European Medicines Agency
Evaluation of Medicines for Human Use

London, 28 October 2008
EMEA/CHMP/539474/2008

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

The Committee for Medicinal Products for Human Use (CHMP) held its October plenary meeting from 20-23 October 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted two positive opinions by consensus and one by majority (Lunivia) on initial marketing authorisations.

New medicinal products

- **Lunivia** (eszopiclone), from Sepracor Pharmaceuticals Ltd, for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening, in adults, usually for short-term duration. EMEA review began on 18 August 2007 with an active review time of 205 days.
- **Vidaza** (azacitidine), from Celgene Europe Ltd, for the treatment of myelodysplastic syndromes and acute myeloid leukaemia in adults who are not eligible for haematopoietic stem-cell transplantation. Vidaza is the 50th orphan medicine to receive a positive opinion by the CHMP. EMEA review began on 30 January 2008 with an active review time of 198 days.

Generic medicinal product

- The Committee adopted a positive opinion for **Pramipexole Teva** (pramipexole), from Teva Pharma B.V., for the treatment of signs and symptoms of idiopathic Parkinson's disease, alone or in combination with levodopa. EMEA review began on 21 November 2007 with an active review time of 196 days. The reference product for Pramipexole Teva is Sifrol, which is already authorised in the European Union, in the indication applied for.

Re-examination procedure concluded

Following a re-examination of a negative opinion adopted in June 2008, the CHMP adopted a final positive opinion by majority for **Opgenra** (recombinant human osteogenic protein-1/eptotermin alfa), from Howmedica International S. de R.L. Opgenra is indicated for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed or is contraindicated.

A separate question-and-answer document with more detailed information on the grounds for the final positive 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.

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Withdrawals

The EMEA has been formally notified by UCB Pharma S.A. of its decision to withdraw the application for an initial marketing authorisation for **Lacosamide Pain UCB Pharma** (lacosamide) film-coated tablets. Lacosamide Pain UCB Pharma was expected to be used for the treatment of diabetic neuropathic pain in adults. A separate press release with more information and a question-and-answer document will be available in the near future.

The EMEA has been formally notified by Astellas Pharma Europe B.V. of its decision to withdraw the application for an initial application for a marketing authorisation application for **Vibativ** (telavancin), 15 mg/ml powder for concentrate for solution for infusion. Vibativ was expected to be used for the treatment of complicated skin and soft tissue infections in adults. A separate press release with more information is available and a question and answer document will be available in the near future.

The EMEA has been formally notified by Wyeth Europa Ltd of its decision to withdraw the application for a marketing authorisation application for **Ellefore** (desvenlafaxine) 50 mg, 100 mg and 200 mg prolonged-release tablets. Ellefore was expected to be used for the treatment of major depressive disorder. A separate press release 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

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

- **Binocrit** (epoetin alfa), from Sandoz GmbH, **Abseamed** (epoetin alfa), from Medice Arzneimittel Putter GmbH&Co. KG, and **Epoetin Alfa Hexal** (epoetin alfa), from Hexal Biotech Forschungs GmbH, to add the indication of increasing the yield of autologous blood from patients in a pre-donation programme. Binocrit, Abseamed and Epoetin Alfa Hexal are currently indicated in the treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients.
- **Erbitux** (cetuximab), from Merck KGaA, to extend the indication to the treatment of patients with squamous cell cancer of the head and neck in combination with platinum-based chemotherapy for recurrent and/or metastatic disease. Erbitux is currently indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in combination with chemotherapy or as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. In combination with radiation therapy, Erbitux is also indicated for the treatment of patients with locally advanced squamous cell cancer of the head and neck.
- **Prezista** (darunavir), from Tibotec, to extend the indication to the treatment of human immunodeficiency virus (HIV-1) infection to include treatment-experienced adult patients. Prezista is currently indicated for the treatment of HIV-1 in combination with other antiretroviral medicines in highly pre-treated adult patients who failed more than one regimen containing a protease inhibitor.
- **Pegasys** (peginterferon alfa-2b), from Roche Registration Ltd, to extend the indication in combination with ribavirin to the treatment of hepatitis C in adults patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) in combination therapy with ribavirin. Pegasys is currently indicated for the treatment of chronic hepatitis C in adult patients who are positive for serum hepatitis C virus RNA, including patients with compensated cirrhosis and/or co-infected with clinically stable HIV. In this indication peginterferon alfa-2b can be used in combination with ribavirin or in monotherapy. It is also indicated for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral

replication, increased alanine aminotransferase (ALT) and histologically verified liver inflammation and/or fibrosis.

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

Updated safety information

- In September 2008, one case of progressive multifocal leukoencephalopathy (PML) was reported in one patient with psoriasis receiving **Raptiva** in the United States (US). The MAH agreed with the CHMP to update sections 4.4 and 4.8 of the Summary of Product Characteristics, sections 2 and 4 of the Package Leaflet with a warning and a description of the case of PML. A Dear Healthcare Professional Communication to inform neurologists and dermatologists of the new emerging information on the risk of PML was also adopted.

- In June 2008, a case of Progressive Multifocal Leukoencephalopathy (PML) was reported in a patient with rheumatoid arthritis receiving **Mabthera** reported in a long-term safety extension clinical study. The case occurred 18 months after the last dose of Mabthera and is confounded by chemotherapy for the patient's development of oropharyngeal cancer. The MAH agreed with the CHMP to update sections 4.4 and 4.8 of the Summary of Product Characteristics, and sections 2 and 4 of the Package Leaflet with a warning and information on PML. A Dear Healthcare Professional Communication to inform rheumatologists and haematologists of the risk of PML was also adopted.

Renewal of conditional approval

The CHMP recommended switching the conditional marketing authorisation for **Prezista** (darunavir) from Janssen –Cilag-Intenational NV, following the first annual renewal, since all specific obligations had been fulfilled. Prezista, co-administered with 100 mg ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in highly pre-treated adult patients who failed more than one regimen containing a protease inhibitor. The conditional marketing authorisation was granted on 12 February 2007.

First positive opinion for switch from prescription-only to non-prescription for a centrally authorised medicine

The CHMP has recommended for the first time that the status for supply of a centrally authorised medicine in the European Union be switched from prescription-only to non-prescription. The medicine concerned is **Alli** (orlistat), from Glaxo Group Ltd. This will enable patients to buy the medicine over-the-counter. A separate press release is available here.

First positive opinion on paediatric extension according to Article 29 of the Paediatric Regulation (1901/2006)

The CHMP gave a positive opinion for a line-extension of **Cozaar** and associated names (losartan potassium), from Merck Sharp & Dohme BV, to add a paediatric formulation of powder and solvent for oral suspension. Cozaar and associated names are authorised at the level of the Member States. This is the first recommendation for a line-extension relating to a new pharmaceutical form for use in the paediatric population on the basis of data generated in accordance with an agreed paediatric investigation plan (PIP). The paediatric formulation has been developed for the treatment of essential hypertension in children and adolescents 6-16 years of age.

Once the CHMP opinion has been transformed into a decision by the European Commission, the company will be able to obtain approval for the paediatric formulation in all EU Member States where the medicine is authorised.

Article 29 of the Paediatric Regulation allows companies to submit to the EMEA an application for a new indication, a new pharmaceutical form or a new route of administration for medicines that are already

authorised at the level of the Member States. Data supporting such applications have to be generated in accordance with an agreed PIP.

This recommendation follows the CHMP opinion adopted at its September 2008 meeting recommending for the first time the use of a centrally-authorised medicine in children based on PIP data. A separate press release is available.

PIPs are drug-development plans that set out measures ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of the medicine for children. PIPs must be agreed in advance by the Agency's Paediatric Committee (PDCO), and are legally binding for companies developing medicines for use in the European Union.

Negative opinion for extension of indication

The CHMP adopted a negative opinion for an extension of indication for **Cymbalta** (duloxetine hydrochloride), from Eli Lilly Nederland B.V., and **Xeristar** (duloxetine hydrochloride), from Boehringer Ingelheim International GmbH. The indication applied for related to the treatment of fibromyalgia with or without depression. Cymbalta and Xeristar are currently approved for the treatment of major depressive episodes, diabetic peripheral neuropathic pain in adults and generalised anxiety disorder. A separate question-and-answer document explaining the grounds for the negative opinion for the extension of indication is available on the EMEA website.

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

Suspension of marketing authorisation

The CHMP recommended the suspension of the marketing authorisation for **Acomplia/Zimulti** (rimonabant), from Sanofi-Aventis. A separate press release and a question-and-answer document are available.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

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

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in September 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 September 2008 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 started

The CHMP started a number of referral procedures 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 medicines concerned are:

- **Avalox** (moxifloxacin hydrochloride) 400mg solution for infusion, from Bayer HealthCare/Bayer Vital GmbH, is an antibiotic agent.
- **Octegra** (moxifloxacin hydrochloride) 400mg solution for infusion, from Bayer HealthCare/Bayer Vital GmbH, is an antibiotic agent.
- **Implanon** (etonogestrel) 68mg subdermal implant, from N.V. Organon/Organon B.V., indicated for contraception.
- **Teicoplanin Hospira** (teicoplanin) 200 and 400mg powder and solvent for injection or infusion, from Hospira UK Limited, indicated for the treatment of specific bacterial infections.

In addition, the Committee started one referral under Article 30 of Directive 2001/83/EC as amended, for **Meronem** and associated names (meropenem), from AstraZeneca BV, used in the treatment of respiratory-tract infections. This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 33rd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 20-21 October 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 29-30 September 2008 and 1 October 2008. For further details, please see **Annex 6**.

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

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2008 CHMP PLENARY MEETING

- The 49th meeting of the CHMP will be held at the EMEA on 17-20 November 2008.
- The next Name Review Group meeting will be held at the EMEA on 4 November 2008.
- The 34th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 17-18 November 2008.

ORGANISATIONAL MATTERS

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

- Follow-up discussion regarding the SAWP-CHMP interactions and the role of the peer review system.
- The adoption of the guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products (EMEA/HMPC/CHMP/CVMP/287539/2005-Rev.1) for 3-month public consultation.

- The adoption of a CHMP briefing Note in the context of the CHMP Work Plan for 2008-2010 regarding international activities and activities with WHO.
- The endorsement of a question-and-answer document on Article 58 which will now be transmitted to the WHO for comments.
- Preliminary discussion regarding requests from applicants to apply for work-sharing approach in the context of variations assessments.
- The revision of the SOP on Peer Review/Quality assurance of the Day 120 CHMP List of Questions and assessment reports (SOP/H/3015).

PROCEDURAL ANNOUNCEMENT

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

Please note that the EMEA will be closed between 24 December 2008 and 2 January 2009 (inclusive).

Marketing Authorisation Holders are therefore requested not to submit Type IA variation applications to the EMEA between 10 and 19 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 9 December 2008 will be finalised before the EMEA Christmas break. Any Type IA variation applications submitted to the EMEA between 10 December 2008 and 2 January of 2009 will start on 5 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 OCTOBER 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	20	5	0	22	14	9	11	81	749
Positive opinions	16	3	0	4	9	11	4	47	476
Negative opinions[1]	0	0	0	0	0	0	2	2	20
Withdrawals prior to opinion	9	1	0	0	4	1	4	19	135
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 OCTOBER 2008 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Chemical	Treatment of HIV-1 infection	X	--
Biological	N/A	N/A	N/A

ANNEX 2 TO CHMP MONTHLY REPORT OCTOBER 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)	988	6190
Type II Variations (positive opinions)	560	4404
Type II Variations (negative opinions)	5	16
Annex II Applications (positive opinions)	26	195
Annual Re-assessment (positive opinions)	21	-
Opinion for renewals of conditional MA's (positive opinions)	3	5
5 Year Renewals (positive opinions)	39	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
8 Extension of indication	6 Positive opinions 2 Negative opinion
31 SPC changes	31 Positive opinions
31 Quality changes	31 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**
Prezista (Darunavir) Janssen-Cilag-Intenational NV	Positive Opinion adopted	Full approval

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Faslodex (fulvestrant) AstraZeneca UK Limited	Positive Opinion adopted	unlimited validity
Temodal (temozolomide) SP Europe	Positive Opinion adopted	unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT OCTOBER 2008

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

Invented Name	Prepandemic influenza vaccine
INN	prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14
Marketing Authorisation Holder	GlaxoSmithKline Biologicals S.A
Proposed ATC code	J07BB02
Indication	Active immunisation against H5N1 subtype of Influenza A virus. This indication is based on immunogenicity data from healthy subjects aged 18-60 years following administration of two doses of vaccine prepared from A/VietNam/1194/2004 NIBRG-14 (H5N1) (see section 5.1). Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals 3.75 µg should be used in accordance with official guidance.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	26.09.2008

Invented Name	Xarelto
INN	rivaroxaban
Marketing Authorisation Holder	Bayer HealthCare AG
Proposed ATC code	B01AX06
Indication	Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	30.09.2008

Invented Name	Tadalafil Lilly
INN	tadalafil
Marketing Authorisation Holder	Eli Lilly Nederland B.V
Proposed ATC code	G04BE08
Indication	Treatment of erectile dysfunction. In order for tadalafil to be effective, sexual stimulation is required. Tadalafil Lilly is not indicated for use by women.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	01.10.2008

Invented Name	Evicel
INN	human fibrinogen / human thrombin
Marketing Authorisation Holder	OMRIX biopharmaceuticals S.A
Proposed ATC code	B02BC
Indication	EVICEL is used as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis (see section 5.1). EVICEL is also indicated as suture support for haemostasis in vascular surgery.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	06.10.2008

Invented Name	Fluticasone furoate GSK
INN	fluticasone furoate
Marketing Authorisation Holder	Glaxo Group Limited
Proposed ATC code	R01AD12
Indication	Fluticasone furoate GSK is indicated for the treatment of: the symptoms of allergic rhinitis.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	06.10.2008

Invented Name	Ceplene
INN	histamine dihydrochloride
Marketing Authorisation Holder	EpiCept GmbH
Proposed ATC code	L03AX14
Indication	Ceplene maintenance therapy is indicated for adult patients with acute myeloid leukaemia in first remission concomitantly treated with interleukin-2 (IL-2). The efficacy of Ceplene has not been fully demonstrated in patients older than age 60.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	07.10.2008

Invented Name	Olanzapine Mylan
INN	olanzapine
Marketing Authorisation Holder	Generics (UK) Ltd

Proposed ATC code	N05AH03
Indication	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder (see section 5.1).
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	07.10.2008

Invented Name	Duloxetine Boehringer Ingelheim
INN	duloxetine
Marketing Authorisation Holder	Boehringer Ingelheim International GmbH
Proposed ATC code	N06AX21
Indication	Duloxetine Boehringer Ingelheim is indicated for women for the treatment of moderate to severe Stress Urinary Incontinence (SUI), (see section 5.1). Treatment of diabetic peripheral neuropathic pain in adults.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	08.10.2008

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

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Mepolizumab	Glaxo Group Limited UK	EU/3/04/213	Treatment of hypereosinophilic syndrome
Temsirolimus	Wyeth Europa Ltd.	EU/3/06/420	Treatment of mantle cell lymphoma

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

	NRG meeting; 29 January 2008		NRG meeting; 01 April 2008		NRG meeting; 14 May 2008		NRG meeting; 29 July 2008		NRG meeting; 30 September 2008		2008	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	18	14	51	52	35	27	48	37	51	28	152	130
Justification for retention of invented name *	3	1	3	1	0	2	4	2	8	5	18	11

*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; 29 January 2008		NRG meeting; 01 April 2008		NRG meeting; 14 May 2008		NRG meeting; 29 July 2008		NRG meeting; 30 September 2008		2008	
Objections	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	21	22	59	51	53	24	80	69	44	19	257	185
Criterion - Safety concerns												
Similarity with other Invented name	18	15	42	36	51	21	72	52	43	17	226	141
Conveys misleading therapeutic/pharmaceutical connotations	1	0	0	1	0	1	1	3	0	0	2	5
Misleading with respect to composition	0	0	0	1	0	0	2	0	0	0	2	1
Criterion - INN concerns												
Similarity with INN	1	1	2	0	1	1	1	2	0	1	5	5
Inclusion of INN stem	0	1	3	0	1	0	0	3	0	1	4	5
Criterion - Other public health concerns												
Unacceptable qualifiers	1	3	9	5	0	0	4	5	0	0	14	13
Conveys a promotional message	0	2	2	8	0	1	0	4	1	0	3	15
Appears offensive or has a bad connotation	0	0	0	0	0	0	0	0	0	0	0	0
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	1	0	0	0	0	0	0	0	1	0
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	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

ANNEX 6 TO CHMP MONTHLY REPORT OCTOBER 2008

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

	1995 - 2007	2008	Overall Total
Scientific Advice	887	168	1055
Follow-up to Scientific Advice	171	39	210
Protocol Assistance	198	39	237
Follow-up to Protocol Assistance	90	14	104
	1346	**260**	**1606**

OUTCOME OF THE OCTOBER 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				
Biological	Treatment of anal fistula		X			X			
Chemical	Treatment of Type 2 diabetes mellitus	X				X	X	X	
Chemical	Treatment of obesity	X				X	X	X	
Chemical	Detection of pancreatic abnormalities in pancreatitis	X				X	X	X	
Biological	Prevention of acute GvHD and acceleration of immune reconstitution following allogeneic stem cell transplantation	X				X	X	X	
Biological	Treatment of ovarian cancer		X				X	X	X
Biological	Treatment of malignant pleural mesothelioma		X			X		X	X

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of malignant melanoma	X				X	X	X	
Biological	Treatment of pancreatic cancer	X						X	
Chemical	Treatment of multiple myeloma	X						X	
Biological	Prophylaxis of venous thromboembolic events			X				X	
Chemical	Prevention of arterial thrombosis in acute coronary syndrome	X						X	
Chemical	Treatment of Alopecia Universalis		X					X	
Chemical	Treatment of lupus erythomatosus		X			X			
Chemical	Treatment of severe sepsis			X				X	
Biological	Broader Advice on vaccines	X				X			
Chemical	Treatment of various viral infections	X				X			
Biological	Broader Advice on vaccines	X				X			
Biological	Prevention of invasive meningococcal disease caused by N. meningitidis serogroup B	X				X		X	
Chemical	Treatment of Endometriosis	X						X	
Chemical	Treatment of Uterine Fibroids	X						X	
Chemical	Treatment of glucocorticoid-induced osteoporosis	X					X	X	
Chemical	Treatment of osteoporosis in postmenopausal women and in men	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 partial onset seizures	X						X	
Chemical	Treatment of primary generalized tonic-clonic seizures in epilepsy	X					X	X	
Chemical	Treatment of chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension				X			X	
Biological	Treatment of retinitis pigmentosa		X			X	X	X	
Biological	Biostaging in colon cancer	X				X		X	
Chemical	Treatment of amyloid A amyloidosis				X			X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 19 Scientific Advice letters, 6 Protocol Assistance letters, 2 Follow-up Scientific Advice and 2 Follow-up Protocol Assistance letters were adopted at the 20-23 October 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 01-03 September 2008. The new requests are divided as follows: 22 Initial Scientific Advice, 8 Follow-up Scientific Advice, 1 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

ANNEX 7 TO CHMP MONTHLY REPORT OCTOBER 2008

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

PHARMACOGENOMICS WORKING PARTY (PgWP)

Reference number	Document	Status[3]
EMEA/324640/2008	PgWP Work Plan for 2009	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/CVMP/QWP/455946/2008	QWP Work Plan for 2009	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").