European Medicines Agency
Evaluation of Medicines for Human Use

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

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) held its June plenary meeting from 18-21 June 2007.

This June plenary meeting saw the election of the new Chair and Vice-Chair of the Committee. Dr. Abadie was elected as Chairperson and Dr. Salmonson as Vice-Chairperson, both with a 3-year mandate that started on the 18th June 2007.

Centralised procedure

Initial applications for marketing authorisation

The CHMP adopted eleven positive opinions by consensus on initial marketing authorisation applications at this meeting, three of which related to similar biological medicinal products:

- **Atriance** (nelarabine), from Glaxo Group Limited, intended for the treatment of T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) of patients in second relapse. **Atriance is the 40th orphan medicinal product to receive a positive opinion.**
  EMEA review began on 21 June 2006 with an active review time of 203 days.
  Atriance is the first medicinal product for which an application was submitted using the Product Information Management (PIM) system. PIM enables the electronic exchange of the product information part of a marketing authorisation application in the European Union. Its aim is to increase efficiency of the management and exchange of the product information and to improve the quality and consistency of the published product information.

- **Gliolan** (5-aminolevulinic hydrochloride), from Medac, intended for the visualisation of malignant tissue during surgery for malignant glioma in adult patients. **Gliolan is the 41st orphan medicinal product to receive a positive opinion**. EMEA review began on 24 May 2006 with an active review time of 199 days.

- **Flebogammadif** [human normal immunoglobulin (IVIg)], from Instituto Grifols S.A., intended for replacement therapy in immunodeficiency and for immunomodulation in immune-mediated diseases. EMEA review began on 27 September 2006 with an active review time of 177 days.

- **Rasilez, Enviage, Sprimeo, Tekturna and Riprazo** (aliskiren), from Novartis Europharm Ltd, intended for the treatment of essential hypertension. EMEA review began on 27 September 2006 for Rasilez and on 25 March 2007 for Enviage, Sprimeo, Tekturna and Riprazo with an active review time of 194 days for Rasilez and 77 days for Enviage, Sprimeo, Tekturna and Riprazo.

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The three positive opinions adopted for similar biological medicinal products related to **Binocrit** (Epoetin alfa), from Sandoz GmbH, **Epoetin alfa Hexal** (Epoetin alfa), from Hexal Biotech Forschungs GmbH, and **Abseamed** (Epoetin alfa), from Medice Arzneimittel Pütter GMBH & Co. These medicinal products are intended for the treatment of anaemia associated with chronic kidney disease and in oncology patients; and to reduce blood transfusion requirements in oncology patients and prior to elective orthopaedic surgery. All three 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 29 March 2006 with an active review time of 205 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.

Extensions of indication and other recommendations

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

- **Arixtra** and **Quixidar** (fondaparinux sodium) 2.5 mg, from Glaxo Group, to extend the indication to add treatment of acute coronary syndromes in patients with unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) for whom urgent (<120 min) invasive management (PCI) is not indicated; and in patients with ST segment elevation myocardial infarction (STEMI) who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy. Arixtra 2.5mg is currently authorised for prevention of venous thromboembolic events (VTE) in patients undergoing major orthopaedic surgery; abdominal surgery and who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery, and in patients who are judged to be at high risk for VTE and are immobilised. Arixtra (5, 7.5 and 10 mg) is also authorised for the treatment of acute deep vein thrombosis (DVT) and treatment of acute pulmonary embolism (PE), except in haemodynamically unstable patients or patients who require thrombolysis or pulmonary embolectomy.

- **Zostavax** (Zoster Vaccine, Live), from Sanofi Pasteur MSD, to extend the indication to individuals 50 years of age or older. Zostavax is currently indicated for prevention of herpes zoster and herpes zoster-related post-herpetic neuralgia (PHN) for individuals 60 years of age or older.

New contraindications

Following a literature review describing the interaction of four known inhibitors of CYP3A (ketoconazole, lopinavir/ritonavir, clarithromycin, saquinavir) with midazolam, the CHMP recommended to vary the product information for all protease inhibitors to contraindicate the concomitant use with *oral* midazolam and to provide further directions concerning co-administration with *parenteral* midazolam in the interaction section of the SPC. The product information for the following protease inhibitors used in the treatment of AIDS/HIV infections has now been amended: **Agenerase, Crixivan, Prezista, Kaletra, Norvir, Telzir** and **Viracept**.

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

Action plan following the recall of Viracept and recommendation to suspend the marketing Authorisation

The CHMP agreed on an action plan to follow-up patients who were exposed to contaminated Viracept (nelfinavir), from Roche Registration Limited, and recommended the suspension of the marketing authorisation to the European Commission. Viracept is an antiretroviral medicine used to treat HIV-1 infected adults, adolescents and children of 3 years of age and older. The recommendation to suspend Viracept follows the recall of the medicinal product from the European market in early June 2007 because some batches had become contaminated during the manufacturing process with ethyl mesylate, a known genotoxic substance (harmful to DNA).

A separate press release and a question-and-answer document with more information are available.

Lists of Questions

The Committee adopted six Lists of Questions on initial applications (four under the mandatory scope, two under the optional scope including one generic application) and one List of Questions on "line extensions" applications (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003.

Detailed information on the centralised procedure

An overview of 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 May 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 May 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 **lansoprazole 15 and 30 mg Gastroresistant Capsules** (lansoprazole), from Teva. The CHMP concluded that bioequivalence with the originator medicinal product has been documented sufficiently and therefore recommended the medicinal product for approval for the treatment of gastro oesophageal reflux disease, ulcers, acid related dyspepsia and as an adjuvant in the eradication of Helicobacter pylori. Referrals under Article 29 are usually initiated because of disagreement among the Member States in the context of the mutual recognition procedure.

The CHMP finalised a referral procedure under Article 31 of the Community code on human medicinal products (Directive 2001/83/EC as amended) for **Piroxicam**. The CHMP concluded that piroxicam should no longer be used for treatment of short-term painful and inflammatory conditions. Piroxicam can still be prescribed for the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. However it should not be the first choice of non-steroidal anti-inflammatory drug (NSAID) treatment in these conditions. This referral was initiated further to the request of the European Commission, in September 2006, because a review of non-selective NSAIDs showed that piroxicam could be associated with a higher risk of gastrointestinal side effects and serious skin reactions than other non-selective NSAIDs. 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 **Coxtral gel 3%** (nimesulide), from Zentiva, because of concerns regarding equivalence with the originator medicinal product. This procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended).

The CHMP started a harmonisation referral for **Gemzar** (gemcitabine), from Lilly, on the request of the European Commission. The procedure was initiated under Article 30 of the Community code on human medicinal products (Directive 2001/83/EC as amended). This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level.

The CHMP started a referral procedure for **ergot-derived dopamine agonists** (bromocriptine,

cabergoline, dihydroergocryptine, lisuride and pergolide), a class of medicines that is primarily used in the treatment of Parkinson's disease. The referral procedure was initiated by the United Kingdom under Article 31 of the Community code on human medicinal products (Directive 2001/83/EC as amended) to re-assess the balance of benefits and risks of all these products in view of the risk of fibrotic disorders and cardiac valvulopathy reported with some of these medicines. Referrals under Article 31 are usually initiated in cases involving the interests of the Community or concerns relating to the protection of public health.

Other procedures

The CHMP started last month a review under Article 107(2) of systemic formulations of **nimesulide**-containing medicinal products due to concerns over serious liver problems.
In view of the complexity of this review and the need to allow adequate time for assessment of the issues, the CHMP agreed to revise the timetable and reach a scientific opinion in September 2007 on whether the marketing authorisations for nimesulide should be maintained, changed, suspended or revoked in the Member States where it is marketed.

Re-examination procedure under Article 9(2) if Regulation (EC) No. 726.2004

The European Medicines Agency has been formally requested by Amgen to re-examine the negative opinion for **Vectibix** (panitumumab) adopted during the CHMP meeting that took place on 21-24 May 2007.

Acomplia review of psychiatric safety profile

The CHMP, as part of the continuous monitoring of the safety of Acomplia/Zimulti (rimonabant), is currently reviewing the available data on psychiatric events (in particular suicidal ideation and depression-related events). The review is expected to be finalised at the July CHMP meeting and its outcome will be communicated then.

Mutual Recognition procedure and Decentralised procedures-Human

The CHMP noted the report from the 19th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 18-20 June 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 4-6 June 2007. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the June 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 April 2007 CHMP plenary meeting:

- The 35th meeting of the CHMP will be held at the EMEA on 16-19 July 2007.
- The next Invented Name Review Group meeting will be held at the EMEA on 16th July 2007.

- The 20th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 16-18 July 2007.
- A SAG Anti-Infectives meeting will take place on the 10th July 2007.

Organisational matters

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

- Initial discussion regarding the proposal for complementary scientific expertise for the future appointment of new Co-Opted members to CHMP.
- The EMEA suggestions for revision of the European Commission guideline on the assessment of similarity and/or clinical superiority for orphan medicinal products. These suggestions related to the section of the guideline on the mechanism of action and were adopted by the Committee for transmission to the European Commission.
- Discussion regarding the meeting of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance and to be held on the 28th June 2007. This meeting will be followed by a Joint EMEA/DG Research Workshop on the 7th Framework programme on the 29th June 2007.
- Follow on discussion on proposals for the Project on Important Public Health Issues for Drug Safety Research conducted by DG Research within the scope for the Health Theme in 7th Framework Programme. The Committee proposed five areas that could potentially benefit from European Commission funding to enhance research.
- Follow on discussion on the multi-disciplinary CHMP ad hoc group on HIV prophylactic vaccines. The Committee adopted the draft agenda for the meeting to be held on the 11th July 2007.
- The Experts Workshop on Creutzfeldt Jacob Disease and urine-derived medicinal products to be held on 12 - 13 July 2007.
- The report on the EMEA Workshop on the Guideline for the first-in-man clinical trials for potential high-risk medicinal products held on the 12th June 2007.
- The report on the ICH meeting held in Brussels on the 6-10 May 2007.

PROCEDURAL ANNOUNCEMENT

- The CHMP agreed to replace the August 2007 plenary meeting by written procedures to be established for certain ongoing applications.

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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	18	3	0	1	12	4	2	40	615
Positive opinions	14	2	0	1	9	2	3	31	410
Negative opinions[1]	0	0	0	0	2	1	0	3	15
Withdrawals prior to opinion	3	1	0	0	3	0	1	8	111
Marketing authorisation granted by the Commission	11	1	0	0	4	4	4	24	389

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)	0	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 JUNE 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	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)	425	4620
Type II Variations (positive opinions)	383	3245
Type II Variations (negative opinions)	0	8
Annex II Applications (positive opinions)	15	157
Annual Re-assessment (positive opinions)	17	-
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	29	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
3 Extensions of indication	3 Positive opinions
33 SPC changes	33 Positive opinions
14 Quality changes	14 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Orfadin (nitisinone) Swedish Orphan International AB	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**
Aprovel (irbesartan) Sanofi Pharma Bristol Myers Squibb SNC	Positive Opinion adopted	Unlimited validity
Karvea (irbesartan Bristol Myers Squibb Pharma EEIG	Positive Opinion adopted	Unlimited validity
EVRA (norelgestromin - ethinylestradiol) Janssen-Cilag International NV	Positive Opinion adopted	The Committee agreed that a further 5-year renewal would be required
Ambirix (inactivated hepatitis A virus hepatitis B surface antigen, rDNA) GlaxoSmithKline Biologicals	Positive Opinion adopted	The Committee agreed that a further 5-year renewal would be required
InductOs (dibotermin alfa) Wyeth Europa Ltd	Positive Opinion adopted	The Committee agreed that a further 5-year renewal would be required
Zavesca (miglustat) Actelion Ltd	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 MAY 2007 CHMP MONTHLY REPORT

Invented Name	Orencia
INN	abatacept
Marketing Authorisation Holder	Bristol-Myers Squibb Pharma EEIG
Proposed ATC code	L04AA24
Indication	For the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease-modifying anti-rheumatic drugs including at least one tumour necrosis factor (TNF) inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate
CHMP Opinion date	22.03.2007
Marketing Authorisation Date	21.05.2007

Invented Name	Revlimid
INN	lenalidomide
Marketing Authorisation Holder	Celgene Europe Limited
Proposed ATC code	L04 AX04
Indication	Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
CHMP Opinion date	22.03.2007
Marketing Authorisation Date	14.06.2007

Invented Name	Altargo
INN	retapamulin
Marketing Authorisation Holder	Glaxo Group Ltd
Proposed ATC code	D06AX13
Indication	Short term treatment of the following superficial skin infections: Impetigo. Infected small lacerations, abrasions, or sutured wounds. See sections 4.4 and 5.1 for important information regarding the clinical activity of retapamulin against different types of *Staphylococcus aureus.* Consideration should be given to official guidance on the appropriate use of antibacterial agents.
CHMP Opinion date	22.03.2007
Marketing Authorisation Date	24.05.2007

Invented Name	Optaflu
Common Name	Influenza vaccine (surface antigen, inactivated, prepared in cell culture
Marketing Authorisation Holder	Novartis Vaccines and Diagnostics GmbH & Co. KG
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza for adults, especially in those who run an increased risk of associated complications. The use of Optaflu should be based on official recommendations.
CHMP Opinion date	26.04.2006
Marketing Authorisation Date	01.06.2007

Invented Name	Soliris
INN	Eculizumab
Marketing Authorisation Holder	Alexion Europe SAS
Proposed ATC code	L04AA25
Indication	Soliris (eculizumab) is indicated for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions.
CHMP Opinion date	26.04.2007
Marketing Authorisation Date	20.06.2007

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

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

	1995 - 2006	2007	Overall Total
Scientific Advice	718	74	792
Follow-up to Scientific Advice	127	20	147
Protocol Assistance	157	24	181
Follow-up to Protocol Assistance	40	12	52
	1042	**130**	**1172**

OUTCOME OF THE JUNE 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 type 2 diabetes mellitus	X					X	X	
Chemical	Treatment of diarrhoea	X					X	X	
Biological	Treatment of diabetes mellitus	X				X	X	X	
Biological	Treatment of short bowel syndrome				X			X	
Biological	Treatment of Systemic Lupus Erythematous	X						X	
Chemical	Treatment of carcinoma of unknown primary	X						X	
Chemical	Treatment of Oesophageal Cancer	X						X	
Biological	Treatment of Neutropenias	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				
Innovative product	Treatment of Pancreatic Cancer		X			X	X	X	
Chemical	Treatment of Relapsing Form of Multiple Sclerosis	X					X	X	
Chemical	Treatment of focal ablation of index tumours in patients with localised Prostate Cancer	X				X	X	X	
Biological	Treatment of CD20-positive B lymphocyte malignancies	X					X		
Biological	Treatment of Severe Combined Immunodeficiency due to adenosine deaminase deficiency		X				X	X	
Biological	Protection against malaria disease and against infection with hepatitis B	X				X	X	X	
Chemical	Prevention of atherothrombotic events			X				X	
Chemical	Prevention of cardiovascular events	X						X	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Prevention of stroke and systemic thromboembolic events			X				X	
Chemical	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension				X		X		
Biological	Diphtheria, Tetanus, acellular Pertussis, Hepatitis B, inactivated Poliomyelitis, adsorbed conjugated Haemophilus influenzae type b vaccine.	X				X	X	X	
Biological	Treatment of Cystic Fibrosis				X		X	X	
Biological	Influenza vaccine			X		X	X	X	
Biological	Treatment of meningococcal septicaemia		X			X	X	X	X
Chemical	Relief of acute pain associated with dental surgery	X						X	
Chemical	Treatment of bone metastases	X						X	
Chemical	Adjunctive therapy in patients with partial-onset seizures	X						X	
Chemical	Treatment of Parkinson's disease			X				X	
Biological	Treatment of relapsing-remitting Multiple Sclerosis	X						X	
Chemical	Treatment of Parkinson's disease	X				X	X	X	
Chemical	Treatment of severe myoclonic epilepsy		X					X	
Chemical	Treatment of hyperphosphataemia	X				X	X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 19 Scientific Advice letters, 4 Protocol Assistance letters, 4 Follow-up Scientific Advice letters and 3 Follow-up Protocol Assistance letters were adopted at the 18-21 June 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 4-6 June 2007. The new requests are divided as follows: 19 Initial Scientific Advice, 3 Follow-up Scientific Advice, 6 Protocol Assistance and 2 Follow-up Protocol Assistance.

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

QUALITY THERAPY WORKING PARTY (QWP)

Reference number	Document	Status[3]
CHMP/CVMP/QWP/ 242720/2007	Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC	Adopted
CHMP/CVMP/QWP/ 221929/2007	Overview of Comments received on the Draft Guideline on Declaration of Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC	Adopted
CHMP/CVMP/QWP/ 221930/2007	Guideline on Quality of combination Herbal Medicinal Products/Traditional Herbal Medicinal Products	Adopted
CHMP/CVMP/QWP/ 249641/2007	Question & Answer document on Applicability of ASMF (Active Drug Master File) Procedure	Noted
CHMP/CVMP/QWP/ 255695/2007	Question & Answer document on implementation of Ph. Eur. Chapters 2.6.12, 2.6.13 and 5.1.4	Noted
CHMP/CVMP/QWP/ 241559/2007	Question and Answer document on Storage conditions	Noted

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CHMP/EWP/260831/2007	Guideline on reporting the results of population pharmacokinetic analyses	Adopted
CHMP/EWP/260830/2007	Overview of comments document	Adopted

PAEDIATRIC WORKING PARTY (PEG)

Reference number	Document	Status[3]
EMEA/211056/2007	Assessment of the paediatric needs diabetes type 1 and 2 – after public consultation	Adopted
EMEA/179886/2007	Overview of comments received on List of Paediatric needs diabetes type 1 and 2	Noted

[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").

ANNEX 7 TO CHMP MONTHLY REPORT JUNE 2007

INVENTED NAME REVIEW GROUP (NRG)

	June 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names [1]	19	16	74	78
Justification for retention of invented name *	4	4	12	15

*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]Justification for retention of a proposed invented name has been postponed to the July NRG meeting

	May 2007		June 2007		2007	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	31	24	35	17	164	128
Criterion - Safety concerns						
Similarity with other Invented name	21	21	28	6	129	95
Conveys misleading therapeutic/pharmaceutical connotations	2	0	1	0	6	0
Misleading with respect to composition	1	0	2	0	4	0
Criterion - INN concerns						
Similarity with INN	1	0	2	4	6	7
Inclusion of INN stem	0	1	0	2	0	5
Criterion - Other public health concerns						
Unacceptable qualifiers	4	2	2	0	6	3
Conveys a promotional message	1	0	0	5	9	16
Appears offensive or has a bad connotation	0	0	0	0	0	2
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	0	0	4	0
Similarity between name of prodrug and related active substance	0	0	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.