European Medicines Agency
Evaluation of Medicines for Human Use

London, 27th November 2008
EMEA/612074/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
NOVEMBER 2008 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its November plenary meeting from 17-20 November 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted five positive opinions by consensus and two by majority (Valdoxan/Thymanax) on initial marketing authorisations.

New medicinal products

- **Nplate** (romiplostim), from Amgen Europe B.V., for the treatment of adult chronic immune (idiopathic) thrombocytopenic purpura (ITP). Nplate is **the 51st orphan medicine** to receive a positive opinion by the CHMP. EMEA review began on 21 November 2007 with an active review time of 203 days.
- **Rasilez HCT (**aliskiren hemifumarate/hydrochlorothiazide), from Novartis Europharm Ltd., for the treatment of essential hypertension in adults. Rasilez HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone. Rasilez HCT is indicated as substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination**.** EMEA review began on 26 December 2007 with an active review time of 195 days.
- **RoActemra** (tocilizumab), from Roche Registration Limited, for the treatment in combination with methotrexate of moderate to severe active rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs or tumour necrosis factor antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate. EMEA review began on 26 December 2007 with an active review time of 205 days.
- **Stelara** (ustekinumab), from Janssen-Cilag International NV, for the treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to other systemic therapies. EMEA review began on 26 December 2007 with an active review time of 204 days.
- **Valdoxan/Thymanax** (agomelatine), from Les Laboratories Servier, for the treatment of major depressive episodes in adults. EMEA review began on 27 September 2007 with an active review time of 203 days.
- **Zevtera** (ceftobiprole medocaril), from Jannsen-Cilag International NV, for the treatment of complicated skin and soft tissue infections. EMEA review began on 20 July 2007 with an active review time of 175 days.

Biosimilar medicines

The Committee adopted a positive opinion by consensus for **Filgrastim Hexal** (filgrastim) from Hexal Biotech Forschungs GmbH and **Zarzio (**filgrastim), from Sandoz GmbH, for the treatment of

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neutropenia. Both medicines have been shown to be similar to Neupogen, from Amgen GmbH, the reference medicinal product already authorised in the European Union, in the indication applied for. EMEA review began on 27 September 2007 with an active review time of 204 days.

Negative opinion

The CHMP adopted a negative opinion by majority recommending the refusal of a marketing authorisation for **Ixempra** (ixapebilone), from Bristol-Myers Squibb EEIG. Ixempra was intended to be used for the treatment of metastatic or locally advanced breast cancer. EMEA review began on 25th October 2007 with an active review time of 203 days.

A separate question-and-answer document with more detailed information about the negative opinion is available here.

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 European Medicines Agency (EMEA) has been formally requested by Sepracor Pharmaceuticals Ltd, to re-examine the positive opinion for **Lunivia** intended to be used for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening, in adults, usually for short-term duration, adopted during the CHMP meeting on 20th – 23rd October 2008. The applicant is challenging the fact that the CHMP did not consider Lunivia to be a new active substance.

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

Following the re-examination of the negative opinion adopted on 24th July 2008, the CHMP confirmed its previous position and adopted a final negative opinion by consensus for **Sovrima** ((idebenone), from Santhera Pharmaceuticals (Deutschland) GmbH, a designated orphan medicine intended to be used for treatment of Friedreich's Ataxia, an inherited condition that causes progressive damage to the nervous system and heart disease.

A separate question-and-answer document with more information about the re-examination procedure is available here.

Withdrawals

- The European Medicines Agency (EMEA) has been formally notified by Novagali Pharma S.A. of its decision to withdraw its application for an initial marketing authorisation for **Vekacia** (ciclosporin) 0.05% eye drops. Vekacia was expected to be used for the treatment of vernal keratoconjunctivitis. Vekacia was designated as an orphan medicine on 6 April 2006. A separate press release and a question-and-answer document with more information are available.
- The question-and-answer document on the withdrawal of application for **Vibativ** (telavancin), 15 mg/ml powder for concentrate for solution for infusion which was originally announced in the October CHMP monthly report is now available on the EMEA website.

Post-authorisation procedures

Extensions of indication and other recommendations

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

- **Enbrel** (etanercept), from Wyeth Europe Ltd, to extend the indication to include the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies. Enbrel is currently indicated for the treatment of rheumatoid arthritis, polyarticular juvenile idiophatic arthritis, psoriatic arthritis, ankylosing spondylitis, and moderate to severe plaque psoriasis in adults.
- **Prezista** (darunavir), from Janssen-Cilag International NV, to extend the indication to include the treatment of antiretroviral-therapy naïve HIV-1 infected adults. This indication comes with a new strength of 400 mg film-coated tablet. Prezista is currently indicated as a combination treatment of HIV-1 infection in highly pre treated adult patients who failed more than one regimen containing a protease inhibitor.

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

Updated safety information

The MAH, Wyeth Europe Ltd, agreed with the CHMP on a Direct Healthcare Professional Communication to oncologists concerning the timing of and monitoring for infusion/hypersensitivity reactions (including some life-threatening and rare fatal reactions) associated with administration of **Torisel** (temsirolimus) 25 mg/ml concentrate and diluent for solution for infusion. Further, it was agreed between the MAH and the CHMP to update sections 4.4 and 4.8 of the Summary of Product Characteristics with further information and recommendations regarding infusion/hypersensitivity reactions.

Other information

Following reports of medication errors between **Advagraf** (prolonged release formulation of tacrolimus to be taken once daily) and **Prograf** (immediate release formulation of tacrolimus to be taken twice daily), some of which have led to serious adverse reactions, the CHMP agreed with the MAH, Astellas Pharma Europe B.V., on a number of actions to prevent such medication errors. A Direct Healthcare Professional Communication will be sent to transplant specialists, general practitioners, hospitals and community pharmacists. Furthermore, the outer packaging will be modified to better differentiate the two formulations. The Summary of Product Characteristics and the Package Leaflet will also be updated to include warnings and precautions. These additional risk minimisation activities will be discussed in an updated risk management plan in which the effectiveness of the actions taken will be measured.

Withdrawals

- The European Medicines Agency (EMEA) has been formally notified by Sanofi-Aventis Pharma S.A. of its decision to withdraw its application for an extension of indication for the centrally authorised medicines **Taxotere** (docetaxel) 20 mg/0.5 ml and 80 mg/2 ml concentrate and solvent for solution for infusion and **Docetaxel Winthrop** (docetaxel) 20 mg/0.5 ml and 80 mg/2 ml concentrate and solvent for solution for infusion. Taxotere and Docetaxel Winthrop were expected to be used for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2 in the following combinations:
  - in combination (given simultaneously) with trastuzumab following a chemotherapy regimen based on doxorubicin and cyclophosphamide;
  - in combination with trastuzumab and carboplatin.

  A separate press release and a question-and-answer document with more information are available.
- The European Medicines Agency (EMEA) has been formally notified by Pfizer Limited of its decision to withdraw its application for a change to the marketing authorisation for the medicine **Viagra** (sildenafil) 50 mg film-coated tablets. The change concerned switching the classification of the medicine from “medicinal product subject to medical prescription” to “medicinal product not subject to medical prescription” (an over-the-counter [OTC] medicine). A separate press release with more information is available.

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

Opinion under Article 5(3) and 57 (1)p of Regulation (EC) No 726/2004

The European Medicines Agency (EMEA) has completed a review of the evidence available on the safety of conventional antipsychotic medicines in elderly patients with dementia. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is some evidence that the use of these medicines can increase the risk of death in this group of patients and therefore recommended that a warning should be included in the product information for all conventional antipsychotics. Further information is available in a question-and-answer document.

Suspension of marketing authorisation

The CHMP recommended the suspension of the marketing authorisation for **Ionsys** (fentanyl hydrochloride), from Janssen-Cilag International NV, because of a defect with the delivery system of the medicine that could lead to patients being overdosed. A separate press release and a question-and-answer document are available.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted eight Lists of Questions on initial applications (including three under the mandatory scope, five under the optional scope) and one List of Questions on a "line extension" application (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 October 2008 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 October 2008 CHMP plenary meeting are provided in **Annex 4**.

Name Review Group (NRG)

Joint NRG/EFPIA Workshop on invented names:

A Joint NRG/EFPIA Workshop took place in the morning of 3rd November 2008 with the purpose of exchanging information including on qualifiers, naming conventions/principles for pre-pandemic flu vaccines, as well as on other aspects of the NRG review process with the aim of improving its predictability of outcome.

Joint NRG/Interest parties meeting on invented names:

A Joint EMEA NRG/Interested parties meeting (EFPIA, AESGP, EGA and EAEPC and NRG Member States representatives) took place in the afternoon of 3rd November 2008 with the aim to:

- present the impact of the latest rev 5 of the Guideline on the Acceptability of names for human medicinal products processed through the Centralised procedure (CPMP/328/95, rev 5) on the CHMP NRG outcome in light of experience since its publication on the EMEA website in January 2008.

- discuss criteria for objections based on potential risk to confusion with names of withdrawn/revoked and suspended medicinal product

- as well as to provide for an opportunity to interact directly with the NRG participants on specific topics or issues identified by the Interested parties.

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 procedures concluded

The CHMP concluded a referral procedure under Article 29 of Directive 2001/83/EC, as amended. This type of procedures is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure. The medicine concerned is:

Implanon (etonogrestel) 68mg subdermal implant, from N.V. Organon/Organon B.V., indicated for contraception. The CHMP was of the opinion that Implanon is an effective method of contraception with no apparent safety concerns and that the benefit-risk balance of Implanon is positive.

The CHMP concluded a referral procedure under Article 30 of 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 recommended the amendment of the Summary of Product Characteristics, labelling and package leaflet for the following medicine:

Diovan and associated names (valsartan)**,** from Novartis group of companies and associated companies, intended for the treatment of essential hypertension, recent myocardial infarction and heart failure.

Referral procedures started

The CHMP started a referral procedure under Article 31 of Directive 2001/83/EC, as amended, for **Gadolinium-containing contrast agents** (gadodiamide, gadopentetic acid, gadobenic acid, gadoxetic acid, gadoteridol, gadobutrol and gadoteric acid), intended for use in patients who are undergoing magnetic resonance imaging, a special type of scan where images of the internal organs are taken. The procedure was initiated by Denmark due to the lack of harmonisation of the product information and risk minimisation measures in relation to the use of these medicines in special groups of patients.

Referrals under Article 31 of Directive 2001/83/EC, as amended, are initiated in cases involving the interests of the Community or concerns relating to the protection of public health.

In parallel, the European Commission initiated a procedure under Article 20 of Regulation (EC) No 726/2004 for the two centrally authorised gadolinium-containing contrast agents, **Optimark** (gadoversetamide) and **Vasovist** (gadofosveset) on the same grounds. These types of procedures are initiated in cases where there are public health concerns with a centrally authorised medicine.

The CHMP started a number of referral procedures under Article 29 of Directive 2001/83/EC, as amended. The medicinal products concerned are:

- **Uman Big 180 IU/ml solution for injection** (Human Hepatitis B Immunoglobulin), from Kedrion SpA, indicated for immunoprophylaxis of hepatitis B in specific circumstances. The procedure was initiated because of potentially serious public health concerns related to the use of the product.
- **Betavert N 8/16 mg** (betahistine dihydrochloride), from Henning Arzneimittel GmbH&Co. KG, used as an anti-vertigo drug. The procedure was initiated, due to disagreements in relation to the therapeutic equivalence with the reference medicinal product.
- **Bleomycine 15 U PCH** (bleomycin sulphate), from Pharmachemie/NL, used as an anti-cancer agent. The procedure was initiated because of potentially serious public health concerns related to the use of the product.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended, for **Valtrex and associated names** (valaciclovir), from GSK group of companies and associated companies, used in the treatment of herpes simplex and herpes zoster (shingles).

Referral procedures withdrawn

The CHMP has been formally notified by Orion Corporation of its decision to withdraw its Mutual Recognition Procedures licenses and applications for the medicinal product **Salbutamol Easyhaler Orion** from the concerned Member States due to business reasons. In May 2008, the CHMP had initiated a referral procedure under Article 29 of Directive 2001/83/EC as amended for **Salbutamol Easyhaler Orion** inhalation powder (salbutamol), from Orion Corporation, due to concerns regarding therapeutic equivalence with the reference medicinal product.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 34th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 17-19 November 2008. 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 23-30 October 2008 For further details, please see **Annex 6**.

Documents prepared by the CHMP Working Parties adopted during the November 2008 CHMP meeting are listed in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2008 CHMP PLENARY MEETING

- The 50th meeting of the CHMP will be held at the EMEA on 15-18 December 2008.
- The next Name Review Group meeting will be held at the EMEA on 27 January 2009.
- The 35th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 15-16 December 2008.

ORGANISATIONAL MATTERS

The main topics addressed during the November 2008 CHMP meeting related to:

- Preliminary discussion of a draft EMEA procedural advice regarding the implementation of the Variation Regulation more specifically focusing on Article 5 recommendation. This advice should address the situation of submission of unforeseen variations and should be made publicly available in the near future.
- Minor revision of post-authorisation sampling and testing proposals. The revised guidance is particularly focused on the decision making process on whether to recommend testing of the active substance.
- The adoption of the draft 2 Revision 2 of the Summary of Product Characteristics guideline for transmission to the European Commission. The main objectives of this revision were to reflect the new requirements in relation to the Paediatric Regulation and further clarification of guidance for some sections i.e. section 4.8 on undesirable effects.
- Preliminary discussion regarding process improvement for post-authorisation commitments and rationalisation of follow-up measures/specific obligations.
- Discussion regarding process improvement for Article 29 referrals (see procedural announcement).
- Preliminary discussion regarding the EU regulatory system and the proposals for an incident management plan for medicines.
- The adoption of the guideline on post-authorisation follow-up of safety and efficacy - risk management of advanced therapy medicinal products and the overview of comments.

- The appointment of Dr Marcos Timón as the Spanish alternate for the Committee on Advanced Therapies Medicinal Products.
- Preliminary discussion on the draft EMEA action plan for 2008-2011 regarding the acceptance of clinical trials in third countries.
- Preliminary discussion on the draft EMEA action plan regarding geriatrics with proposed on-going actions and strategy. A workshop on medicines for elderly to consult stakeholders on CHMP/EMEA ongoing actions and strategy will be held in the 2nd or 3rd quarter of 2009. A contact point for any questions concerning medicines for the elderly is now operational: geriatrics@emea.europa.eu.

PROCEDURAL ANNOUNCEMENT

- **Process improvement for Article 29 referrals**

In order to improve the efficiency of the Article 29 referrals, the CHMP has agreed to put in place an additional workflow process, as an opportunity for quicker resolution of the divergences underlying the referrals.

When the issues raised require immediate interactions with the Applicant/ Marketing Authorisation Holders (MAH), the currently established procedure will apply (for details, see Q&A on EMEA website), but if the CHMP consider that there is no immediate need to involve the MAH/Applicant at this stage, a shortened workflow will be implemented.

The CHMP will use 30 days to assess the issues following which there will either be:

- Adoption of a positive or negative opinion,
- Changes to the Product Information with consultation of the Applicant/MAH or
- Adoption of a List of Questions (LoQ) to be addressed to the Applicant/MAH. In case a list of questions is adopted, the timeframe for the Applicants to submit their responses will be 1 month.

The shortened workflow will be implemented from the November CHMP meeting onwards, including procedures starting at the November CHMP. It will follow the already described timetable as presented in the Q&A on EMEA website, under the heading "referrals triggered by the MAH/Applicant. A more extensive Q&A referral is under preparation and will be released in Q1 2009.

- **Submission of Type IA and Type IB variations in December 2008**

The EMEA will be closed between 24th December 2008 and 2nd January 2009 (inclusive).

Marketing Authorisation Holders are therefore requested not to submit Type IA variation applications to the EMEA between 10th and 19th December 2008 (inclusive) because 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) would coincide with the official closure of the EMEA.

Type IA variation applications submitted no later than 9th December 2008 will be finalised before the EMEA Christmas break. Any Type IA variation applications submitted to the EMEA between 10th December 2008 and 2nd January of 2009 will start on 5th January 2009.

Marketing Authorisation Holders intending to apply for Type IB variations in December 2008 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 NOVEMBER 2008

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2008								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	21	6	0	28	14	10	11	90	758
Positive opinions	20	3	0	4	13	11	5	56	485
Negative opinions[1]	0	0	0	0	0	1	2	3	21
Withdrawals prior to opinion	10	1	0	0	4	1	5	21	137
Marketing authorisation granted by the Commission	16	4	0	4	8	7	4	43	477

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2008	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	5
PMF (Click here for a list of PMF certifications)	2	13
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 NOVEMBER 2008 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

ANNEX 2 TO CHMP MONTHLY REPORT NOVEMBER 2008

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

Activity	2008	Overall total 1995 onwards
Type I Variations (positive notifications)	1081	6283
Type II Variations (positive opinions)	627	4471
Type II Variations (negative opinions)	5	16
Annex II Applications (positive opinions)	32	201
Annual Re-assessment (positive opinions)	21	-
Opinion for renewals of conditional MA's (positive opinions)	3	5
5 Year Renewals (positive opinions)	42	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
2 Extension of indication	2 Positive opinions
28 SPC changes	28 Positive opinions
37 Quality changes	37 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	**N/A**	**N/A**

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**
Emadine (emedastine) Alcon Laboratories (UK) Ltd	Positive Opinion adopted	unlimited validity
Reyataz (atazanavir sulphate) Bristol-Myers Squibb Pharma EEIG	Positive Opinion adopted	unlimited validity
Zevalin (ibritumomab tiuxetan) Bayer Schering Pharma AG	Positive Opinion adopted	unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT NOVEMBER 2008

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE OCTOBER 2008 CHMP MONTHLY REPORT

Invented Name	N/A
INN	N/A
Marketing Authorisation Holder	N/A
Proposed ATC code	N/A
Indication	N/A
CHMP Opinion date	N/A
Marketing Authorisation Date	N/A

ANNEX 4 TO CHMP MONTHLY REPORT NOVEMBER 2008

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE OCTOBER 2008 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Autologous Tumor-Derived gp96 Heat Shock Protein- peptide Complex	Antigenics Therapeutics Limited	EU/3/05/270	Treatment of renal cell carcinoma

ANNEX 5 TO CHMP MONTHLY REPORT NOVEMBER 2008
INVENTED NAME REVIEW GROUP (NRG)

	NRG meeting 4 November 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names	37	27	240	185
Justification for retention of invented name *	0	1	18	12

**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.*

	NRG meeting 4 November 2008		2008	
Objections	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	49	43	306	228
Criterion - Safety concerns				
Similarity with other Invented name	43	36	269	177
Conveys misleading therapeutic/pharmaceutical connotations	1	0	3	5
Misleading with respect to composition	1	0	3	1
Criterion - INN concerns				
Similarity with INN	0	4	5	9
Inclusion of INN stem	4	2	8	7
Criterion - Other public health concerns				
Unacceptable qualifiers	0	0	14	13
Conveys a promotional message	0	1	3	16
Appears offensive or has a bad connotation	0	0	0	0
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	1	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.

ANNEX 6 TO CHMP MONTHLY REPORT NOVEMBER 2008

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

	1995 - 2007	2008	Overall Total
Scientific Advice	887	188	1075
Follow-up to Scientific Advice	171	43	214
Protocol Assistance	198	43	241
Follow-up to Protocol Assistance	90	18	108
	1346	**292**	**1638**

OUTCOME OF THE NOVEMBER 2008 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 Fabry disease		X				X	X	
Chemical	Treatment of functional constipation	X				X	X	X	
Chemical	Treatment of type 2 Diabetes mellitus			X				X	
Chemical	Treatment of lupus nephritis		X			X	X	X	
Chemical	Treatment of prostatic cancer			X				X	
Chemical	Prevention of chronic rejection following lung transplantation				X			X	X
Biological	Treatment of Castleman's Disease				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 pancreatic cancer	X						X	
Chemical	Treatment of prostate cancer	X						X	
Biological and chemical	Treatment of hepatocellular carcinoma	X						X	
Chemical	Prevention of acute transplant rejection in allogenic, cardiac or hepatic transplants	X						X	
Chemical	Treatment of myelofibrosis.	X				X	X	X	
Chemical	Treatment of advanced breast cancer	X						X	
Chemical	Reduction of hypercalcaemia in patients with tertiary hyperparathyroidis	X						X	
Chemical	Treatment of hypertension	X						X	
Chemical	Treatment of acute decompensated heart failure	X				X	X	X	
Chemical	Treatment of discoid lupus erythomatosus and subacute cutaneous lupus erythematosus				X			X	
Chemical	Treatment of HIV-1 infection		X			X		X	
Chemical	Treatment of onychomycosis		X					X	
Chemical	Treatment of orthopoxvirus diseases including smallpox	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	Treatment of anovulation, stimulation of follicular development and spermatogenesis	X				X	X	X	
Chemical	Treatment of acute pain			X				X	
Biological	Treatment of osteoarthritis and/or chronic pain	X						X	
Biological	Treatment of Alzheimer's Disease	X						X	
Chemical	Adjuvant treatment in moderate to severe closed head injury		X					X	
Biological	Treatment of retinal vein occlusion and central retinal vein occlusion	X						X	
Chemical	Treatment of pseudomonas aeruginosa lung infection in cystic fibrosis		X					X	X
Biological	Treatment of retinal vein occlusion	X				X	X	X	
Biological	Treatment of Immunglobulin-E mediated allergic diseases	X				X	X	X	
Chemical	Treatment of autosomal dominant polycystic kidney disease	X						X	
Biological	Treatment of birch pollen allergic rhinitis and/or conjunctivitis	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	Treatment of IgE-induced allergic diseases	X				X	X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 20 Scientific Advice letters, 6 Protocol Assistance letters, 3 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 17 – 20 November 2008 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 32 new Requests for which the procedure started at the SAWP meeting held on 28-30 October 2008. The new requests are divided as follows: 19 Initial Scientific Advice, 8 Follow-up Scientific Advice, 3 Initial Protocol Assistance and 2 Follow-up Protocol Assistance.

ANNEX 7 TO CHMP MONTHLY REPORT NOVEMBER 2008

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE NOVEMBER 2008 CHMP MEETING

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CHMP/BWP/ 531039/2008 EMEA/CHMP/BWP/ 596200/2008	Revision of the guideline on "Allergen Products: Production and Quality Issues" Overview of comments received	Adopted
EMEA/CHMP/BWP/ 505885/2008	Concept paper on the revision of the guideline on epidemiological data on blood transmissible infections.	Adopted

GENE THERAPY WORKING PARTY (GTWP)

Reference number	Document	Status[4]
EMEA/CHMP/GTWP/ 607698/2008	ICH Considerations on Oncolytic Viruses.	Adopted for 4-month public consultation

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/QWP/ 306970/2007 EMEA/CHMP/QWP/ 567962/2008	Guideline on radiopharmaceuticals Overview of comments received	Adopted
EMEA/ CHMP/QWP/569959/2008	Concept Paper on the revision of the Parametric Release guideline	Adopted for 3-month public consultation
EMEA/CHMP/CVMP/ QWP/595769/2008	Questions and Answers document on information on storage orientation recommendations in the product information for pressurized metered dose inhalers	Adopted
EMEA/555991/2007	New Questions and Answers document regarding the Design Space or PAT elements	Adopted

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CHMP/EWP/18504/2006	Guideline on the Clinical development of products for specific immunotherapy for the treatment of allergic	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").
[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").

EMEA/CHMP/EWP/ 330620/2008	diseases. Overview of comments received	
EMEA/CHMP/EWP/ 633/02 Rev.2	Guideline on the Clinical Development of Medicinal Products for Treatment of HIV Infection.	Adopted
CHMP/EWP/520088/2008	Appendix 2 to the Guideline on the evaluation of Anticancer Medicinal Products in Man on Haematological Malignancies	Adopted for 6-month public consultation