European Medicines Agency
Evaluation of Medicines for Human Use

London, 8th October 2008
EMEA/CHMP/505537/2008

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

The Committee for Medicinal Products for Human Use (CHMP) held its September plenary meeting from 22-25 September 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted four positive opinions on initial marketing authorisations and four positive opinions for 'informed consent' applications; all opinions were adopted by consensus:

New medicinal products

- **Azarga** (brinzolamide / timolol), from Alcon Laboratories (UK) Ltd, intended to decrease intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction. EMEA review began on 26 December 2007 with an active review time of 177 days.
- **Kuvan** (sapropterin dihydrochloride), from Merck KGaA, for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients of 4 years of age and over with phenylketonuria (PKU) who have been shown to be responsive to such treatment. Kuvan is also indicated for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment. Kuvan is the 49th orphan medicine to receive a positive opinion by the CHMP. EMEA review began on 23 November 2007 with an active review time of 200 days.
- **Zypadhera** (olanzapine pamoate), from Eli Lilly Nederland B.V., intended for maintenance treatment of adult patients with schizophrenia. EMEA review began on 20 July 2007 with an active review time of 198 days.

Generic medicinal products

- **Irbesartan krka** (Irbesartan hydrochloride), from Krka d.d. Novo Mesto, for treatment of essential hypertension and treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen. EMEA review began on 26 December 2007 with an active review time of 205 days. The reference product for Irbesartan krka is Aprovel, which is already authorised in the European Union (EU), in the applied indication.

Positive opinion for 'informed consent' applications

The Committee adopted four positive opinions for 'informed consent' applications. This type of marketing authorisation application requires that reference is made to an authorised medicine and that the marketing authorisation holder of this reference product has given consent to the use of the dossier in the application procedure. The medicines concerned are:

- **Jalra** (vildagliptin) and **Xiliarx** (vildagliptin), from Novartis Europharm Ltd, for the treatment of type 2 diabetes mellitus. EMEA review began on 27 July 2008 with an active review time of 60 days. Reference product for both medicines is Galvus.

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- **Vildagliptin/metformin hydrochloride Novartis** and **Zomarist** (vildagliptin / metformin hydrochloride), from Novartis Europharm Ltd, for the treatment of type 2 diabetes mellitus. EMEA review began on 27 July 2008 with an active review time of 60 days. Reference product for both medicines is Eucreas.

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

The EMEA has been formally requested by Santhera Pharmaceuticals (Deutschland) GmbH, to re-examine the negative opinion for **Sovrima** intended to be used for treatment of Friedreich's Ataxia, an inherited condition that causes progressive damage to the nervous system and heart disease, adopted during the CHMP meeting on 21st - 24th July 2008.

Withdrawal

The EMEA has been formally notified Celgene Europe Ltd of Pharmion Ltd's decision to withdraw its application for a marketing authorisation application for **Orplatna (**satraplatin) 10 mg and 50 mg capsules. Orplatna was expected to be used, in combination with prednisone and prednisolone, in the treatment of patients with metastatic hormonerefractory prostate cancer who have failed prior chemotherapy. 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 Pfizer of its decision to withdraw its application for a marketing authorisation application for **Exulett** (dalbavancin), 500 mg powder for concentrate for solution for infusion. Exulett was expected to be used for complicated skin and soft tissue infections in adults when known or suspected to be caused by susceptible Gram-positive bacteria. A separate press release with more information and a question-and-answer document are available.

The EMEA has been formally notified by Takeda Global Research & Development Centre (Europe) Ltd of its decision to withdraw its application for a marketing authorisation application for **Ramelteon** (ramelteon) 4 and 8 mg tablets. Ramelteon was expected to be used for the treatment of primary insomnia in patients aged 18 years or over. A separate press release with more information and a question-and-answer document are available.

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.

Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP gave a positive opinion by consensus to extend the indication of **Cancidas** (caspofungin), from Merck Sharp & Dohme, to paediatric patients (12 months – 17 years of age). Cancidas is currently authorised for the treatment of severe fungal infections in adults.

This is the first recommendation for the use of a medicine in children on the basis of clinical trial data generated in accordance with an agreed paediatric investigation plan (PIP). A separate press release is available: http://www.emea.europa.eu/humandocs/Humans/EPAR/cancidas/50283008en.pdf

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

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

The EMEA has been formally requested by Aventis Pharma S.A to re-examine the negative opinion adopted during the CHMP meeting on 21st – 24th July 2008 for the extension of indication for both **Taxotere** (docetaxel) and **Docetaxel Winthrop** (docetaxel). These medicines were intended to be used to treat operable breast cancer overexpressing the protein HER2, in addition to surgery either in combination

with trastuzumab following treatment with doxorubicin and cyclophosphamide, or in combination with trastuzumab and carboplatin.

Renewal of conditional approval

The CHMP recommended renewing the conditional marketing authorisation for **Isentress** (raltegravir) from Merck Sharp & Dohme Ltd, following the first annual renewal to confirm that the benefit-risk balance remains positive. Isentress is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-experienced adult patients with evidence of HIV-1 replication despite ongoing anti-retroviral therapy. The conditional marketing authorisation was granted on 20th December 2007.

The CHMP recommended renewing the conditional marketing authorisation for **Diacomit** (stiripentol), an orphan medicinal product from Laboratoires Biocodex, following the second annual renewal to confirm that the benefit-risk balance remains positive. Diacomit is indicated for use in conjunction with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI, Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate. The conditional marketing authorisation was granted on 4th January 2007.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

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

Detailed information on the centralised procedure

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

The Committee concluded a referral procedure for **Efexor** (venlafaxine), from Wyeth Europa Ltd, for the treatment of major depressive episodes, and for prevention of major depressive episodes. The CHMP recommended by majority the harmonisation of the Summary of Product Characteristics, Package Leaflet and Labeling across the European Union.

The Committee concluded a referral procedure for **Efexor Depot** (venlafaxine), from Wyeth Europa Ltd, for the treatment of major depressive episodes, general anxiety disorder, social anxiety disorder, panic disorder, and for prevention of major depressive episodes. The CHMP recommended by majority the

harmonisation of the Summary of Product Characteristics, Package Leaflet and Labelling across the European Union.

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:

- **Budesonide Sandoz** 32/64 µg nasal spray (budesonide), from Sandoz Pharmaceutical GmbH, indicated for the treatment and prevention of signs and symptoms of seasonal and perennial allergic rhinitis. The procedure was initiated because of a disagreement between the Member States whether the paediatric population should be included.
- **Loratadine Sandoz** 10, 10 mg tablets (loratadine), from Sandoz BV, intended for symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria. The procedure was initiated because of concerns by some Member States over bioequivalence of the medicine with the innovator product.
- **Prokanazol** 100 mg, hard capsules (itraconazole), from PRO.MED.CS Praha a.s., intended for the treatment of certain fungal infections. The procedure was initiated because of concerns by some Member States over bioequivalence of the medicine with the innovator product.

In addition, the Committee started one 'harmonisation referral' for **Protium and associated names** (pantoprazole) from Nycomed group of companies and associated companies, used in the treatment of gastroesophageal reflux disease. This type of procedure is initiated under Article 30 of Directive 2001/83/EC as amended, with a view to harmonising product information for medicinal products authorised at Member State level.

Referral procedures withdrawn

The EMEA has been formally notified by Wyeth Europe Limited of its decision to withdraw its licenses and applications for the medicinal product **Anya** from the concerned Member States. In November 2007, the CHMP had initiated a referral procedure under Article 29 of Directive 2001/83/EC as amended for **Anya** film-coated tablet (levonorgestrel/ethinyl estradiol), from Wyeth AB, because of concerns pertaining to efficacy and safety.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 32nd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 22-24 September 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 1-3 September 2008. For further details, please see **Annex 6**.

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

UPCOMING MEETINGS FOLLOWING THE SEPTEMBER 2008 CHMP PLENARY MEETING

- The 48th meeting of the CHMP will be held at the EMEA on 20-23 October 2008.
- The next Name Review Group meeting will be held at the EMEA on 30 September 2008.
- The 33rd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 20-22 October 2008.

ORGANISATIONAL MATTERS

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

- Preliminary discussion regarding the implementation of the Variations Regulation and the subsequent tasks (i.e. drafting relevant guidelines etc...).
- Follow-up discussion regarding international activities and activities with the WHO.
- Follow-up discussion regarding the general issue of non-prescription medicinal products accessing the centralised procedure. Members from the Association of the European Self-Medication Industry (AESGP) were invited to participate in some aspect of the general discussion.
- Preliminary discussion regarding the acceptance of clinical trials conducted in third countries, for evaluation in Marketing Authorisation Applications. The Committee noted the EMEA proposals to implement the Work Programme issued at request of the Management Board regarding clinical trials conducted in third countries, for evaluation in Marketing Authorisation Applications. Further development on this project will take place over the coming months.
- The adoption of the revised mandate for the Scientific Advice Working Party (EMEA/CHMP/SAWP/69686/04 Rev 6) which is now taking into consideration the recently implemented "Biomarker Qualification Procedure".
- The future SAG Diabetes and Endocrinology meeting (date tbc) on the revision of diabetes guideline and on cardiovascular outcome studies in diabetes.
- Discussion regarding comments received on the GCP guideline on advanced therapy medicinal products published by the European Commission for public consultation earlier this year. The following Working Parties have been consulted (GTWP, CPWP, BWP, SAWP and EWP) in parallel to relevant EMEA sectors. These comments raised will now be transmitted to the European Commission by the end September/early October 2008.
- Nomination of the 4 out of 5 alternates members for the CHMP representatives on the Committee for Advanced Therapy Medicinal Products.
- Follow-up discussion regarding interactions between the EMEA and the European Food Safety Authority (EFSA) in relation to the opinion on "antibiotic resistant marker (ARM) genes used as marker genes in genetically modified plants".
- Finalisation of the agenda for the informal CHMP meeting to be held in Paris on 6 - 7th October 2008.
- Follow up discussion regarding the European Commission 7th Framework Programme and the subsequent funding of various projects. The Committee noted the outcome from the 2nd call for research proposals relating mainly to the establishment of the safety of non-steroidal anti-inflammatory drugs (NSAIDs) and assessing their relative cardiovascular diseases and gastrointestinal safety. The Committee also noted the proposal for the 3rd call for research proposal more orientated towards the response for additional EU policy needs in various topics (i.e. adapting off-patent medicines to the specific needs of paediatric populations and the study of the arrhythmogenic potential of different classes of medicines).

PROCEDURAL ANNOUNCEMENT

Changes to the provision of final language versions of the product information for medicinal products for human use

Applicants are required from the October 2008 CHMP meeting to provide the final language versions of the product information for medicinal products for human use (Annexes to the Opinion) in all EU languages and Norwegian and Icelandic as bookmarked PDF documents. In order to allow applicants sufficient time to perform this task, the period for applicants to implement Member States comments and to prepare the final product information Annexes in PDF, will be extended by 3 calendar days.
The EMEA is providing additional guidance on the EMEA website to assist applicants in the preparation of the PDF documents. The QRD Convention published on its website should be followed and compliance should be checked and confirmed by the applicant using a dedicated form before submitting the final language versions of Annexes in PDF format. Annexes that do not comply with the formatting guidelines will have to be rejected and the applicant will be required to resubmit them. Further information in relation to this announcement can be found here. The "Linguistic Review Process of Product Information in the Centralised Procedure" and the "Pre-Submission/ Post-Authorisation Procedural Advice" documents will be updated to reflect this.

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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 SEPTEMBER 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	16	14	9	10	74	742
Positive opinions	15	3	0	3	8	10	4	43	472
Negative opinions[1]	0	0	0	0	1	0	2	3	21
Withdrawals prior to opinion	6	1	0	0	4	1	4	16	132
Marketing authorisation granted by the Commission	14	3	0	3	7	5	3	35	469

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 SEPTEMBER 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

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)	906	6108
Type II Variations (positive opinions)	492	4336
Type II Variations (negative opinions)	3	14
Annex II Applications (positive opinions)	21	190
Annual Re-assessment (positive opinions)	21	-
Opinion for renewals of conditional MA's (positive opinions)	2	4
5 Year Renewals (positive opinions)	37	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
1 Extension of indication	1 Positive opinion
56 SPC changes	56 Positive opinions
49 Quality changes	49 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Aldurazyme (laronidase) Genzyme B.V	Positive Opinion adopted	remaining under exceptional circumstances
Atriance (Nelarabine) GlaxoSmithKline	Positive Opinion adopted	remaining under exceptional circumstances
Increlex (Mecasermin) Tercica Inc (US),	Positive Opinion adopted	remaining under exceptional circumstances
Velcade (bortezomib) Janssen-Cilag International NV	Positive Opinion adopted	remaining under exceptional circumstances

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Isentress (raltegravir) Merck Sharp & Dohme	Positive Opinion adopted	Conditional renewal
Diacomit (stiripentol) Laboratoires Biocodex	Positive Opinion adopted	Conditional renewal

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Simulect (basiliximab) Novartis Europharm	Positive Opinion adopted	unlimited validity
Micardis (telmisartan) Boehringer Ingelheim	Positive Opinion adopted	unlimited validity
Pritor (telmisartan) Bayer AG	Positive Opinion adopted	unlimited validity
Kinzalmono (telmisartan) Bayer AG	Positive Opinion adopted	unlimited validity

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

Invented Name	Filgrastim ratiopharm
INN	filgrastim
Marketing Authorisation Holder	Ratiopharm GmbH
Proposed ATC code	L03AA02
Indication	Filgrastim ratiopharm is indicated for the 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 for the 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. Filgrastim ratiopharm is indicated for the mobilisation of peripheral blood progenitor cells (PBPC). In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 10^9/l, and a history of severe or recurrent infections, long term administration of Filgrastim ratiopharm is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. Filgrastim ratiopharm is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.
CHMP Opinion date	24.07.2008
Marketing Authorisation Date	15.09.2008

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

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Everolimus	Novartis Europharm Limited	EU/3/07/449	Treatment of renal cell carcinoma
Recombinant human IL-1beta of the IgG1/K class	Regeneron UK	EU/3/07/439	Treatment of cryopirin-associated periodic syndromes (Familial Cold Urticaria Syndrome (FCUS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID), also known as Chronic Infantile Neurological Cutaneous Articular Syndrome (CINCA))
Thiotepa	Adienne S.r.l	EU/3/06/424	Conditioning treatment prior to haematopoietic progenitor cell transplantation

ANNEX 5 TO CHMP MONTHLY REPORT SEPTEMBER 2008

INVENTED NAME REVIEW GROUP (NRG)

	September 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names[1]	48	37	152	131
Justification for retention of invented name *[2]	4	2	10	6

*In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the EMEA website.
[1] One of the proposed invented name requests has been postponed to the November 2008 NRG meeting
[2] None of the justifications for retention of a proposed invented name has been postponed to the November 2008 NRG meeting

	July 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	80	69	160	142
Criterion - Safety concerns				
Similarity with other Invented name	72	52	183	124
Conveys misleading therapeutic/pharmaceutical connotations	1	3	2	4
Misleading with respect to composition	2	0	2	1
Criterion - INN concerns				
Similarity with INN	1	2	5	4
Inclusion of INN stem	0	3	4	4
Criterion - Other public health concerns				
Unacceptable qualifiers	4	5	14	13
Conveys a promotional message	0	4	2	15
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 SEPTEMBER 2008
PRE-AUTHORISATION: SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE
EMEA CENTRALISED PROCEDURES

	1995 - 2007	2008	Overall Total
Scientific Advice	887	149	1036
Follow-up to Scientific Advice	171	37	208
Protocol Assistance	198	33	231
Follow-up to Protocol Assistance	90	12	102
	1346	**231**	**1577**

OUTCOME OF THE SEPTEMBER 2008
CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Final Scientific Advice Procedures

Substance	**Intended indications(s)**	**Type of Request**				**Topic**			
		New		**Follow-up**		**Pharma ceutical**	**Pre-clinical**	**Clinical**	**Significant Benefit**
		SA	**PA**	**SA**	**PA**				
Chemical	Treatment of Type 2 Diabetes Mellitus	X					X	X	
Biological	Treatment of colorectal liver metastases	X						X	
Biological	Treatment of cutaneous T-cell Lymphoma		X			X		X	
Biological	Detection of clear cell renal cell cancer	X						X	
Chemical	Treatment of malignant bowel obstruction in advanced cancer	X						X	
Biological	Treatment of immunodeficiency due to adenosine deaminase deficiency		X			X	X		
Chemical	Treatment of malignant pleural mesothelioma	X					X	X	

Chemical	Treatment of non-small cell lung cancer		X					X	X
Chemical	Treatment of multiple lipid disorders	X						X	
Biological	Treatment of dermatomyositis				X			X	
Biological	Prevention of RhD alloimmunisation	X				X	X	X	
Chemical	Treatment of chronic hepatitis C			X		X		X	
Biological	Acetylcholine inhibitor	X				X			
Biological	Treatment of rheumatoid arthritis	X					X		
Biological	Treatment of multiple sclerosis			X			X		
Chemical	Treatment of status epilepticus	X					X	X	
Chemical	Treatment of major depressive episodes	X						X	
Biological	Treatment of Alzheimer's disease	X				X	X	X	
Chemical	Treatment of asthma	X						X	
Chemical	Treatment of Duchenne muscular dystrophy		X					X	
Chemical	Treatment of atopic keratoconjunctivitis			X				X	
Biological	Treatment of neovascular (wet) age-related macular degeneration	X				X			
Chemical	Control of hyperphosphataemia in chronic kidney disease	X					X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 15 Scientific Advice letters, 4 Protocol Assistance letters, 3 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letters were adopted at the 22-25 September 2008 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 35 new Requests for which the procedure started at the SAWP meeting held on 01-03 September 2008. The new requests are divided as follows: 24 Initial Scientific Advice, 2 Follow-up Scientific Advice, 7 Initial Protocol Assistance and 2 Follow-up Protocol Assistance.

ANNEX 7 TO CHMP MONTHLY REPORT SEPTEMBER 2008

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

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CHMP/BWP/ 67410/2007)	Compilation of comments on the guideline on virus safety evaluation of biotechnological investigational medicinal products	Adopted
EMEA/CHMP/BWP/ 207941/2008	BWP Work Programme for 2009	Adopted

BLOOD WORKING PARTY (BPWP)

Reference number	Document	Status[3]
EMEA/CHMP/BPWP/238 377/2008	BPWP Work Plan for 2009	Adopted

VACCINE WORKING PARTY (VWP)

Reference number	Document	Status[3]
EMEA/CHMP/VWP/ 437782/2008	VWP Work Plan for 2009	Adopted

GENE THERAPY WORKING PARTY (GTWP)

Reference number	Document	Status[3]
EMEA/CHMP/GTWP/ 168855/2008	GTWP Work Plan for 2009	Adopted

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

Reference number	Document	Status[3]
EMEA/CHMP/BMWP/ 340689/2008	BMWP Work Plan for 2009	Adopted
WHO/BS/0.82101	WHO guideline for abbreviated licensing pathways for certain biological therapeutic products	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").

WORKING PARTY ON CELL-BASED PRODUCTS (CPWP)

Reference number	Document	Status[3]
EMEA/CHMP/CPWP/ 319258/2008	CPWP Work Plan for 2009	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/INS/GMP/445735/ 2008	GMP for active substances: Question-and-Answer document on the declaration by the Qualified Person to be submitted in dossiers	Adopted

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/CHMP/EWP/3118 90/2007	Guideline on the evaluation of medicinal products for cardiovascular disease prevention	Adopted
EMEA/331393/2008	EWP Work Plan for 2009-2010	Adopted

EMEA HUMAN SCIENTIFIC COMMITTEES WORKING PARTY WITH PATIENTS AND CONSUMER ORGANISATIONS (PCWP)

Reference number	Document	Status[3]
EMEA/261645/2008	Briefing note on a proposal for involvement and participation of patients'/consumers' representatives in the meetings of the CHMP Pharmacovigilance Working Party	Adopted

PHARMACOVIGILANCE WORKING PARTY (PhVWP)

Reference number	Document	Status[3]
EMEA/CHMP/PhVWP/ 383898/2008	Draft PhVWP Work Programme for 2009	Adopted
Draft Volume 9A of the Rules Governing Medicinal Products in the EU Revision 2008	Draft Volume 9A of the Rules Governing Medicinal Products in the EU Revision 2008	Adopted
EMEA/CHMP/PhVWP/ 503449/2007	Draft CHMP Guideline on the Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis against Infectious Diseases	Adopted for 3-month public consultation