD(h)	Agreement reached in the CMD(h)	Arbitrations referred to CHMP
2006	--	121*	--	--	--

25 Decentralised Procedures (regarding **65** products) started in April 2006. The categories of these procedures are as follows:

24 abridged applications including **8** multiple applications.

1 known active substance (already authorised in at least one member state), which was an initial application.

The new Decentralised procedures started related to **1** full dossier and **24** generic applications.

The procedures consisted of **25** chemical substances[3].

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

* The number of procedures from new applications in process for the months of January, February and March provided in previous press releases were incorrect. The correct numbers were 22 for January, 34 for February and 30 for March. This gives a total of 96 procedures in process as of 31 March 2006.

Number of countries involved in the new applications in Decentralised procedures started in April 2006.

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (3)	1
DE (3)	1
DE (3)	1
DE (3)	1
DE (3)	1
DK (6)	8
DK (3)	7
DK (3)	5
DK (1)	3
FR (3)	5
NL (2)	18
NL (2)	11
NL (2)	9
NL (2)	2
NL (3)	19
NL (3)	7
NL (3)	5
NL (3)	1
SE (3)	10
UK (3)	17
UK (3)	3
UK (2)	14
UK (1)	9
UK (1)	8
UK (1)	1

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **337** type IA variations, **176** type IB variations and **109** type II variations were finalised during the month of April 2006. **16** renewals were finalised in this period.

The status as of 30th April of variations and renewals 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	Renewals finalised	Arbitrations referred to CHMP
2006	1329	708	529	93	--

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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