European Medicines Agency
Evaluation of Medicines for Human Use

London, 26th February 2009
EMEA/97795/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
FEBRUARY 2009 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its February plenary meeting from 16-19 February 2009.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted ten positive opinions by consensus on initial marketing authorisation application..

New medicinal products

- **Conbriza** (bazedoxifene), from Wyeth Europa Ltd. Conbriza is indicated for the treatment of postmenopausal osteoporosis in women at increased risk of fracture. EMEA review began on 27 September 2007 with an active review time of 202 days.
- **Exalief** (eslicarbazepine acetate) and **Zebinix** (eslicarbazepine acetate), from BIAL-Portela & C, S.A. Exalief and Zebinix are indicated as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. EMEA review began on 26 March 2008 with an active review time of 205 days.
- **Pantozol Control** (pantoprazole) from Nycomed GmbH. Pantozol Control is indicated for the short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults. The medicine will be available without prescription. EMEA review began on 28 May 2008 with an active review time of 197 days.
  In addition, positive opinions were adopted for **Controloc Control, Somac Control, Pantecta Control** and **Pantoloc Control** from Nycomed GmbH. These medicines contain the same active substance (pantoprazole) and are intended for the same indication as Pantozol Control. They will also be available without prescription. Start date for these four medicines was 23 November 2008, with an active review time of 80 days.
- **Removab** (catumaxomab), from Fresenius Biotech GmbH. Removab is indicated for the intraperitoneal treatment of malignant ascites in patients with Ep~CAM-positive carcinomas where standard therapy is not available or no longer feasible. EMEA review began on 30 January 2008 with an active review time of 203 days.

Generic medicinal products:

- The Committee adopted a positive opinion for **Rivastigmine Teva** (rivastigmine), from Teva Pharma B.V., indicated for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Rivastigmine Teva is a generic of Exelon, which has been authorised in the EU since 12 May 1998. EMEA review began on 23 July 2008 with an active review time of 177 days.

Summaries of opinion for these medicinal products are available here. Further information will be included in the European Public Assessment Reports (EPARs) once the European Commission has granted final approval.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Negative opinion

The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Biferonex** (interferon-beta-1a), from BioPartners GmbH. Biferonex was intended for the treatment of adult patients with relapsing remitting multiple sclerosis characterised by two or more exacerbations in the previous two years. EMEA review began on 15 August 2007 with an active review time of 205 days.

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

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

The EMEA has been formally requested by Orphan Europe S.A.R.L to re-examine the negative opinion for **Vedrop** (tocofersolan) intended to be used for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from cystic fibrosis, congenital chronic cholestasis or hereditary chronic cholestasis adopted during the CHMP meeting on 19–22 January 2009.

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

Following the re-examination of the positive opinion adopted on 23rd October 2008, the CHMP re-confirmed its previous position for **Lunivia** (eszopiclone), from Sepracor Pharmaceuticals Ltd 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. The CHMP concluded that no meaningful clinical difference could be established between eszopiclone and zopiclone regarding safety and efficacy and therefore recommended the refusal of the New Active Substance Status to Lunivia.

Withdrawals

The EMEA has been formally notified by Merck Sharp & Dohme Ltd of its decision to withdraw its application for a centralised marketing authorisation for **Vorinostat MSD** (vorinostat), 100 mg hard capsules. Vorinostat MSD was expected to be used for the treatment of patients with advanced stage cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease, and who have failed at least two prior systemic therapies. Vorinostat MSD was designated as an orphan medicine on 21 June 2004. A separate press release document with more information is available and a question-and-answer document will be available in the near future.

Post-authorisation procedures

Extensions of indication and other recommendations

There were no opinions on extensions of indication in February 2009.

Removal of contraindication

The CHMP recommended removing a contraindication for **Telzir**, from Glaxo Group Ltd, saying that patients with severe hepatic impairment should not be treated with the medicine. Telzir in combination with low dose ritonavir is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1)-infected adults, adolescents and children of 6 years and above in combination with other antiretroviral medicinal products.

The CHMP recommended removing a contraindication for **Avastin**, from Roche Registration Ltd, saying that patients with untreated CNS metastases should not be treated with the medicine. Avastin in combination with other anticancer regimens is indicated for the treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, non-small cell lung cancer and renal cell carcinoma

A summary of opinion can be found here.

Addition of new contraindication and warning for **Rasilez** and other aliskiren medicines

The CHMP recommended adding a contraindication to the Product Information for aliskiren, stating that it must not be used in patients who have experienced angioedema (swelling of the tissues beneath the skin) when taking aliskiren in the past. The CHMP also recommended the inclusion of a warning, stating that patients who develop signs of angioedema should stop treatment and seek medical attention.

A separate press release with more information on the recommendation is available.

CHMP recommends suspension of marketing authorisation for **Raptiva**

The CHMP recommended the suspension of the marketing authorisation for **Raptiva** (efalizumab), from Serono Europe Ltd. The CHMP concluded that the benefits of Raptiva no longer outweigh its risks, because of modest efficacy and increased safety concerns including the occurrence of progressive multifocal leukoencephalopathy (PML) in patients taking the medicine.

A separate press release and question-and-answer document are available.

Other information

The CHMP introduced a new warning in section 4.4 of the SPC for **Exjade** (deferasirox) following post-marketing reports (both spontaneous and from clinical trials) of pancytopenia or aggravation of pancytopenia in patients treated with Exjade. Exjade is indicated for the treatment of chronic iron overload due to frequent blood transfusions.

The CHMP recommended that the product information for all centrally authorised **angiotensin II receptor antagonists** (AIIRAs) be updated regarding their use during lactation. Following a review of the safety of these medicines pertaining to their use during pregnancy and lactation by the Pharmacovigilance Working Party and the CHMP, the Committee adopted a harmonised wording recommending that alternative treatments with better established safety profiles be used during breast-feeding, especially while nursing a newborn or preterm infant. This wording is to be included in section 4.6 of the SPCs and section 2 of the Package Leaflets for these medicines. The Committee has also recommended that the contraindication for lactation be deleted, where applicable.These recommendations concern the following medicinal products: Aprovel, Karvea, Irbesartan BMS and Irbesartan Winthrop (irbesartan); CoAprovel, Karvezide, Irbesartan Hydrochlorothiazide BMS and Irbesartan Hydrochlorothiazide Winthrop (irbesartan and hydrochlorothiazide); Micardis, Pritor and Kinzalmono (telmisartan); MicardisPlus, PritorPlus and Kinzalkomb (telmisartan and hydrochlorothiazide); and Exforge, Copalia, Dafiro and Imprida (valsartan).

The CHMP introduced a new warning in section 4.4 of the SPC for **Adrovance** and **Fosavance** (alendronate sodium / colecalciferol) to include information on low energy stress fractures. This followed a review of cases of atypical stress fractures following the use of bisphosphonates by the Pharmacovigilance Working Party and the CHMP. The CHMP further highlighted the uncertainty of a class effect for the other bisphosphonates and that unnecessary and inappropriate switching of bisphosphonates should be avoided at this point in time.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted seven Lists of Questions on initial applications (including one under the mandatory scope and six under the optional scope).

Consultation procedure on an ancillary substance in a medical device

The Committee also adopted a positive opinion on human thrombin in the context of its use as ancillary medicinal substance in **Floseal Hemostatic Matrix (Floseal VH S/D)** from **Baxter AG**. The applicant/Notified Body for the consultation procedure is **TÜV SÜD Product Service GmbH**. EMEA review began on 27 February 2008 with an active review time of 204 days.

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 January 2009 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 January 2009 CHMP plenary meeting are provided in **Annex 4**.

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 5**.

REFERRAL PROCEDURES

Referral procedures concluded

The CHMP concluded a referral procedure under Article 29 of Directive 2001/83/EC, as amended for **Budesonide Sandoz and associated names**, 32 or 64 µg, suspension (budesonide), from Sandoz Pharmaceuticals GmbH. The medicine is indicated for the treatment and prevention of signs and symptoms of seasonal and perennial allergic rhino-conjunctivitis as well as the treatment of nasal polyps. The procedure was initiated because of disagreements between the Member States regarding the inclusion of the indication in paediatric populations. The CHMP concluded that therapeutic equivalence to the originator in adults is proven and that safety in paediatric populations is established. Therefore the CHMP concluded that the benefit-risk balance of these medicines is positive and recommended granting of the marketing authorisations.

Referrals under Article 29 of Directive 2001/83/EC, as amended, are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure.

A separate question-and-answer-document with more information on the recommendation is available.

Other procedures

The Danish Medicines Agency has asked the Committee to draw up an opinion on the suspected association between the use of bisphosphonates and osteonecrosis of the jaw . This review procedure has been initiated under Article 5(3) of Regulation (EC) No 726/2004 and will result in a CHMP scientific opinion, which will be made publicly accessible.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 37th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-17 February 2009. 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 28-30 January 2009. For further details, please see **Annex 6**.

Documents prepared by the CHMP Working Parties adopted during the February 2009 CHMP meeting are listed in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE FEBRUARY 2009 CHMP PLENARY MEETING

- The 53rd meeting of the CHMP will be held at the EMEA on 16-19 March 2009.
- The next Name Review Group meeting will be held at the EMEA on 17 March 2009.
- The 38th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 16-17 March 2009.

ORGANISATIONAL MATTERS

The main topics addressed during the February 2009 CHMP meeting related to:

- Follow up discussion on the new Variation Regulation No 1234/2008 and presentation of the draft EU procedural guideline on variations, together with a number of documents for variation classification. All documents were adopted and will now be transmitted to the European Commission and subsequently released for public consultation.
- An update regarding the handling of submissions for centrally authorised products in relation to Art 45 and Art 46 of the Paediatric Regulation 1901/2006, as amended.
- Follow-up discussion regarding process improvement for post-authorisation commitments and rationalisation of follow-up measures (FUMs) and specific obligations focusing on quality FUMs. A pilot phase will be put in place for a few months to assess whether the proposed measures will lead to a possible reduction of redundant or unnecessary FUMs.
- Follow-up discussion on the procedural advice on evaluation of advanced-therapy medicinal products. Further discussion will take place at the next CHMP meeting.
- Discussion of the re-examination procedure to include advanced-therapy medicinal products (EMEA/CHMP/50745/2005 Rev.1). The updated document will be adopted at the next CHMP meeting.
- The proposed draft agenda for the CHMP informal meeting to be held early March 2009 in Prague under the Czech presidency of the European Union.

PROCEDURAL ANNOUNCEMENT

Article 46 of the Paediatric Regulation (EC) No 1901/2006

Marketing Authorisation Holders (MAHs) of centrally authorised products are reminded that Article 46 of Regulation (EC) No 1901/2006, as amended is the obligation for the MAH to submit to the EMEA any MAH-sponsored clinical studies involving the use in the paediatric population of an authorised medicinal product, whether or not they are part of a Paediatric Investigation Plan (PIP). The study should be submitted within 6 months of its completion irrespective whether it will be submitted later on as part of a variation, extension or new stand-alone marketing authorisation application.

The submission of Article 46 paediatric study should include the following documents, preferably presented in accordance with appropriate headings and numbering of the EU_CTD format :

- Cover Letter including information on the context in which the Article 46 paediatric study submission is made (e.g. submission as part of FUM/SO, stand alone study or study included in a development program) and statement that there are no regulatory consequences identified by the MAH.

- A short critical expert overview clarifying the context of the data, including information on the pharmaceutical formulation used in the study, the existence of a suitable paediatric formulation and if relevant, conditions for an extemporaneous formulation

- Final clinical study report

- For a paediatric study that is part of a development program, a line listing of all the concerned studies

In case amendments to be introduced to SPC, labelling and/or PL are identified by the MAH, a variation should be submitted directly containing the article 46 paediatric study. The application should be presented in EU-CTD format accordingly to the guidance for type II variation.

An update of the Post-Authorisation Procedural Advice document will be published shortly on the EMEA website to provide further guidance in that regard.

Noël Wathion
Head of Unit
Post-Authorisation Evaluation of Medicines for Human Use, Tel. (+44-20) 74 18 85 92

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 FEBRUARY 2009

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2009								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	2	1	0	6	1	0	2	12	782
Positive opinions	3	5	0	2	3	0	0	13	506
Negative opinions[1]	1	0	0	0	1	0	0	2	23
Withdrawals prior to opinion	0	0	0	0	0	0	1	1	140
Marketing authorisation granted by the Commission	4	0	0	1	5	1	2	13	498

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2009	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	6
PMF (Click here for a list of PMF certifications)	0	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 FEBRUARY 2009 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 FEBRUARY 2009

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

Activity	2009	Overall total 1995 onwards
Type I Variations (positive notifications)	146	6515
Type II Variations (positive opinions)	190	4733
Type II Variations (negative opinions)	0	16
Annex II Applications (positive opinions)	23	206
Annual Re-assessment (positive opinions)	2	-
Opinion for renewals of conditional MA's (positive opinions)	1	7
5 Year Renewals (positive opinions)	16	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
0 Extension of indication	0 Positive opinions
73 SPC changes	73 Positive opinions
32 Quality changes	32 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Xagrid (anagrelide) Shire Pharmaceutical Contracts Ltd	Positive Opinion adopted	The marketing authorisation remains 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**
Abilify (aripiprazole) Otsuka Pharmaceutical Europe Ltd	Positive Opinion adopted	Unlimited validity
Levemir (insulin detemir) Novo Nordisk A/S, Rapporteur	Positive Opinion adopted	Unlimited validity
NovoRapid (insulin aspart) Novo Nordisk A/S	Positive Opinion adopted	Unlimited validity
Kentera (oxybutynin) Nicobrand Ltd	Positive Opinion adopted	Unlimited validity
Rebetol (ribavirin) Schering-Plough Europe	Positive Opinion adopted	Unlimited validity
ReFacto (moroctocog alfa) Wyeth Europa Ltd	Positive Opinion adopted	Unlimited validity
Sustiva (efavirenz) Bristol Myers Squibb Pharma EEIG	Positive Opinion adopted	Recommending additional renewal
Stocrin (efavirenz) Merck Sharp & Dohme	Positive Opinion adopted	Recommending additional renewal

ANNEX 3 TO CHMP MONTHLY REPORT FEBRUARY 2009

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE JANUARY 2009 CHMP MONTHLY REPORT

Invented Name	Opgenra
INN	eptotermin alfa
Marketing Authorisation Holder	Howmedica International S. de R. L
Proposed ATC code	M05BC02
Indication	Opgenra is indicated for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed or is contra-indicated.
CHMP Opinion date	23.10.2008
Marketing Authorisation Date	19.02.2009

Invented Name	Valdoxan
INN	agomelatine
Marketing Authorisation Holder	Les Laboratoires Servier
Proposed ATC code	NO6AX22
Indication	Treatment of major depressive episodes in adults.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	19.02.2009

Invented Name	Thymanax
INN	agomelatine
Marketing Authorisation Holder	Les Laboratoires Servier
Proposed ATC code	NO6AX22
Indication	Treatment of major depressive episodes in adults.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	19.02.2009

Invented Name	Zarzio
INN	filgrastim
Marketing Authorisation Holder	Sandoz GmbH
Proposed ATC code	L03AA02
Indication	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. Mobilisation of peripheral blood progenitor cells (PBPC). In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. Treatment of persistent neutropenia (ANC ≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	06.02.2009

Invented Name	Filgrastim Hexal
INN	filgrastim
Marketing Authorisation Holder	Hexal AG
Proposed ATC code	L03AA02
Indication	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. Mobilisation of peripheral blood progenitor cells (PBPC). In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of

	infection-related events. Treatment of persistent neutropenia (ANC ≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	06.02.2009

Invented Name	Nplate
INN	romiplostim
Marketing Authorisation Holder	Amgen Europe B.V
Proposed ATC code	Not yet assigned
Indication	Nplate is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Nplate may be considered as second line treatment for adult non-splenectomised patients where surgery is contra-indicated.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	04.02.2009

Invented Name	Efient
INN	prasugrel
Marketing Authorisation Holder	Eli Lilly Nederland B.V
Proposed ATC code	Not yet assigned
Indication	Efient, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	23.02.2009

Invented Name	Firmagon
INN	degarelix
Marketing Authorisation Holder	Ferring Pharmaceuticals A/S

Proposed ATC code	L02BX02
Indication	FIRMAGON is a gonadotrophin releasing hormone (GnRH) antagonist indicated for treatment of adult male patients with advanced hormone-dependent prostate cancer.
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	17.02.2009

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE JANUARY 2009 CHMP MEETING

Active substance	Sponsor/applicant	EU Designation Number & Date of Orphan Designation	Designated Orphan Indication
Treprostinil sodium (inhalation use)	United Therapeurics Europe Ltd	EU/3/04/197	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension.

ANNEX 5 TO CHMP MONTHLY REPORT FEBRUARY 2009
INVENTED NAME REVIEW GROUP (NRG)

	NRG meeting; 27 Jan 2009		NRG meeting; 17 Mar 2009		NRG meeting; 12 May 2009		NRG meeting; 28 Jul 2009		NRG meeting; 15 Sep 2009		NRG meeting; 24 Nov 2009		2009	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	47	52											47	52
Justification for retention of invented name *	5	1											5	1

*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; 27 January 2009		NRG meeting; 17 March 2009		NRG meeting; 12 May 2009		NRG meeting; 28 July 2009		NRG meeting; 15 September 2009		NRG meeting; 24 November 2009		2009	
Objections	Accepted	Rejected	Accepte	Rejecte	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	120	65											120	65
Criterion - Safety concerns														
Similarity with other Invented name	100	56											100	56
Conveys misleading therapeutic/pharmaceutical connotations	6	0											6	0
Misleading with respect to composition	0	0											0	0
Criterion - INN concerns														
Similarity with INN	2	3											2	3
Inclusion of INN stem	3	0											3	0
Criterion - Other public health concerns														
Unacceptable qualifiers	4	1											4	1
Conveys a promotional message	1	0											1	0
Appears offensive or has a bad connotation	1	1											1	1
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	3	4											3	4
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 FEBRUARY 2009

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

	1995 - 2008	2009	Overall Total
Scientific Advice	887	42	929
Follow-up to Scientific Advice	171	6	177
Protocol Assistance	198	5	203
Follow-up to Protocol Assistance	90	0	90
	1346	**53**	**1399**

OUTCOME OF THE FEBRUARY 2009
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				
Biological	long term control of porphobilinogen deaminase deficiency and prevention of acute intermittent porphyria attacks	X					X		
Chemical	treatment of irritable bowel syndrome	X						X	
Chemical	prevention of upper gastrointestinal ulcers	X				X	X	X	
Biological	treatment of diabetes mellitus	X				X			
Biological	treatment of diabetes mellitus	X				X	X	X	
Biological	treatment of diabetes mellitus	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 type 2 diabetes mellitus	X					X	X	
Chemical	treatment of gastro-entero-pancreatic neuroendocrine tumours		X			X	X	X	
Chemical	treatment of ovarian cancer	X					X	X	
Chemical	treatment of relapsing-remitting multiple sclerosis	X				X			
Chemical	treatment of acute myeloid leukaemia		X					X	
Chemical	treatment of ovarian cancer		X				X	X	X
Chemical	prophylaxis of organ rejection in solid organ transplant patients			X				X	
Biological	Treatment of breast cancer	X				X	X		
Chemical	diagnosis and follow up tumour imaging in Medullary Thyroid Carcinoma		X			X	X	X	
Chemical	treatment of onchocerciasis			X			X	X	
Chemical	treatment of visceral leishmaniasis			X			X	X	
Biological	treatment of idiopathic thrombocytopenic purpura	X						X	
Biological	treatment and prevention of deep vein thrombosis and pulmonary embolism, prevention	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 eschar in deep partial thickness and full thickness burns		X			X			
Chemical	treatment of proliferating infantile hemangiomas	X					X	X	
Biological	replacement therapy in primary and secondary immunodeficiencies	X				X	X	X	
Biological	Treatment of chondral defects up to 10 cm	X				X	X	X	
Chemical	treatment of major depressive disorder	X				X		X	
Biological	treatment of moderate to severe chronic pain	X						X	
Biological	treatment of chronic peripheral neuropathic pain	X						X	
Chemical	treatment of peripheral neuropathic pain	X						X	
Biological	treatment of progressive Multiple Sclerosis			X				X	
Chemical	treatment of Alzheimer's disease	X					X	X	
Chemical	treatment of neuropathic low back pain	X					X	X	
Chemical	treatments of psychosis	X						X	
Chemical	treatment of psychosis	X						X	
Chemical	treatment of conduct disorder	X						X	
Chemical	treatment of dementia	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 chronic obstructive pulmonary disease	X				X	X	X	
Chemical	treatment of asthma	X						X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 5 Protocol Assistance letters and 4 Follow-up Scientific Advice letters were adopted at the 16-19 Feb 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 17 new Requests for which the procedure started at the SAWP meeting held on 28-30 Jan 2009. The new requests are divided as follows: 12 Initial Scientific Advice, 1 Follow-up Scientific Advice, 3 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

ANNEX 7 TO CHMP MONTHLY REPORT FEBRUARY 2009

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE FEBRUARY 2009 CHMP MEETING

BLOOD PRODUCT WORKING PARTY (BPWP)

Reference number	Document	Status[3]
CPMP/BPWG/859/95 rev.3	Guideline on Core SmPC for Human Normal Immunoglobulin for Intravenous Administration (IVIg)	Adopted
CPMP/BPWG/388/95 rev.1	Guideline on the Clinical Investigation of Human Normal Immunoglobulin for Intravenous Administration (IVIg),	Adopted
EMEA/CHMP/BPWP/ 399089/2007	Overview of Comments received on Draft Guideline on Core SmPC for Human Plasma Fibrinogen Products	Adopted

WORKING PARTY ON CELL BASED PRODUCTS (CPWP)

Reference number	Document	Status[3]
EMEA/CHMP/CPWP/ 83508/2009	Guideline on Xenogeneic Cell Based Medicinal Products (Revision of the Points to Consider on Xenogeneic Cell-therapy Product)	Adopted for 6-month public consultation.

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/CHMP/EWP/ 692702/2008	Reflection Paper on the Extrapolation of Results from Clinical Studies conducted outside Europe to the EU-population	Adopted for 3-month public consultation
EMEA/CHMP/EWP/ 15839/2009	Concept Paper on the need for a Guideline on the Evaluation of Drugs for the Treatment of Gastroesophageal Reflux Disease	Adopted for 3-month public consultation
CPMP/EWP/558/95 Rev 1 EMEA/CHMP/EWP/43 5635/2008	Concept Paper on revision of the Note for Guidance on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections	Adopted for 3-month public consultation
CPMP/EWP/562/98 EMEA/CHMP/EWP/81 97/2009	Concept Paper on the need for revision of the Points to Consider on Clinical Investigations of Medicinal Products in the Chronic Treatment of Patients with Chronic Obstructive Pulmonary Disease	Adopted for 3-month public consultation
CPMP/EWP/240/95 Rev. 1 EMEA/CHMP/EWP/ 533066/2008	Guideline on clinical development of Fixed Combination Medicinal Products Overview of comments received on the guideline	Adopted
EMEA/CHMP/EWP/ 11877/2009	Concept Paper on developments of Guideline on the Treatment of Premenstrual Dysphoric Disorders (PMDD)	Adopted for 3-month public consultation

HEALTH CARE PROFESSIONALS WORKING GROUP (HCPWG)

Reference number	Document	Status[3]
EMEA/185036/2008	EMEA/CHMP Working Group with Healthcare Professionals' Organisations: Final recommendations and proposals for action	Adopted
EMEA/536569/2008	Overview of comments received on the guideline EMEA/CHMP Working Group with Healthcare Professionals' Organisations: Final recommendations and proposals for action	Adopted