European Medicines Agency
Evaluation of Medicines for Human Use

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

The Committee for Medicinal Products for Human Use (CHMP) held its October plenary meeting from 15-18 October 2007.

The Chairman welcomed Dr. Outi Lapatto-Reiniluoto as the newly nominated CHMP alternate from Finland and Prof. Lechat as the newly nominated CHMP alternate from France.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted 7 positive opinions by consensus on initial marketing authorisation applications, including 2 for biosimilar medicinal products and one for a generic medicinal product, recommending the granting of a marketing authorisation for the following medicinal products:

- **Abraxane** (5 mg/ml nanoparticle albumen bound paclitaxel), from Abraxis BioScience Limited, for the treatment as monotherapy of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard anthracycline-containing therapy is not indicated. EMEA review began on 27 September 2006 with an active review time of 202 days.

- **Atripla** [efavirenz/emtricitabine/tenofovir disoproxil (as fumarate)], from Bristol-Myers Squibb Gilead Sciences And Merck Sharp & Dohme Limited, for treatment of human immunodeficiency virus-1 (HIV-1) infection in adults. EMEA review began on 25 October 2006 with an active review time of 202 days.

- **Avamys** (fluticasone furoate), from Glaxo Group Ltd, for the treatment of the symptoms of allergic rhinitis. EMEA review began on 16 August 2006 with an active review time of 202 days.

- **Nevanac** (nepafenac), from Alcon Laboratories (UK) Limited, for the prevention and treatment of postoperative pain and inflammation associated with cataract surgery. EMEA review began on 24 January 2007 with an active review time of 205 days.

Positive opinion for similar biological medicinal products

The CHMP adopted positive opinions by consensus for the biosimilar medicinal product **Silapo** [epoetin zeta (rhEPO)], from Stada Arzneimittel AG, and **Retacrit** [epoetin zeta (rhEPO)], from Hospira Enterprises B.V., intended for the treatment of anaemia associated with chronic kidney disease and in oncology patients to treat anaemia and reduce blood-transfusion requirements, and to increase the yield of autologous blood in a pre-donation programme. Both medicinal products have been shown to be similar to Eprex/Erypo, the reference medicinal product already authorised in the EU in the applied indications. EMEA review began on 19 July 2006 for Silapo and 20 May 2007 for Retacrit with an active review time of 202 and 85 days respectively.

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Positive opinion for a generic medicinal product

The CHMP adopted a positive opinion for **Olanzapine Teva** (olanzapine), from Teva Pharma BV, for the treatment of schizophrenia and moderate to severe manic episode. The reference product for Olanzapine Teva is Zyprexa, from Eli Lilly Nederland B.V., which is already authorised in the EU, in the applied indications. EMEA review began on 27 December 2006 with an active review time of 177 days.

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

The EMEA has been formally requested by Wyeth Europa Limited, to re-examine the negative opinion for **Mylotarg** (gemtuzumab ozogamicin) to be used for the re-induction treatment of CD33-positive acute myeloid leukaemia patients in first relapse who are not candidates for other intensive re-induction chemotherapy regimens (e.g. high-dose ARA-C), adopted during the CHMP meeting on 17-20 September 2007.

Withdrawal

The EMEA has been formally notified by GlaxoSmithKline Biologicals s.a. of its decision to withdraw the application for a scientific opinion for the medicinal product **Globorix** vaccine (DTPw-HBV/Hib-MenAC, powder and suspension for suspension for injection). Globorix was intended to be used exclusively for markets outside of the European Union (EU). The application for Globorix was submitted under **Article 58** of Regulation (EC) No 726/2004, which allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in cooperation with the World Health Organization (WHO), on products that are intended for use outside the EU. A separate press release and question-and-answer document with more information are available.

Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP gave 5 positive opinions by consensus on applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Ariclaim** (duloxetine), from Eli Lilly Nederland B.V., to extend the indication to include diabetic peripheral neuropathic pain in adults. Ariclaim is currently authorised in women for the treatment of moderate to severe stress urinary incontinence.

- **MabCampath** (alemtuzumab), from Genzyme B.V., to extend the indication to first line treatment of B-cell chronic lymphocytic leukaemia (B-CLL) in patients for whom fludarabine combination chemotherapy is not appropriate. MabCampath was initially authorised for the second-line treatment of patients with chronic lymphocytic leukaemia (CLL) who have been treated with alkylating agents.

- **Remicade** (infliximab), from Centocor B.V., to update the psoriatic arthritis indication with improvement of physical function and reduction of the rate of progression of peripheral joint damage. Remicade is currently indicated for the treatment of rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

- **Taxotere** (docetaxel), from Aventis Pharma S.A., and **Docetaxel Winthrop** (docetaxel), from Aventis Pharma S.A., to change the indication for head and neck cancer from induction treatment in combination with cisplatin and 5-fluorouracil of inoperable locally advanced squamous cell carcinoma to induction treatment in combination with cisplatin and 5-fluorouracil of locally advanced squamous cell carcinoma. Taxotere and Docetaxel Winthrop are currently indicated for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer.

Negative opinion for extension of indication

The CHMP adopted a negative opinion by consensus for an extension of indication of **Zavesca** (miglustat), from Actelion Ltd. The indication applied for related to the treatment of neurological manifestations in patients with Niemann-Pick type C disease, an inherited neurodegenerative disease of childhood and adolescence. Zavesca is an orphan medicinal product. It is currently approved for the oral treatment of mild to moderate type 1 Gaucher disease. A separate question-and-answer document explaining the grounds for the negative opinion for the extension of indication is available on the EMEA website.

Summaries of opinions for all mentioned products, including their full indication, can be found here.

Re-examination procedure (Type II variations) under Article 6(9) of Commission Regulation (EC) No 1085/2003

The EMEA has been formally requested by Ipsen Ltd to re-examine the negative opinion for the extension of indication for **Nutropin AQ** (somatropin) to include the long-term treatment of children with severe idiopathic short stature (ISS) not explained by growth hormone deficiency (GHD) or other medical conditions and with a predicted adult height at least 1 standard deviation score (SDS) below the target height, adopted during the CHMP meeting on 17-20 September 2007.

Re-assessment of the benefits and risks of rosiglitazone and pioglitazone concluded

Finalising a review of rosiglitazone and pioglitazone, the CHMP confirmed that the benefits of these medicines continue to outweigh the risks. In addition, the Committee recommended to modify the product information for **Avandia** (rosiglitazone), from GlaxoSmithKline, to reflect the conclusions of the review. A separate press release and a question-and-answer document with more information are available, together with the summary of opinion.

Renewal of conditional approval

The CHMP recommended renewing the conditional marketing authorisation for Diacomit (stiripentol), from Laboratoires Biocodex, following the first annual renewal to confirm that the benefit-risk balance remains positive. Diacomit is indicated for the treatment of severe myoclonic epilepsy in infants in conjunction with clobazam and valproate. The conditional marketing authorisation was granted in January 2007.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted 3 Lists of Questions on initial applications under the optional 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 September 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 September 2007 CHMP plenary meeting are provided in **Annex 4**.

Name Review Group (NRG)

EMEA hosted a Joint meeting with Interested Parties (AESGP, EFPIA, EGA and EAEPC) and NRG Member States representatives on 15 October 2006. The upcoming revision 5 of the 'Guideline on the Acceptability of invented names for human medicinal products processed through the centralised procedure', gave grounds for discussion for this fifth annual interested parties meeting. The meeting report and the presentations will be published shortly.

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 5**.

REFERRAL PROCEDURES

Referral procedure concluded

The CHMP recommended the revocation of the marketing authorisation for a number of generic medicinal products containing **cetirizine dihydrochloride** because the bioequivalence with the reference medicinal product could not be established. The procedures were initiated by the Netherlands under Article 36 of Directive 2001/83/EC as amended for the following products and associated trade names: Cetirizine dihydrochloride-APEX 10mg, Cetirizine dihydrochloride Copyfarm 10mg, Cetirizine dihydrochloride Dermapharm 10mg and Cetirizine dihydrochloride Nordic Drugs 10 mg film-coated tablets. Further to a CHMP review conducted in 2006, the concerned national marketing authorisations were suspended by the European Commission because of concerns regarding good clinical and laboratory practices (GCP/GLP) compliance that impacted on the quality and reliability of bioequivalence studies supporting the marketing authorisations. Due to GCP concerns still identified in a further study, the CHMP recommended the revocation of the marketing authorisations for these generic medicinal products.

The CHMP finalised a procedure under Article 107, initiated as a result of the evaluation of pharmacovigilance data, for **cough medicines containing clobutinol**, following the suspension of the marketing authorisation for these medicines in Germany, due to concerns regarding side-effects affecting the heart. The CHMP concluded that the benefits of these medicines do not outweigh their risks and therefore recommended that the marketing authorisations for clobutinol-containing medicines be withdrawn throughout the EU. A separate press release and a question-and-answer document with more information are available.

Referral procedures started

The CHMP started a referral procedure for **Rapinyl 50, 100, 200, 300, 400, 600 and 800 microgram** (fentanyl citrate), from ProStrakan Ltd, intended for the treatment of pain. The referral procedure was initiated under Article 29(4) of 2001/83/EC because of a disagreement among some Member States whether additional data demonstrating efficacy and safety of Rapinyl in the management of breakthrough pain is required. Referral procedures under Article 29(4) are normally initiated because of disagreement between Member States on applications for medicinal products based on potential serious risk to public health.

At the request of the European Commission, the CHMP started a harmonisation referral under Article 30 of the Directive 83/2001/EC as amended for **Zyrtec/Reactine** (cetirizine), from UCB, because the product information for these medicines in the EU Member States shows clinically important differences in the approved indications and posology, as well as in further sections of the summary of product characteristics, in particular with regard to the paediatric population. Article 30 referrals are normally initiated with a view to harmonising product information for medicinal products authorised at Member State level.

OPINION UNDER ARTICLE 5(3) and 57(1)p OF REGULATION (EC) N° 726/2004

Back in October 2006, the EMEA received a request from the European Commission (EC) for the CHMP to draw up an opinion on the basis of Articles 5(3) and 57(1) of Regulation (EC) No 726/2004, on the potential risks of carcinogens, mutagens and substances toxic to reproduction (CMR) when these substances are used as excipients of medicinal products for human use. During its October meeting, the Committee adopted a final opinion concluding that Directive 2001/83 EC and Directive 78/25/EEC and/or 94/36/EC as amended and several guidelines supported the rigorous evaluation for safe use of excipients in medicinal products. The benefit-risk evaluation is a continuous process where new data on the safety of medicinal products and/or their excipients are regularly supplied and evaluated. Should any safety concern arise from this evaluation, appropriate safety measures would be taken on the concerned medicinal product(s) consistent with the current legal and regulatory framework in order to protect public health.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 22nd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 15-17 October 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 01-03 October 2007. For further details, please see **Annex 6**.

Documents prepared by the CHMP Working Parties adopted during the October 2007 CHMP meeting are listed in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2007 CHMP PLENARY MEETING

- The 38th meeting of the CHMP will be held at the EMEA on 12-15 November 2007.
- The next Name Review Group meeting will be held at the EMEA on 12th November 2007.
- The 23rd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 12-14 November 2007.

ORGANISATIONAL MATTERS

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

- Discussion on the finalisation of ICH Topic E 15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.
- The nomination of Prof. Borvendeg (Hungarian CHMP member) to be appointed on the Committee for Orphan Medicinal Products as a CHMP representative following the departure of Dr. Dunne (United Kingdom).
- Discussion on the update of the Draft 2 Revision 2 of the Guideline on Summary of Product Characteristics. The aim is to release this updated version to the public for an external consultation by the end of the year.
- The adoption of a draft Reflection Paper on “Pharmacovigilance Urgent Measures” - Procedure under Article 107(2) of Directive 2001/83/EC, as amended. The document will now be sent to the European Commission.
- Initial discussion on the learning acquired on EU Risk Management Plans (RMP). Once these discussions have been finalised, interactive workshops with companies will be scheduled.
- Initial discussion on the Advanced Therapies Regulation and consequences for the CHMP.
- Initial discussion on the draft implementation plan / innovative drug development approaches, based on the final report from the EMEA/CHMP-think tank group on innovative drug development.

- Discussion on the Data analysed by Data Monitoring Committees**.**
- The draft Agenda for the FDA/EMEA meeting on evaluation of pandemic/prepandemic influenza vaccines for licensing/marketing authorisation to be held at the EMEA on 26-27 November 2007.
- The draft Agenda for the EMEA/ICH Workshop on viral vector shedding to be held in Rotterdam on 30 October 2007 in conjunction with the annual meeting of the XVth Annual Congress of the European Society of Gene and Cell Therapy.
- The draft Agenda for the ICH Gene Therapy Discussion Group meeting to be held in Rotterdam on 31 October – 1 November 2007.
- The nomination of Dr. Silva Lima to participate in the WHO Pilot Phase exercise with developing Countries Regulatory Authorities

PROCEDURAL ANNOUNCEMENT

- Submission of Type IA and Type IB variations in December 2007

  Please note that the EMEA will be closed between 24 December 2007 and 2 January 2008 (inclusive).

  Marketing Authorisation Holders are therefore requested not to submit Type IA variation applications to the EMEA between 10 and 21 December 2007 (inclusive) because of the 14-day timeframe for the Agency to acknowledge the validity of the submitted Type IA variation (see article 4 of Commission Regulation (EC) No 1085/2003) as this would coincide with the official closure of the EMEA.

  Type IA variation applications submitted no later than 7 December 2007 will be finalised before the EMEA Christmas break. Any Type IA variation applications submitted to the EMEA between 10 December 2007 and 2 January of 2008 will start on 3 January 2008.

  Marketing Authorisation Holders intending to apply for Type IB variations in December 2007 are encouraged to liaise with the EMEA prior to their submission.

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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

ANNEX 1 TO CHMP MONTHLY REPORT OCTOBER 2007

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	34	5	0	4	17	8	6	74	649
Positive opinions	17	4	0	4	13	7	5	50	429
Negative opinions[1]	0	0	0	0	2	1	0	3	15
Withdrawals prior to opinion	3	1	0	0	5	0	2	11	114
Marketing authorisation granted by the Commission	21	1	0	1	9	6	8	46	411

PRE-AUTHORISATION: SCIENTIFIC SERVICES

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

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

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

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)	809	5005
Type II Variations (positive opinions)	658	3520
Type II Variations (negative opinions)	2	10
Annex II Applications (positive opinions)	27	169
Annual Re-assessment (positive opinions)	19	-
Opinion for renewals of conditional MA's (positive opinions)	1	1
5 Year Renewals (positive opinions)	44	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
5 Extensions of indication	8Positive opinions
39 SPC changes	38 Positive opinions 1 Negative OPinion
22 Quality changes	22 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Aldurazyme (laronidase) Genzyme B.V.	Positive Opinion adopted	The product remains under exceptional circumstances.

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Diacomit (stiripentol) Laboratoires Biocodex,	Positive Opinion adopted	N/A

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Quadramet (samarium [153Sm] lexidronam) CIS bio International	Positive Opinion adopted	Unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT OCTOBER 2007

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

Invented Name	Galvus
INN	vildagliptin
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	A10BH02
Indication	Vildagliptin is indicated in the treatment of type 2 diabetes mellitus: As dual oral therapy in combination with metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin, a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance, a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.
CHMP Opinion date	19.07.2007
Marketing Authorisation Date	26.09.2007

Invented Name	Zalasta
INN	olanzapine
Marketing Authorisation Holder	Krka, d.d., Novo mesto
Proposed ATC code	N05AH03
Indication	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder (see section 5.1).
CHMP Opinion date	19.07.2007
Marketing Authorisation Date	27.09.2007

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

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
N/A	N/A	N/A	N/A

ANNEX 5 TO CHMP MONTHLY REPORT OCTOBER 2007

INVENTED NAME REVIEW GROUP (NRG)

	October 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names[1]	46	25	132	132
Justification for retention of invented name *[2]	4	1	21	25

*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 October NRG meeting

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

	October 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	30	59	243	222
Criterion - Safety concerns				
Similarity with other Invented name	29	45	200	165
Conveys misleading therapeutic/pharmaceutical connotations	0	0	7	1
Misleading with respect to composition	1	1	7	1
Criterion - INN concerns				
Similarity with INN	0	6	7	17
Inclusion of INN stem	0	4	0	10
Criterion - Other public health concerns				
Unacceptable qualifiers	0	1	6	4
Conveys a promotional message	0	2	11	21
Appears offensive or has a bad connotation	0	0	0	3
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	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.

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

	1995 - 2006	2007	Overall Total
Scientific Advice	718	128	846
Follow-up to Scientific Advice	127	36	163
Protocol Assistance	157	33	190
Follow-up to Protocol Assistance	40	21	61
	1042	**218**	**1260**

OUTCOME OF THE OCTOBER 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 prostate cancer	X					x	X	
Chemical	Treatment of multiple myeloma.	X						X	
Chemical	Treatment of pancreatic cancer		X					X	X
Chemical	Treatment of astrocytomas, angiomyolipomata, and lymphangioleiomyomatosis	X						X	
Biological	Treatment of Non-Hodgkin-Lymphoma	X						X	
Chemical	Treatment of Soft Tissue Sarcoma		X				X	X	X
Chemical	Treatment of ovarian cancer	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 Anaplastic astrocytoma		X			X	X	X	X
Biological	Treatment of deep vein thrombosis and pulmonary embolism	X				X	X	X	
Biological	Treatment of anemia	X				X	X	X	
Biological	Treatment and prevention of bleeding	X				X	X	X	
Biological	Treatment of acute bleeding in patients with congenital fibrinogen deficiency	X						X	
Biological	Prevention of bleeding in hemophilia A			X			X	X	
Biological	Treatment of invasive candidiasis				X			X	
Biological	Prevention of tuberculosis		X			X		X	
Chemical	Treatment of onychomycosis	X					X	X	
Chemical	Treatment of benign prostatic hyperplasia	X						X	
Chemical	Treatment of urinary incontinence		X					X	
Biological	Slowing of disease progression dementia of the Alzheimer type			X				X	
Chemical	Treatment of epilepsy	X					X	X	
Chemical	Treatment of symptomatic neurogenic orthostatic hypotension	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 fibromyalgia	X					X	X	
Chemical	Treatment of chronic obstructive pulmonary disease	X						X	
Biological	Treatment of diffuse alveolar hemorrhage		X				X	X	
Chemical	Treatment of asthma and chronic obstructive pulmonary disease	X				X	X	X	
Chemical	Treatment of Cystic Fibrosis.		X			X		X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 16 Scientific Advice letters, 7 Protocol Assistance letters, 2 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letters were adopted at the 18-21 June CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 25 new Requests for which the procedure started at the SAWP meeting held on 1-3 October 2007. The new requests are divided as follows: 16 Initial Scientific Advice, 5 Follow-up Scientific Advice, 1 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

ANNEX 7 TO CHMP MONTHLY REPORT OCTOBER 2007

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

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

Reference number	Document	Status[3]
EMEA/CHMP/BMWP/ 102046/2006	Guideline on Similar Medicinal Products Containing Recombinant Interferon Alpha	Adopted for 6-month public consultation.

CHMP PHARMACOGENETICS WORKING PARTY (PgWP)

Reference number	Document	Status[3]
EMEA/CHMP/PGxWP/ 201914/2006	Reflection Paper on Pharmacogenomic Samples, testing and data handling	Adopted

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/CHMP/EWP/ 453780/2007	Recommendation for Revision of the Note for Guidance on Epilepsy	Adopted for 3-month public consultation.
CPMP/EWP/4151/00 Rev. 1	Guideline on the requirements for clinical documentation for Orally Inhaled Products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD)	Adopted for 3-month public consultation.
CHMP/EWP/2459/02	Guideline on Methodological Issues in Confirmatory Clinical Trials planned with an Adaptive Design	Adopted

[3] 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").