European Medicines Agency
Evaluation of Medicines for Human Use

London, 29th January 2009
EMEA/39660/2009

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

The Committee for Medicinal Products for Human Use (CHMP) held its January plenary meeting from 19-22 January 2009.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted two positive opinions by consensus on initial marketing authorisations.

New medicinal products

- **Synflorix** (pneumococcal polysaccharide conjugate vaccine (adsorbed)), from GlaxoSmithKline Biologicals. Synflorix is indicated for the active immunisation against invasive disease and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age. EMEA review began on 30 January 2008 with an active review time of 209 days.

Generic medicinal products:

- **Ribavirin Teva** (ribavirin), from Teva Pharma B.V., indicated for the treatment of hepatitis C. The reference product for Ribavirin Teva is Rebetol, which is already authorised in the European Union (EU) in the indication applied for. EMEA review began on 28 May 2008 with an active review time of 203 days.

Positive opinion for 'informed consent' applications

The Committee adopted one positive opinion by consensus for an 'informed consent' application. 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.

- **Fertavid** (follitropin beta), from Schering-Plough Europe. 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 reference product for Fertavid is Puregon. EMEA review began on 27 July 2008 with an active review time of 89 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.

Negative opinion

The CHMP adopted a negative opinion by consensus recommending the refusal of a marketing authorisation for **Vedrop** (tocofersolan), from Orphan Europe S.A.R.L. Vedrop was intended 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. EMEA review began on 27 September 2007 with an active review time of 210 days.

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

Withdrawals

The question-and-answer document on the withdrawal of application for **Advexin** (contusugene ladenovec), which was originally announced in the December CHMP monthly report, is now available on the EMEA website.

Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP gave two positive opinions by consensus for application for extensions of indications, adding new treatment options for the following previously approved medicine:

- **Protopic** (tacrolimus), from Astellas Pharma GmbH, to extend the indication to maintenance treatment. Protopic 0.1% ointment is currently indicated for treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. Protopic 0.03% ointment is indicated for treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids and treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies such as topical corticosteroids.
- **MabThera** (rituximab), from Roche Registration Ltd, to extend the indication to first-line treatment of patients with chronic lymphocytic leukaemia (CLL) in combination with chemotherapy. MabThera is currently authorised for the treatment of Non-Hodgkins-Lymphoma and severe active rheumatoid arthritis.

A summary of opinion for the above-mentioned products, including their full indications, can be found here.

New contraindication recommended

The CHMP recommended that **Fareston** (toremifene), from Orion Pharma, should not be used in patients at risk of prolonged QT intervals or other heart problems. Fareston is currently authorised in the EU as hormone treatment for hormone-dependent metastatic breast cancer in postmenopausal women.

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

Withdrawals

The question-and-answer document on the withdrawal of application for an extension of indication for **Invega** (paliperidone) prolonged-release tablets, which was originally announced in the December CHMP monthly report, is now available on the EMEA website.

Other information

The CHMP heard the Oversight Committee of the D.A.D study who presented the achievements over the last ten years and their commitment to continue to support the study until 2012. A separate press release will be released shortly.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

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

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in December 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 December 2008 CHMP plenary meeting are provided in **Annex 4**.

REFERRAL PROCEDURES

Referral procedures concluded

The CHMP concluded two referral procedures under Article 29 of Directive 2001/83/EC, as amended. This type of procedure 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:

Trimetazidine-ratiopharm, 35 mg, modified release tablets, (trimetazidine), from ratiopharm GmbH and **Mephatrim**, 35 mg, modified-release tablets, (trimetazidine), from Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda. Both medicines are indicated for the treatment of heart disease.
The CHMP concluded that the available data for these two medicines had shown that there is bioequivalence to the reference medicinal product, and that their benefits and risks are taken as being the same as those of the reference product. The CHMP therefore recommended that they should be granted a marketing authorisation in all concerned Member States.

Separate question-and-answer documents with more information about Trimetazidine-ratiopharm and Mephatrim are available.

The CHMP concluded one referral procedure under Article 36 of Directive 2001/83/EC, as amended. This type of procedure is initiated where one or more Member States consider that there are public health issues relating to a product that may require harmonised regulatory action across the EU.

Atifor Chiesi 12 mcg/Atimos/Forair (Formoterol HFA 12mcg), intended for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient.
The Committee concluded that these medicines should not be used in children aged from 5 to 12 years because their efficacy could not be demonstrated in this age group. The Committee therefore recommended that the marketing authorisations for these medicines should be changed accordingly.

The CHMP concluded one referral procedure under Article 31 of Directive 2001/83/EC, as amended. This type of procedure is initiated in cases involving the interests of the Community or concerns relating to the protection of public health. The CHMP concluded that **methylphenidate**-containing medicines remain suitable for the treatment of children aged six years or older and adolescents with attention deficit/hyperactivity disorder (ADHD). The Committee also recommended that the product information

be made consistent across the EU so that all patients, carers and prescribers have the same information for safer and more appropriate use of these medicines.

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

Referral procedures started

The CHMP started a referral procedure under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended), because of disagreement on the grounds for approval, for the following product:

Myderison, 50 mg, 150 mg, film-coated tablets, (tolperison hydrochloride), from MEDITOP Pharmaceutical Co. Ltd., indicated for the treatment of spasticity of the skeletal muscles.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 36th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 19-20 January 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 05-07 January 2009 For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the January 2009 CHMP meeting are listed in **Annex 6**.

UPCOMING MEETINGS FOLLOWING THE JANUARY 2009 CHMP PLENARY MEETING

- The 52nd meeting of the CHMP will be held at the EMEA on 16-19 February 2009.
- The next Name Review Group meeting will be held at the EMEA on 27 January 2009.
- The 37th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 16-17 February 2009.

ORGANISATIONAL MATTERS

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

- Follow up discussion on the new Variation Regulation No 1234/2008. The Committee was informed on key aspects and implementation proposals of such Regulation. The concept of “work sharing” amongst the Committee was also discussed. Further discussion regarding the implementation will take place in February 2009.
- Follow up discussion regarding process improvement for post-authorisation commitments and rationalisation of follow-up measures/specific obligations.
- The adoption of the Revised CHMP Rules and Procedure taking into consideration activities of the recently implemented Committee on Advanced Medicinal Therapies (EMEA/CHMP/111481/2004 Rev 2). The Revised CHMP Rules and Procedure will be adopted by the Management Board in March 2009.
- Follow up discussion regarding interactions between the CHMP and the SAWP in view of improving the peer review concept for scientific advice.

PROCEDURAL ANNOUNCEMENT

- **Modified eligibility requests for fixed dose combinations**

The EMEA would like to raise applicants' awareness regarding the fact that eligibility criteria for access to the centralised procedure for fixed dose combinations will change in the future.

To date, new fixed-dose combinations of known active substances were considered analogous to new active substances and therefore eligible to the centralised procedure under the optional scope Art 3(2)a of Regulation (EC) No 726/2004.

From the date of the publication of this report, applicants will now be asked to justify their request for access to the centralised procedure for fixed-dose combinations under the optional scope Art 3(2)b of Regulation (EC) No 726/2004. Applicants will be requested to justify their request under either significant therapeutic, technical, scientific innovation or in the interest of patients at Community level. The pre-submission guidance will be updated accordingly in the very near future.

- **Procedural guidance on the application of the paediatric Regulation requirements to new indications, new routes of administration, and/or new pharmaceutical forms**

Application requirements

The EMEA would like to remind Marketing Authorisation Holders of the entry into force of Regulation (EC) No 1901/2006, as amended (Paediatric Regulation) as of **26 January 2009** with the application of the requirements of Article 8 concerning:

- Applications for new indications, new routes of administration, and/or new pharmaceutical forms for an authorised medicinal product which is protected either by a supplementary protection certificate under Regulation (EEC) No 1768/92, or by a patent which qualifies for the granting of the supplementary protection certificate.

At the time of submission, such application must include one or more of the following in order for the application to be regarded as valid:

- The results of all studies performed and details of all information collected in compliance with an agreed Paediatric Investigation Plan (PIP).
- A decision of the EMEA on a PIP including any deferral granted
- A decision of the EMEA granting a product-specific waiver
- A decision of the EMEA granting a class waiver on condition

In accordance with Article 8, the PIP or Waiver application as well as decision should cover both the new and existing indications, routes of administration, and/or pharmaceutical forms.

This requirement applies irrespective of the type of application submitted for such a change(s) i.e. variation, extension or new marketing authorisation application and irrespective of whether the change is related to adult or paediatric use.

The requirements concerns applications submitted from 26 January 2009 (i.e. date of submission of a valid application).

The Global Marketing Authorisation (GMA) concept together with the notion of 'same marketing authorisation holder' applies to PIP or Waiver applications as well as to variations, extension and new marketing authorisation applications falling under the requirements of Article 7 and 8. Where relevant, applicants should also consider whether any modification to an agreed or ongoing PIP/Waiver decision is required in case the GMA concept had not been applied, in order to avoid difficulties at validation of the subsequent regulatory submission.

This information is to be included in Module 1.10 of the application dossier – NTA (Vol 2B): http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm#2b

The following types of application are exempted from the application of Articles 7 and 8:

- Generics (Art 10(1) of Directive 2001/83/EC)
- Hybrid medicinal products (Art 10(3) of Directive 2001/83/EC)
- Similar biological medicinal products (Art 10(4) of Directive 2001/83/EC)
- Medicinal products containing active substance(s) of well-established medicinal use (Art 10a of Directive 2001/83/EC)
- Homeopathic medicinal products (Art 13-16 of Directive 2001/83/EC)
- Traditional herbal medicinal products (Art 16a-16i of Directive 2001/83/EC)

When planning the submission of an application falling under the requirements of Article 7 or 8, applicants have to take into account the need for a compliance check of the PIP, or relevant parts of it. Applicants and Marketing authorisation Holders are strongly encouraged to request the opinion of the Paediatric Committee on compliance before the submission of their application, in order not to delay validation.

Further information on the application of the GMA concept to Articles 7 and 8 as well as on the compliance check could be found
- on the EMEA website in section “Medicines for children”: http://www.emea.europa.eu/htms/human/paediatrics/introduction.htm and
- in the procedural announcement of the June 2008 CHMP Monthly Report: http://www.emea.europa.eu/pdfs/human/press/pr/32726508en.pdf

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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 JANUARY 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	1	1	0	1	1	0	1	5	775
Positive opinions	0	0	0	1	2	0	0	3	496
Negative opinions[1]	1	0	0	0	0	0	0	1	22
Withdrawals prior to opinion	0	0	0	0	0	0	0	0	139
Marketing authorisation granted by the Commission	1	0	0	1	2	0	1	5	490

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2009	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	0	5
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 JANUARY 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 JANUARY 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)	49	6418
Type II Variations (positive opinions)	85	4628
Type II Variations (negative opinions)	0	16
Annex II Applications (positive opinions)	20	203
Annual Re-assessment (positive opinions)	1	-
Opinion for renewals of conditional MA's (positive opinions)	1	7
5 Year Renewals (positive opinions)	8	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
3 Extension of indication	3 Positive opinions
55 SPC changes	55 Positive opinions
27 Quality changes	27 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Atryn (recombinant antithrombin alfa) LEO Pharma A/S	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**
Tyverb (lapatinib ditosylate monohydrate) Glaxo Group Limited	Positive Opinion adopted	Recommending renewal of the conditional Marketing Authorisation

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Cetrotide (cetrorelix) Ares Serono (Europe) Ltd	Positive Opinion adopted	Unlimited validity
Cholestagel (colesevelam) Genzyme Europe B.V	Positive Opinion adopted	Unlimited validity
Beromun (tasonermin) Boehringer Ingelheim International GmbH	Positive Opinion adopted	Unlimited validity
Dukoral (oral cholera vaccine) SBL Vaccin AB	Positive Opinion adopted	Unlimited validity
Litak (cladribine) Lipomed GmbH	Positive Opinion adopted	Unlimited validity
Lysodren (mitotane) Laboratoire HRA Pharma	Positive Opinion adopted	Unlimited validity
Velcade (bortezomib) Janssen-Cilag International NV	Positive Opinion adopted	Recommending additional renewal
Regranex (bercaplermin), Janssen-Cilag International NV	Positive Opinion adopted	Recommending additional renewal

ANNEX 3 TO CHMP MONTHLY REPORT JANUARY 2009

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

Invented Name	Vidaza
INN	azacitidine
Marketing Authorisation Holder	Pharmion Ltd.
Proposed ATC code	L01BC07
Indication	Vidaza is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation with: intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification
CHMP Opinion date	23.10.2008
Marketing Authorisation Date	17.12.2008

Invented Name	Pramipexole Teva
INN	pramipexole
Marketing Authorisation Holder	Teva Pharma B.V
Proposed ATC code	N04B C05
Indication	Pramipexole Teva is indicated for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or “on off” fluctuations).
CHMP Opinion date	23.10.2008
Marketing Authorisation Date	18.12.2008

Invented Name	RoActemra
INN	tocilizumab
Marketing Authorisation Holder	Roche Registration Limited
Proposed ATC code	L04AC07
Indication	RoActemra, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active

	rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	16.01.2009

Invented Name	Stelara
INN	ustekinumab
Marketing Authorisation Holder	Janssen-Cilag International NV
Proposed ATC code	L04AC05
Indication	STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and PUVA.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	16.01.2009

Invented Name	RasilexHCT
INN	Aliskiren/ hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09XA52
Indication	Treatment of essential hypertension in adults. Rasilez HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone. Rasilez HCT is indicated as substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination.
CHMP Opinion date	20.11.2008
Marketing Authorisation Date	16.01.2009

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

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Recombinant human monoclonal antibody to human IL-1 beta of the IgG1/K class	Novartis Europharm Limited	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)
Eltrombopag olamine	GlaxoSmithKline Trading Services Limited	EU/3/07/467	Treatment of idiopathic thrombocytopenic
Recombinant human acid alphaglucosidase	Genzyme Europe BV	EU/3/00/018	Treatment of glycogen storage disease type II (Pompe's disease)
Imatinib mesylate	Novartis Europharm Ltd	EU/3/01/061	Treatment of malignant gastrointestinal stromal tumours
Sildenafil citrate	Pfizer Limited - UK	EU/3/03/178	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
Sitaxentan sodium	Encysive (UK) Ltd UK	EU/3/04/234	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
Trabectedin	PharmaMar SA Sociedad Unipersonal	EU/3/03/171	Treatment of ovarian cancer

ANNEX 5 TO CHMP MONTHLY REPORT JANUARY 2009

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

	1995 - 2008	2009	Overall Total
Scientific Advice	887	26	913
Follow-up to Scientific Advice	171	0	171
Protocol Assistance	198	3	201
Follow-up to Protocol Assistance	90	0	90
	1346	**29**	**1375**

Final Scientific Advice Procedures

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of Coeliac Disease	X				X	X	X	
Chemical	Treatment of cancer-related cachexia	X					X	X	
Chemical	Prophylaxis of organ rejection in solid organ transplant patients	X						X	
Chemical	Treatment of rheumatoid arthritis	X					X	X	
Chemical	Treatment of locally advanced or metastatic breast cancer	X				X			

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Prevention of venous thromboembolic events, treatment of venous thromboembolic disease presenting with deep vein thrombosis, pulmonary embolism or both.	X				X	X	X	
Chemical	Treatment of acute ischemic stroke	X						X	
Chemical	Prevention of stroke/systemic embolic events in non-valvular atrial fibrillation			X				X	
Chemical	Reduction of LDL-C, total cholesterol, and non-HDL cholesterol			X			X	X	
Biological	Treatment of eschar in deep partial thickness and full thickness burns		X			X			
Chemical	Treatment of HIV infection	X					X	X	
Chemical	Prevention of human cytomegalovirus disease following transplant therapy		X					X	
Biological	Prevention of disease caused by Salmonella typhi	X				X		X	
Biological	Treatment for trauma derived cartilage injury	X						X	
Chemical	Treatment of Parkinsons’s disease	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 postoperative pain after orthopaedic surgeries	X					X	X	
Chemical	Treatment of Reading Disorder	X						X	
Chemical	Treatment of Attention-Deficit/ Hyperactivity Disorder	X						X	
Chemical	Treatment of Alzheimer's disease	X					X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 15 Scientific Advice letters, 2 Protocol Assistance letters and 2 Follow-up Scientific Advice letters were adopted at the 19-22 January 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 29 new Requests for which the procedure started at the SAWP meeting held on 19-22 January 2009. The new requests are divided as follows: 22 Initial Scientific Advice, 4 Follow-up Scientific Advice and 3 Initial Protocol Assistance.

ANNEX 6 TO CHMP MONTHLY REPORT JANUARY 2009

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

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CHMP/BWP/ 481473/2008	Concept paper on the need to update the current Annex Guideline for Cell Culture Inactivated Influenza Vaccine with respect to the derivation of cell-isolated influenza vaccine viruses	Adopted

BLOOD PRODUCT WORKING PARTY (BPWP)

Reference number	Document	Status[3]
EMEA/CHMP/BPWP/ 122007/2005	Guideline on Core SPC for Human Plasma Fibrinogen products	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/CVMP/ QWP/17760/2009	Revised guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submission and variations	Adopted for 6-month public consultation subject to final adoption by CVMP

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/CHMP/EWP/ 20097/2008	Guideline on the Development of Medicinal Products for the Treatment of Alcohol Dependence	Adopted for 6-month public consultation
CPMP/EWP/566/98 Rev. 2	Revision of the guideline on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders	Adopted for 6-month public consultation
EMEA/CHMP/EWP/ 644261/2008	Concept Paper on the Need for a Paediatric Addendum for the Pulmonary Arterial Hypertension Guideline	Adopted for 2-month public consultation
EMEA/CHMP/EWP/7895/ 2009	Concept Paper on the Need for the Development of a Paediatric Addendum to the CHMP Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders	Adopted for 2-month public consultation

[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").

Reference number	Document	Status[3]
CPMP/EWP/238/95 Rev.3	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	Adopted for 6-month public consultation
CPMP/EWP/4151/00 Rev 1	Guideline on the Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD)	Adopted

EMEA HUMAN SCIENTIFIC COMMITTES WORKING PARTY WITH PATIENTS AND CONSUMERS ORGANISATIONS (PCWP)

Reference number	Document	Status[3]
EMEA/483439/2008	Rules of Involvement of Members of Patients' / Consumers' and Healthcare Professionals' organizations in Committees related activities	Adopted

SCIENTIFIC ADVICE WORKING PARTY (SAWP)

Reference number	Document	Status[3]
EMEA-H-4260-01-Rev 5	Guidance for companies requesting Scientific Advice and Protocol Assistance	Adopted
EMEA/CHMP/SAWP/ 72894/2008 EMEA/380215/2008	Qualification of novel methodologies for drug development: guidance to applicants Overview of comments received	Adopted
EMEA/24517/2009	Parallel EMEA-FDA scientific advice guidance update 2009	Adopted