European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
JULY 2007 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its July plenary meeting from 16-19 July 2007.

This meeting was the last meeting in the current 3-year term of the co-opted members and also the very last CHMP meeting for three of the CHMP co-opted members, Dr Rotblat, Dr. Haase and Dr Kurki. The Chairman, on behalf of the Committee, thanked these members for their work and efforts in both the previous CPMP Committee and in the CHMP over the last few years.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted six positive opinions by consensus on initial marketing authorisation applications, one of which related to a generic of a centrally authorised product:

- **Celsentri** (maraviroc), from Pfizer Limited, for use, in combination with other antiretroviral medicinal products, in treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable. EMEA review began on 27 December 2006 with an active review time of 169 days.

- **Cervarix**[1] (Human Papillomavirus vaccine [Types 16, 18]), from GlaxoSmithKline Biologicals, intended for prophylaxis against high-grade cervical intraepithelial neoplasia (CIN grades 2 and 3) and cervical cancer caused by human papillomavirus (HPV) types 16 and 18. EMEA review began on 29 March 2006 with an active review time of 202 days.

- **Ecalta** (anidulafungin), from Pfizer Limited, for the treatment of invasive candidiasis in adult non-neutropenic patients. EMEA review began on 27 September 2006 with an active review time of 210 days.

- **Galvus** (vildagliptin), from Novartis Pharma AG, for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin, sulphonylurea or thiazolidinedione. EMEA review began on 16 August 2006 with an active review time of 203 days.

- **Yondelis** (trabectedin), from PharmaMar S.A., for the treatment of advanced soft tissue sarcoma. Yondelis is the **42nd orphan medicinal product** to receive a positive opinion. EMEA review began on 16 August 2006 with an active review time of 210 days.

Positive opinion for the first generic medicine for human use

The CHMP adopted the first positive opinion for a generic medicine for human use. The product concerned, **Zalasta** (olanzapine), from Krka d.d. Novo Mesto, is intended for the treatment of schizophrenia and moderate to severe manic episode. The reference product for Zalasta is Zyprexa, from Eli Lilly Nederland B.V., which is already authorised in the EU, in the applied indications.

[1] The summary of opinion for Cervarix has now been published following finalisation of the procedure.

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EMEA review began on 25 October 2006 with an active review time of 177 days. A separate press release is available on the EMEA website.

Negative opinion

The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Natalizumab Elan Pharma 300 mg** (natalizumab), from Elan Pharma. Natalizumab was intended to treat moderate to severe active Crohn's disease in patients who had an inadequate response to or could not take conventional treatments for the disease and who have evidence of active inflammation. It was to be used alone or in combination with other medicines for Crohn's disease. EMEA review began on 18 October 2004 with an active review time of 204 days. A separate question-and-answer document explaining the grounds for the negative opinion for natalizumab is available on the EMEA website.

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

Re-examination procedure under Article 9(2) of Regulation (EC) No. 726/2004

Following the re-examination of the negative opinion adopted during the CHMP meeting that took place on 23-26 April 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Genasense** (oblimersen), from Genta Development Ltd, intended for the treatment of advanced or metastatic melanoma. A separate question-and-answer document with more information about the re-examination procedure is available.

Withdrawals

Following the re-examination under Article 9(2) of Regulation (EC) No. 726/2004 of the negative opinion for **Cerepro** (adenovirus-mediated *Herpes simplex* virus-thymidine kinase gene) adopted during the CHMP meeting that took place on 23-26 April 2007, the Committee was informed by Ark Therapeutics Ltd of its decision to withdraw their application for the re-examination. More information is available in a separate press release and question-and-answer document.

POST-AUTHORISATION PROCEDURES

Suspension opinion

The CHMP was updated on the actions taken following the June CHMP meeting in which the suspension of the marketing authorisation for **Viracept** was recommended.

- On 6 July 2007, the EMEA convened a meeting, with Roche, the Spanish and Swiss regulatory authorities, the European Commission and the World Health Organization (WHO). The company reported on the progress made with their action plan to address the reasons why the contamination occurred, and to prevent it from happening again. The company plans to have a full report available by mid-August for assessment by the CHMP.
- On 18 July 2007, the Pharmacovigilance working party reviewed the proposal from Roche for patients' registries.
- Since the June meeting, the EMEA toxicology experts have reviewed the proposed toxicity studies from Roche, designed to identify more precisely what level of exposure to the contaminant (EMS) is harmful. The company has planned three studies, two of which are planned to start by the end of this month.

Based on progress made with the action plan described above, the CHMP will discuss at the September plenary whether the lifting of the suspension of the marketing authorisation can be recommended. Further information will be available in a separate question-and-answer document to be published on the EMEA website in the very near future.

Extensions of indication and other recommendations

The CHMP gave seven positive opinions for applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Aclasta** (zoledronic acid), from Novartis Europharm Ltd, to extend the indication to include the treatment of osteoporosis in post-menopausal women at increased risk of fracture. Aclasta is currently indicated for the treatment of Paget's disease of the bone.

- **Aranesp and Nespo** (darbepoetin alfa), from Amgen Europe B.V. and Dompé Biotec S.p.A, to remove a restriction of the use of Aranesp and Nespo, to also allow treatment of anaemia in children younger than 11 years of age with chronic renal failure. Aranesp and Nespo are currently indicated for treatment of anaemia associated with chronic renal failure and symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

- **Avastin** (bevacizumab), from Roche Registration Ltd, to extend the indication to include first-line treatment, in combination with platinum-based chemotherapy, of patients with unresectable, advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology. Avastin is currently indicated in combination with intravenous 5-fluorouracil/folinic acid or intravenous 5-fluorouracil/folinic acid/irinotecan for first-line treatment of patients with metastatic carcinoma of the colon or rectum and in combination with paclitaxel for first-line treatment of patients with metastatic breast cancer.

- **Cubicin** (daptomycin), from NOVARTIS EUROPHARM LTD, to extend the indication to include treatment of right-sided infective endocarditis (RIE) due to *Staphylococcus aureus* and *Staphylococcus aureus* bacteraemia (SAB) when associated with RIE or with cSSTI. Cubicin is currently authorised for treatment of complicated skin and soft-tissue infections in adults.

- **Glustin** (pioglitazone), from Takeda Global R&D Centre (Europe) Ltd, to include the use of pioglitazone as triple oral therapy in combination with metformin and a sulphonylurea, in patients with insufficient glycaemic control despite dual oral therapy. Additionally, the CHMP recommended the inclusion of the combination therapy with insulin in type-2 diabetes mellitus patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance.

- **Telzir** (fosamprenavir), from Glaxo Group, to include treatment against HIV infection of adolescents and children aged 6 years or older. Telzir is currently indicated in combination with low dose ritonavir for the treatment of HIV-1 infected adults in combination with other antiretroviral medicinal products.

New contraindications

Following an assessment of the information on psychiatric adverse events with **Acomplia** (rimonabant), from Sanofi-Aventis, the CHMP recommended the addition of a contraindication that the medicine must no longer be used in patients with ongoing major depression, and/or with ongoing treatment with antidepressants, because of the risk of psychiatric side-effects. A separate press release and a question-and-answer document are available.

Following the assessment of a type II variation for **Vistide** (cidofovir), from Pfizer Enterprises SARL, the CHMP recommended the addition of a new contraindication that the medicine must no longer be used in patients unable to receive probenecid. Probenecid is contraindicated in patients with a clinically significant allergy to probenecid or other sulfa-containing medications.

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

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted seven Lists of Questions on initial applications (four under the mandatory scope, and three under the optional scope including one generic application) and two Lists 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 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 June 2007 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 June 2007 CHMP plenary meeting are provided in **Annex 4**.

REFERRAL PROCEDURES

Referral procedure concluded

The CHMP finalised a referral procedure under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended), for **Xeomin** (clostridium botulinum type A neurotoxin complex), from Merz Pharmaceuticals GmbH, indicated for the symptomatic management of blepharospam and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults. This procedure was initiated because of disagreement between Member States regarding the proposed posology and the need for data in repeated administration and on immunogenicity. The CHMP recommended the granting of the marketing authorisation for Xeomin.

The CHMP finalised referral procedures under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended), for Fentanyl-containing transdermal patches from Ratiopharm GmbH (**Fentanyl-ratiopharm 25/50/75/100 µg/h Matrixpflaster** and **Fentanyl-ratiopharm 25/50/75/100 µg/h TTS**), indicated for the management of severe chronic pain. This procedure was initiated because of disagreement between Member States regarding the scope of the proposed indication, the contraindications and the demonstration of bioequivalence with the reference medicinal product. The CHMP concluded that the benefits of Fentanyl-ratiopharm and associated names outweighed the risks and that the marketing authorisations should be granted.

The CHMP concluded the referral procedure under Article 31 of the Community code on human medicinal products for **Veralipride** containing medicinal products, from Sanofi Aventis, indicated for the treatment of hot flushes. The CHMP concluded that the risks of veralipride in the treatment of hot flushes associated with the menopause in women were greater than its benefits and therefore recommended the withdrawal of the marketing authorisation for medicinal products containing veralipride. The procedure was initiated at the request of the European Commission during the September 2006 CHMP meeting. Further information is available in a separate press release and a question-and-answer document.

Referral procedures started

The CHMP started referral procedures under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) for **Pulairmax** (budenoside), from IVAX Pharmaceuticals UK, intended for the treatment of persistent bronchial asthma. The procedure was initiated because of concerns over bioequivalence with the reference medicinal product.

The CHMP began a harmonisation referral procedure under Article 30 of the Community code on human medicinal products for **Ciflox** and **Uniflox** (ciprofloxacin), from Bayer Pharma SA, intended for the treatment of various bacterial infections. Article 30 referrals are initiated with a view to harmonising product information for medicinal products authorised at Member State level.

The CHMP started a referral under Article 31 of the Community code on human medicinal products for **methylphenidate-containing products** intended for the treatment of attention deficit hyperactivity disorder and narcolepsy, because of safety concerns related to cardiovascular events and cerebrovascular disorders. The procedure was initiated at the request of the European Commission.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 20th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-17 July 2007. For further details, please see the relevant press release on the CMD(h) website under the heading Press Releases: http://www.hma.eu/

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 July 2007. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the July 2007 CHMP meeting are listed in **Annex 6**.

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 is provided in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE JULY 2007 CHMP PLENARY MEETING:

- The 36th meeting of the CHMP will be held at the EMEA on 17-20 September 2007.
- The next Invented Name Review Group meeting will be held at the EMEA on 17th September 2007.
- The 21st CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 17-19 September 2007.

ORGANISATIONAL MATTERS

The main topics addressed during the July 2007 CHMP meeting related to:

- The appointment of four new co-opted Committee Members to join the Committee adding specific areas of complementary expertise in the fields of quality (non biologicals), quality and safety (biologicals) with expertise in Advanced Therapies (Gene, Cell and Tissue Therapies) and pharmacovigilance with expertise in pharmacoepidemiology and risk management. The four members appointed were Dr. Robert (Luxembourg), Dr. Schneider (Germany), Dr. Ruiz (Spain) and Dr. Persson (Sweden). Under the CHMP Rules of Procedure, the Committee may appoint up to five co-opted members with a three year mandate to provide additional expertise as necessary.
- Half year report on activities of the various Working Parties.
- A Biosimilar Working Party Workshop on Immunogenicity Assessment of Therapeutic Proteins to be held on September 4th 2007 and intended to complement the external consultation with a discussion among experts on the key issues relevant to the assays and methods used to explore and assess the Immunogenicity of Therapeutic Proteins.
- A Biosimilar Working Party/Biologics Working Party Joint Assessors Training on Assessment of Similar Biological Medicinal Products to be held on the 11th-12th October 2007.

- Finalisation of the review of recombinant factor VIII products and inhibitor development. The conclusions of the review will be available in a public statement on the EMEA website in the very near future.
- A future training session on the Assessment of survival and other time-to-event data to be held on the 9th October 2007.
- The agenda of a Workshop/Training Session on Diagnostics that will be held on the 4th December 2007.
- The adoption of the Guideline on Compassionate use of Medicinal Products, pursuant to Article 83 of Regulation (EC) No 726/2004 (EMEA/504533/2006) and the Questions and Answers document (EMEA/CHMP/721144/2006).
- The adoption of the Guideline on strategies to identify and mitigate risks for first in human Clinical Trials with investigational medicinal products (EMEA/CHMP/SWP/294648/2007). This guideline will come into effect on the 1st September 2007.
- The involvement of WHO experts/observers in procedures according to "Article 58" of Regulation (EC) No 726/2004.
- Follow on discussion on the revision of the Note for Guidance on Summary of Product Characteristics. It is anticipated that a final draft will be released for public consultation in the fourth quarter of 2007.
- A report on the outcome of the meeting on the multi-disciplinary CHMP ad hoc group on HIV prophylactic vaccines held on the 11th July 2007.
- The adoption of the Draft Mandate, Objectives and Rules of Procedure for the GCP Inspectors Working Group (GCP IWG) (EMEA/239486/2007).
- A report on the first meeting from the Paediatric Committee (PDCO) held on the 4th – 5th July 2007.
- Discussion with regards to Article 107 procedure.
- Discussion on the next 2-year Work Programme for the European Risk Management Strategy.
- A proposed European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC) and Perspectives for the Future, to be held on the 3rd October 2007.

PROCEDURAL ANNOUNCEMENT

Quality manufacturing changes of medicinal products and timeframes for their implementation

MAHs planning to introduce major variations in the manufacturing process of biological authorised medicinal products are kindly reminded to contact the EMEA Product Team Leader well in advance of submitting the application(s) in order to discuss their filing strategy and strategy for managing the transition to the new manufacturing process, including anticipated transitional timeframes and pharmacovigilance monitoring.

MAHs are also reminded to contact the EMEA Product Team Leader well in advance of submitting variations to introduce the use of process analytical technology (PAT).

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

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2007								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	23	3	0	4	12	5	2	49	624
Positive opinions	15	2	0	2	10	5	3	37	416
Negative opinions[2]	0	0	0	0	2	1	0	3	15
Withdrawals prior to opinion	3	1	0	0	4	0	2	10	113
Marketing authorisation granted by the Commission	14	1	0	0	5	4	4	28	393

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2007	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	1	4
Consultation for medical devices[3]	1	3
PMF (Click here for a list of PMF certifications)	2	11
VAMF	0	0

[2] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[3] 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 JULY 2007 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Biological	N/A	N/A	N/A
Chemical	Hereditary angioedema	X	
Chemical	Treatment of HIV infection		X

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

Activity	2007	Overall total 1995 onwards
Type I Variations (positive notifications)	505	4700
Type II Variations (positive opinions)	485	3347
Type II Variations (negative opinions)	0	8
Annex II Applications (positive opinions)	23	165
Annual Re-assessment (positive opinions)	18	-
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	42	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
8 Extensions of indication	8 Positive opinions
61 SPC changes	61 Positive opinions
32 Quality changes	32 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Fuzeon (enfuvirtide) Roche Registration Ltd,	Positive Opinion	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**
Actraphane (insulin human, rDNA) Novo Nordisk,	Positive Opinion adopted	Unlimited validity
Mixtard (insulin human, rDNA) Novo Nordisk	Positive Opinion adopted	Unlimited validity
Actrapid (insulin human, rDNA) Novo Nordisk	Positive Opinion adopted	Unlimited validity
Cerezyme (imiglucerase) Genzyme B.V	Positive Opinion adopted	Unlimited validity
Insulatard (insulin human, rDNA) Novo Nordisk	Positive Opinion adopted	Unlimited validity
Protaphane (Iinsulin human, rDNA) Novo Nordisk	Positive Opinion adopted	Unlimited validity
Sifrol (pramipexole) Boehringer Ingelheim International GmbH	Positive Opinion adopted	Unlimited validity
Mirapexin (pramipexole) Boehringer Ingelheim International GmbH	Positive Opinion adopted	Unlimited validity
Somavert (pegvisomant) Pfizer Limited	Positive Opinion adopted	Unlimited validity
Velosulin (insulin human, rDNA) Novo Nordisk	Positive Opinion adopted	Unlimited validity
Cialis (tadalafil) Lilly ICOS Limited,	Positive Opinion adopted	The Committee agreed that a further 5-year renewal would be required

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE JUNE 2007 CHMP MONTHLY REPORT

Invented Name	Siklos
INN	hydroxycarbamide
Marketing Authorisation Holder	Addmedica SAS
Proposed ATC code	L01XX05
Indication	Siklos is indicated for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic Sickle Cell Syndrome.
CHMP Opinion date	26.04.2007
Marketing Authorisation Date	29.06.2007

Invented Name	Circadin
INN	melatonin
Marketing Authorisation Holder	Neurim Pharmaceuticals EEC Ltd
Proposed ATC code	N05CM17
Indication	Circadin is indicated as monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.
CHMP Opinion date	26.04.2007
Marketing Authorisation Date	29.06.2007

Invented Name	Pergoveris
INN	follitropin alfa / lutropin alfa
Marketing Authorisation Holder	Serono Europe Limited
Proposed ATC code	G03GA05 / G03GA07
Indication	Pergoveris is indicated for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials, these patients were defined by an endogenous serum LH level < 1.2 IU/l.
CHMP Opinion date	26.04.2007
Marketing Authorisation Date	25.06.2007

Invented Name	Invega
Common Name	paliperidone
Marketing Authorisation Holder	Janssen-Cilag International NV
Proposed ATC code	N05AX13
Indication	INVEGA is indicated for the treatment of schizophrenia**.**
CHMP Opinion date	26.04.2007
Marketing Authorisation Date	25.06.2007

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE JUNE 2007 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Sorafenib tosylate (Nexavar)	Bayer Health Care AG	EU/3/06/364 11/05/2006	Treatment of hepatocellular carcinoma

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

	1995 - 2006	2007	Overall Total
Scientific Advice	718	89	807
Follow-up to Scientific Advice	127	23	150
Protocol Assistance	157	32	957
Follow-up to Protocol Assistance	40	13	53
	1042	**157**	**1199**

OUTCOME OF THE JULY 2007 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	Treatment of diabetes mellitus	X						X	
Chemical	Treatment of type 2 diabetes mellitus.			X		X		X	
Chemical	Treatment of obesity.	X						X	
Chemical	Treatment of gastro-oesophageal reflux disease.	X					X	X	
Chemical	Treatment of type 2 diabetes mellitus.			X			X	X	
Chemical	Treatment of Chronic Myeloid Leukaemia.		X					X	
Biological	Treatment of breast cancer.	X				X	X	X	
Biological	Treatment of squamous cell carcinoma of the head and neck.				X	X	X	X	X

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of actinic keratosis.			X				X	
Biological	Treatment of bleeding.	X					X	X	
Chemical	Treatment of hypertension.	X					X	X	
Chemical	Treatment of chronic thromboembolic pulmonary hypertension.		X					X	X
Chemical	Treatment of hypertension.	X						X	
Biological	Prevention of scarring.		X					X	
Chemical	Treatment of congenital ichthyoses.		X					X	X
Chemical	Treatment of UV-A and visible light-induced photosensitivity disorders.		X					X	
Biological	Prevention of chronic Hepatitis C infection.	X					X	X	
Biological	Immunisation against influenza virus infection.	X					X	X	
Biological	Immunisation against influenza virus infection.	X				X		X	
Biological	Immunisation against Neisseria meningitides infection.	X				X	X	X	
Biological	Immunisation against Streptococcus pneumoniae infection.		X					X	
Chemical	Treatment of HIV-1 infections.	X				X	X	X	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Repair of cartilage defects.	X				X	X	X	
Chemical	Treatment of Duchenne muscular dystrophy.		X					X	
Chemical	Treatment of the signs and symptoms of paediatric autistic spectrum disorder.	X					X	X	
Biological	Treatment of Cystic Fibrosis.		X					X	X
Biological	Treatment of neovascular age-related macular degeneration.	X					X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 15 Scientific Advice letters, 8 Protocol Assistance letters and 3 Follow-up Scientific Advice letters and 1Follow-up Protocol Assistance were adopted at the 16-19 July CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 33 new Requests for which the procedure started at the SAWP meeting held on 2-4 July. The new requests are divided as follows: 24 Initial Scientific Advice, 4 Follow-up Scientific Advice, 1 Initial Protocol Assistance and 4 Follow-up Protocol Assistance.

ANNEX 6 TO CHMP MONTHLY REPORT JULY 2007

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE JULY 2007 CHMP MEETING

BLOOD PRODUCTS WORKING PARTY (BPWP)

Reference number	Document	Status[4]
CPMP/BPWG/1561/99	Revised Draft Guideline on the Clinical Investigation of Human recombinant Factor VIII and IX Products	Adopted for 6-month public consultation
CHMP/BPWG/198/95 rev. 1	Revised draft Guideline on the Clinical Investigation of Human plasma derived Factor VIII and IX Products	Adopted for 6-month public consultation
CPMP/BPWG/1625/1999	Revised Core SPC for Human plasma derived and recombinant coagulation Factor IX products	Adopted for 6-month public consultation
CPMP/BPWG/1619/1999	Revised Core SPC for Human plasma derived and recombinant coagulation Factor VIII products	Adopted for 6-month public consultation

VACCINE WORKING PARTY (VWP)

Reference number	Document	Status[4]
EMEA/CHMP/308136/ 2007	Concept Paper on the revision of guidance for DNA vaccines	Adopted for 3-month public consultation
EMEA/CHMP/308139/ 2007	Concept Paper on the development of a Guideline on live recombinant vector vaccines	Adopted for 3-month public consultation

Working Party on Similar Biological (Biosimilar) Medicinal Products (BMWP)

Reference number	Document	Status[4]
EMEA/CHMP/BMWP/ 101695/2006	Draft Guideline on Comparability of Biotechnology-Derived Medicinal Products after a change in the manufacturing process – non clinical and clinical issues	Adopted.

[4] 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").

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[4]
EMEA/CHMP/QWP/ 396951/2006	Guideline on Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product	Adopted.

SAFETY WORKING PARTY (SWP)

Reference number	Document	Status[4]
EMEA/CHMP/SWP/ 294648/2007	Guideline on strategies to identify and mitigate risks for first in human Clinical Trials with investigational medicinal products	Adopted and will come into effect on the 1st September 2007

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[4]
EMEA/EWP/263148/2006	Guideline on Clinical Investigation of Immunosuppressants for Solid Organ Transplantation	Adopted for 6-month public consultation
EMEA/EWP/369963/2005	Guideline on the Development of Medicinal Products for the Treatment of Nicotine Dependence	Adopted for 6-month public consultation
EMEA/EWP/310566/2007	Concept Paper on the need for revision of the Guideline on Clinical Investigation of Hypnotic Medicinal Products	Adopted for 3-month public consultation
EMEA/CHMP/EWP/ 311890/2007	Guideline on the evaluation of medicinal products for cardiovascular disease prevention	Adopted for 6-month public consultation
CPMP/EWP/553/95 Rev. 1	Guideline on Alzheimer's Disease (Dementia)	Adopted for 6-month public consultation
CPMP/EWP/563/95 Rev. 1	Guideline on Parkinson's Disease	Adopted for 6-month public consultation

PAEDIATRIC COMMITTEE (PDCO)[5]

Reference number	Document	Status[4]
EMEA/288917/2007	List of paediatric needs - Psychiatry	Adopted for public consultation

[5] The previous Paediatric Working Party has ceased to exist and the Paediatric Committee is now in full operation.

ANNEX 7 TO CHMP MONTHLY REPORT JULY 2007

INVENTED NAME REVIEW GROUP (NRG)

	July 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names [1]	5	14	79	92
Justification for retention of invented name *[2]	3	4	15	19

*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]One justification for retention of a proposed invented name has been postponed to the September NRG meeting

[2] Two proposed invented name requests have been postponed to the September NRG meeting

	July 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	24	11	188	139
Criterion - Safety concerns				
Similarity with other Invented name	19	11	148	106
Conveys misleading therapeutic/pharmaceutical connotations	1	0	7	0
Misleading with respect to composition	2	0	6	0
Criterion - INN concerns				
Similarity with INN	0	0	6	7
Inclusion of INN stem	0	0	0	5
Criterion - Other public health concerns				
Unacceptable qualifiers	0	0	6	3
Conveys a promotional message	1	0	10	16
Appears offensive or has a bad connotation	0	0	0	2
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	5	0
Similarity between name of prodrug and related active substance	0	0	0	0

See Guideline on the Acceptability of Invented names for human medicinal products processed through the Centralised procedure (CPMP/328/98) for detailed explanations of criteria used.