European Medicines Agency
Evaluation of Medicines for Human Use

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

The Committee for Medicinal Products for Human Use (CHMP) held its January plenary meeting from 21-24 January 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted three positive opinions by consensus on initial marketing authorisation applications:

- **Effentora** (fentanyl citrate), from Cephalon U.K., for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. EMEA review began on 21 March 2007 with an active review time of 204 days.

- **Pradaxa** (dabigatran etexilate mesilate), from Boehringer Ingelheim International, for the prevention of venous thromboembolic events. EMEA review began on 21 February 2007 with an active review time of 205 days.

- **Thalidomide Pharmion** (thalidomide), from Pharmion Ltd, for the treatment of multiple myeloma. EMEA review began on 21 February 2007 with an active review time of 177 days. Thalidomide is the 45th orphan medicine to receive a positive opinion.

  A separate press release and a question-and-answer document explaining the grounds for the positive opinion and the risk management plan approved by the CHMP are available.

Negative opinion

The CHMP adopted a negative opinion recommending the refusal of a marketing authorisation for **Lenalidomide-Celgene Europe** (lenalidomide), from Celgene Europe. Lenalidomide-Celgene Europe was intended to be used for the treatment of anaemia due to myelodysplastic syndromes. It was designated as an orphan medicine. EMEA review began on 28 September 2005 with an active review time of 176 days.

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

Summaries of opinion for these medicinal products are available on the EMEA website http://www.emea.europa.eu/htms/human/opinion/opinion.htm. Further information will be included in the European Public Assessment Report (EPAR) once the European Commission has granted final approval.

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

Following the re-examination of the negative opinion adopted in September 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Mylotarg** (gemtuzumab ozogamicin), from Wyeth Europa Limited. Mylotarg was intended for the re-induction treatment of CD33-positive acute myeloid leukaemia adult patients in first relapse who are not candidates for other intensive re-induction chemotherapy regimens (e.g. high-dose Ara-C).

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A separate question-and-answer document with more detailed information on the grounds for the final negative opinion is available here.

The EMEA has been formally requested by Pharming Group N.V, to re-examine the negative opinion for **Rhucin** (recombinant human C1 inhibitor) intended to be used in the treatment of acute attacks of angioedema in patients with hereditary angioedema, adopted during the CHMP meeting on 10-14 December 2007.

The EMEA has been formally requested by Neurochem Luco II SARL, to re-examine the negative opinion for **Kiacta** (eprodisate disodium) intended to be used in the treatment of amyloid A (AA) amyloidosis, adopted during the CHMP meeting on 10-14 December 2007.

Withdrawal

The EMEA has been formally notified by Marvel Lifesciences Ltd of its decision to withdraw its applications for centralised marketing authorisation for the medicines **Insulin Human Rapid Marvel, Insulin Human Long Marvel and Insulin Human 30/70 Mix Marvel** (insulin human). These medicines were expected to be used for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis and for the initial control of diabetes mellitus and diabetes mellitus in pregnancy. A separate press release with more information is available. The question-and-answer document will be available in the near future.

Post-authorisation procedures

New contraindications

The CHMP recommended the addition of a new contraindication for rosiglitazone-containing medicines (**Avandia**, **Avandamet**, **Avaglim**), stating that rosiglitazone must not be used in patients with an acute coronary syndrome. The CHMP also recommended the inclusion of a new warning stating that rosiglitazone is not recommended in patients with ischaemic heart disease and/or peripheral artery disease.

A separate press release on these changes is available here.

In addition the CHMP agreed to change the product information for Avaglim (rosiglitazone maleate/glimepiride) to delete the contraindication for its use in combination with insulin.

Updated Safety information

The CHMP finalised a safety review carried out to evaluate the evidence suggesting an increased risk of serious and potentially fatal cardiovascular events (heart attack, stroke, heart failure, and sudden death) when epoetins are administered to treat anaemia in patients with chronic kidney disease. The results of two studies and a meta-analysis recently published, suggest that treatment of anaemia with epoetins in patients with chronic kidney disease may under some circumstances be associated with an increase in the risk of mortality and cardiovascular morbidity. In addition, data from recent clinical trials also showed a consistent unexplained excess mortality in patients with anaemia associated with cancer who have been treated with epoetins. Following CHMP request, the MAHs of the centrally authorised epoetins (**Aranesp (darbepoetin alfa), Neorecormon (epoetin beta), Dynepo (epoetin delta), Mircera (methoxy polyethylene glycol-epoetin beta) and Binocrit/Epoetin Alfa Hexal/Abseamed HX575 (recombinant human erythropoietin alfa)** have amended sections 4.1, 4.2, 4.4 and 5.1 of their SPC through a type II variation to include these warnings. The CHMP adopted these variations by consensus.

The CHMP recommended the inclusion of a warning in the prescribing information for **CellCept** (mycophenolate mofetil) related to cases of Progressive Multifocal Leukoencephalopathy (PML), sometimes fatal, reported in patients treated with CellCept. Physicians should consider PML in the differential diagnosis in patients reporting neurological symptoms.

The CHMP recommended the revision of section 4.1 of the SPC of abacavir containing products (**Ziagen II/45, Kivexa II/18 and Trizivir II/46**) to inform prescribers that screening for carriage of the HLA-B*5701 allele should be performed before initiating treatment with abacavir, and abacavir should not be used in patients known to carry the HLA-B*5701 allele.

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

Withdrawal

The EMEA has been formally notified by Ipsen Ltd of its decision to withdraw the application for an extension of indication for the centrally authorised medicine **NutropinAq** (somatropin). NutropinAq was expected to be used for the treatment of children with severe idiopathic short stature (short height not explained by growth hormone deficiency or other medical conditions) with a predicted adult height of at least one standard deviation score below the target height. A separate press release with more information is available. The question-and-answer document will be available following the CHMP February 2008 meeting.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted eight Lists of Questions on initial applications (one under the mandatory scope, and seven under the optional scope) and one List of Questions on a "line extensions" 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 2007 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 2007 CHMP plenary meeting are provided in **Annex 4**.

Name Review Group (NRG)

See procedural announcement on submission of proposed invented names and new NRG meetings schedule.

Statistical information on the outcome of the checking of acceptability of proposed invented names for medicinal products processed through the centralised procedure will be provided after adoption of the NRG conclusion by the CHMP.

REFERRAL PROCEDURES

Referral procedures started

The CHMP started a referral procedure for **medicinal products containing a fixed combination of dextropropoxyphene and paracetamol,** intended for the treatment of pain, because of safety concerns related to overdose. The procedure was initiated by the European Commission under Article 31 of Directive 2001/83/EC, as amended.

The CHMP started a referral procedure for **Ribavirin iQur**, 200 mg hard capsules, 200 mg, 400 mg, 600 mg film-coated tablets, (ribavirin), from iQur Pharmaceuticals, because of disagreements on the grounds for approval of the medicine in the context of the decentralised procedure. Ribavirin iQur is

indicated for the treatment of chronic hepatitis C (HCV) and to be used only in combination with peginterferon-α2a or interferon-α2a. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC), as amended.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC, as amended, at the request of the European Commission, in order to harmonise the product information across the EU of the following authorised medicines:

- **Tritace,** 1.25 mg, 2.5 mg, 5 mg and 10 mg capsules and tablets, (ramipril), from Sanofi-Aventis, indicated for the treatment of mild to moderate hypertension in patients of 55 years or more who have clinical evidence of cardiovascular disease, stroke or peripheral vascular disease or in diabetic patients of 55 years or more with cardiovascular risk factors.
- **Tritazide,** 5 mg/ 25 mg and 25 mg/125 mg tablets, (ramipril and hydrochlorothiazide), from Sanofi-Aventis, indicated for the treatment of hypertension in patients (in whom combination therapy is appropriate), who have been stabilised on the individual components given in the same proportion.

The CHMP started a referral procedure for **Menomune**, (Meningococcal Polysaccharide Vaccine**,** Groups A, C, Y and W-135 combined), from Sanofi Pasteur MSD, indicated for prophylaxis of meningitis caused by the meningococcal bacteria groups A, C, Y and W-135. The procedure was initiated by Italy under Article 36 of Directive 2001/83/EC, as amended, because of manufacturing concerns.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 25th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 21-23 January 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, held on 7-9 January 2008. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the December 2007 CHMP meeting are listed in **Annex 6**.

UPCOMING MEETINGS FOLLOWING THE JANUARY 2008 CHMP PLENARY MEETING

- The 41st meeting of the CHMP will be held at the EMEA on 19-21 February 2008.
- The Name Review Group meeting was held at the EMEA on 29th January 2008.
- The 26th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 19-21 February 2008.
- A SAG Anti-Infective meeting will be held on the 15th February 2008 at the EMEA.
- A SAG HIV/Viral diseases meeting will be held on the 28th February 2008 at the EMEA.

ORGANISATIONAL MATTERS

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

- The re-election of Dr. Robert as Chair of the Quality Working Party
- The re-election of Dr. Silva Lima as Chair of the Safety Working Party and Dr. Jan Willem Van der Laan as Vice Chair.
- Discussion on the EDQM summary and conclusions on potentially genotoxic impurities and European pharmacopoeia monographs (CHMP/CVMP/QWP/544307/2007).
- Discussion on the survey of MAHs for medicinal products containing active substances in the form of mesilates, (di)isetionates, tosilates or besilate. A letter will be sent to relevant MAHs requesting them

to confirm to competent authorities that a risk analysis has been carried out and to inform on the outcome of such analysis.

- Preliminary discussion with regard to paediatric formulations. The CHMP in collaboration with the PDCO agreed that further guidance was needed and proposed a reflection paper to be developed in the near future.
- Follow-on discussion with regard to biomarker qualification process.
- Follow-on discussion on the Advanced Therapies Regulation and the CHMP nominations to the future Committee on Advanced Therapies.
- Follow-on discussion on the EC legislative proposals to strengthen and rationalise the EU Pharmacovigilance system as part of the external consultation process.
- The finalisation of the Recommendation on "Pharmacovigilance Urgent Measures" procedure under Article 107(2) of Directive 2001/83/EC, as amended.
- Preliminary discussion regarding the appointment of a fifth Co-opted CHMP member.
- Discussion regarding the rejection rate of names of medicinal products processed through the centralised procedure and initial experience on names for non-prescription medicines.
- Preliminary discussion regarding the definition of requirements for ISO Standards and the expertise required from CHMP Working Parties. This is part of the objectives of the ICH M5 topic to develop harmonised electronic transmission standards that build on the regulatory and technical processes currently established in the three ICH regions and observer countries.
- Preliminary discussion regarding the final report of the expert meeting on Clinical trials and protection of trial subjects in low income and developing countries held on 6th November 2007.
- Follow-on discussion regarding CHMP meeting organisation resulting in the decision to initiate the CHMP Plenary meeting at 11 am on the Monday of the CHMP week.

PROCEDURAL ANNOUNCEMENT

- Submission of proposed invented names - new Name Review Group (NRG) meeting schedule

Applicants/MAHs are advised that NRG meetings are rescheduled to occur for a full day every other month to improve the review process. As a result, Applicants/MAHs should take these new dates into account when planning any upcoming proposed invented name notifications. The CHMP will adopt the conclusions the week following the NRG meeting.

For dates of submission please see the EMEA Pre-submission Guidance :
http://www.emea.europa.eu/htms/human/presub/q04-2.htm

- Planned submission of new variations

The EMEA also wishes to remind Applicants that preliminary discussion with regard to coming variations submission should take place with the appointed Rapporteur, Co-Rapporteur and EMEA Project Team Leader well in advance of the foreseen submission.

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This CHMP Monthly Report and other documents are available on the Internet at the following address:
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ANNEX 1 TO CHMP MONTHLY REPORT JANUARY 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	0	0	0	0	2	0	1	3	670
Positive opinions	1	1	0	0	0	0	2	4	433
Negative opinions[1]	0	0	0	0	0	0	1	1	19
Withdrawals prior to opinion	0	0	0	0	3	0	0	3	119
Marketing authorisation granted by the Commission	3	1	0	0	0	0	0	4	421

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2008	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	0	4
PMF (Click here for a list of PMF certifications)	0	11
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

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OUTCOME OF THE JANUARY 2008 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Chemical	Higher risk myelodysplastic syndrome	X	
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)	57	5259
Type II Variations (positive opinions)	60	3704
Type II Variations (negative opinions)	0	10
Annex II Applications (positive opinions)	7	176
Annual Re-assessment (positive opinions)	2	-
Opinion for renewals of conditional MA's (positive opinions)	0	2
5 Year Renewals (positive opinions)	2	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
1 Extensions of indication	1 Positive opinion
36 SPC changes	36 Positive opinions
23 Quality changes	23 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Xigris (drotrecogin alfa (activated)) Eli Lilly Nederland B.V	Positive Opinion adopted	The product remains under exceptional circumstances.
Ventavis (iloprost) Bayer Schering AG	Positive Opinion adopted	The product remains under exceptional circumstances.

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	N/A	N/A

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Carbaglu (carglumic acid) Orphan Europe SARL	Positive Opinion adopted	Unlimited validity
Hepsera (adefovir dipivoxil) Gilead Science International Limited	Positive Opinion adopted	Unlimited validity

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE DECEMBER 2007 CHMP MONTHLY REPORT

Invented Name	Olanzapine Teva
INN	olanzapine
Marketing Authorisation Holder	Teva Pharma B.V.
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.
CHMP Opinion date	18.10.2007
Marketing Authorisation Date	12.12.2007

Invented Name	Silapo
INN	epoetin zeta
Marketing Authorisation Holder	Stada Arzneimittel AG
Proposed ATC code	B03XA01
Indication	Treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis (See section 4.4). Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis (See section 4.4). Treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (e.g. cardiovascular status, pre-existing anaemia at the start of chemotherapy). Silapo can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin (Hb) 10-13 g/dl [6.2-8.1 mmol/l], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).
CHMP Opinion date	18.10.2007

Marketing Authorisation Date	18.12.2007

Invented Name	Retacrit
INN	epoetin zeta
Marketing Authorisation Holder	Hospira Enterprises B.V.
Proposed ATC code	B03XA01
Indication	Treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis (See section 4.4). Treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis (See section 4.4). Treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma, and at risk of transfusion as assessed by the patient's general status (e.g. cardiovascular status, pre-existing anaemia at the start of chemotherapy). Retacrit can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin (Hb) 10-13 g/dl [6.2-8.1 mmol/l], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).
CHMP Opinion date	18.10.2007
Marketing Authorisation Date	18.12.2007

Invented Name	Isentress
Common Name	raltegravir
Marketing Authorisation Holder	Merck Sharp & Dohme Ltd.
Proposed ATC code	J05AX08
Indication	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. This indication is based on safety and efficacy data from two double-blind, placebo-controlled trials of 24 weeks duration in treatment-experienced patients (see section 5.1).
CHMP Opinion date	15.11.2007
Marketing Authorisation Date	20.12.2007

Invented Name	Tesavel

Common Name	sitagliptin
Marketing Authorisation Holder	Merck Sharp & Dohme Ltd
Proposed ATC code	A10BH01
Indication	To improve glycaemic control in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control. To improve glycaemic control in combination with a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance. To improve glycaemic control in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control. *For patients with type 2 diabetes mellitus in whom use of a PPARγ agonist (i.e. a thiazolidinedione) is appropriate, TESAVEL is indicated: I*n combination with the PPARγ agonist when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control.
CHMP Opinion date	15.11.2007
Marketing Authorisation Date	10.01.2008

Invented Name	Ivemend
Common Name	fosaprepitant dimeglumine
Marketing Authorisation Holder	Merck Sharp & Dohme Ltd
Proposed ATC code	Not yet assigned.
Indication	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy. IVEMEND is given as part of a combination therapy (see section 4.2).
CHMP Opinion date	15.11.2007
Marketing Authorisation Date	11.01.2008

Invented Name	Avamys
Common Name	Fluticasone furoate
Marketing Authorisation Holder	Glaxo Group Limited
Proposed ATC code	R01AD12
Indication	Adults, adolescents (12 years and over) and children (6 – 11 years) Avamys is indicated for the treatment of the symptoms of allergic rhinitis.

CHMP Opinion date	18.10.2007
Marketing Authorisation Date	11.01.2008

Invented Name	Abraxane
Common Name	paclitaxel
Marketing Authorisation Holder	Abraxis BioScience Ltd
Proposed ATC code	L01CD01
Indication	Abraxane monotherapy is indicated for the treatment of metastatic breast cancer in patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated (See also section 4.4).
CHMP Opinion date	18.10.2007
Marketing Authorisation Date	11.01.2008

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE DECEMBER 2007 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
N/A	N/A	N/A	N/A

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ANNEX 5 TO CHMP MONTHLY REPORT JANUARY 2008

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

	1995 - 2007	2008	Overall Total
Scientific Advice	887	18	905
Follow-up to Scientific Advice	171	2	173
Protocol Assistance	198	5	203
Follow-up to Protocol Assistance	90	3	93
	1346	**28**	**1374**

OUTCOME OF THE JANUARY 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 type 2 diabetes mellitus	X						X	
Biological	Treatment of rheumatoid arthritis	X				X	X	X	
Chemical	Treatment of acute myeloid leukemia		X				X	X	X
Chemical	Treatment of lymphoblastic leukaemia/ lymphoblastic lymphoma		X					X	X
Biological	Treatment of Methotrexate toxicity		X					X	
Chemical	Treatment of gastric carcinoid		X				X	X	
Chemical	Treatment of psoriasis	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 Acute Lymphoblastic Leukemia		X			X	X	X	X
Chemical	Treatment of ovarian cancer				X			X	X
Biological	Treatment of sarcoma	X				X	X	X	
Biological	Prophylaxis and treatment of transplant rejection	X						X	
Chemical	Conditioning treatment prior to haemotopoietic progenitor cell transplantation				X			X	
Biological	Prophylaxis of venous thromboembolic events	X						X	
Biological	Treatment of anaemia	X						X	
Chemical	Treatment of atopic dermatitis	X						X	
Biological	Treatment of acute renal failure	X						X	
Biological	Treatment of Shiga-toxin producing bacterial infection				X			X	
Biological	Prevention of invasive disease caused by Neisseria Meningitidis			X		X		X	
Chemical	Treatment of Staphylococcus aureus bacteremia	X						X	
Biological	Prevention of herpes zoster and related post-herpetic neuralgia	X						X	
Chemical	Treatment of Hypoactive Sexual Desire Disorder	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 late stage Parkinsons Disease	X				X	X	X	
Chemical	Management of cancer pain	X						X	
Chemical	Treatment of Alzheimer's disease	X					X	X	
Chemical	Treatment of refractory partial onset seizures	X					X	X	
Biological	Treatment of Alpha1-Proteinase Inhibitor (A1-PI) deficiency and emphysema	X						X	X
Chemical	Treatment of asthma and chronic obstructive pulmonary disease	X					X	X	
Biological	Treatment of diabetic macular oedema		X					X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 18 Scientific Advice letters, 5 Protocol Assistance letter, 2 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 21-24 January 2008 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 26 new Requests for which the procedure started at the SAWP meeting held on 7-9 January 2008. The new requests are divided as follows: 18 Initial Scientific Advice, 3 Follow-up Scientific Advice, 4 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

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

BLOOD PRODUCTS WORKING PARTY (BPWP)

Reference number	Document	Status[3]
EMEA/CHMP/BPWP/ 361857/2006	Report of the EMEA expert meeting held on 5-6 July 2006 on the revision of the Core SPC and EMEA NfG for Human Normal Immunoglobulin IV administration	Adopted.

SAFETY WORKING PARTY (SWP)

Reference number	Document	Status[3]
CHMP/SWP/150115/2006	Guideline on Drug-Induced Hepatotoxicity in Non-Clinical Studies	Adopted for 6-month public consultation.
CHMP/SWP/258498/2005	Guideline on Non-Clinical development of fixed combinations of medicinal products	Adopted.
EMEA/CHMP/SWP/ 169215/2005	Guideline on the Need for Pre-clinical Testing of Human Pharmaceuticals in Juvenile Animals	Adopted.
EMEA/CHMP/SWP/ 534549/2007	Concept paper on the need for the Revision of the Note for Guidance on Photosafety Testing	Adopted for 3-month public consultation.

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CHMP/EWP/18463/06	Guideline on Ulcerative Colitis	Adopted.
EMEA/CHMP/EWP/ 566954/2007	Concept Paper on the development of a CHMP Guideline on the clinical investigations of Medicinal Products for the treatment of Pulmonary Hypertension	Adopted for 3-month public consultation.
EMEA/CHMP/EWP/ 12025/2008	Recommendation for Revision of the Points to Consider on the clinical evaluation of New Agents for Invasive Fungal Infections	Adopted for 3-month public consultation.
EMEA/CHMP/EWP/ 20119/2008	Concept Paper on the development of a Guideline on the treatment of Attentional Deficit Hyperactivity Disorder (ADHD)	Adopted for 3-month public consultation.
EMEA/CHMP/EWP/ 20808/2008	Concept Paper on Haematological Malignancies	Adopted for 3-month public consultation.
EMEA/CHMP/267575/ 2006	Appendix 1 to the Guideline on the evaluation of Anticancer Medicinal Products in Man (CHMP/EWP/205/95 Rev. 3) - Methodological Considerations for using Progression-Free Survival (PFS) as Primary Endpoint in Confirmatory Trials for Registration	Adopted.

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EMEA/CHMP/EWP/ 12052/2008	Concept Paper on the Harmonisation and Update of the Clinical Aspects in the Authorised Conditions of Use for Radiopharmaceuticals and other Diagnostic Medicinal Products	Adopted for 3-month public consultation.