European Medicines Agency
Evaluation of Medicines for Human Use

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

The Committee for Medicinal Products for Human Use (CHMP) held its May plenary meeting on 26-29 May 2009.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

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

New medicinal products

- **Afinitor** (everolimus), from Novartis Europharm Ltd., intended for the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. The review began on 23 July 2008, with an active review time of 206 days. Afinitor is the **55th orphan medicine** to receive a positive opinion from the CHMP.
- **Mozobil** (plerixafor), from Genzyme Europe B.V., intended for use in combination with granulocyte-colony stimulating factor (G-CSF) to enhance the mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma whose cells mobilise poorly. The review began on 25 June 2008, with an active review time of 207 days. Mozobil is the **56th orphan medicine** to receive a positive opinion from the CHMP.
- **Samsca** (tolvaptan), from Otsuka Pharmaceutical Europe Ltd, intended for the treatment of hyponatraemia secondary to syndrome of inappropriate antidiuretic hormone secretion (SIADH). The review began on 27 February 2008, with an active review time of 207 days.

Generic medicinal products

The Committee adopted six positive opinions by consensus recommending a marketing authorisation for generic medicines of Plavix (clopidogrel, as hydrogen sulphate), the reference medicine already authorised in the European Union. The medicines concerned are:

- **Clopidogrel 1A Pharma** (clopidogrel, as besilate)**, Clopidogrel ratiopharm GmbH** (clopidogrel, as besilate)**, Clopidogrel Acino** (clopidogrel, as besilate) **and Clopidogrel Hexal** (clopidogrel, as besilate), all from Acino Pharma GmbH,
- **Clopidogrel Teva** (clopidogrel, as hydrogen sulphate), from Teva Pharma B.V.,
- **Grepid** (clopidogrel, as besilate), from Pharmathen S.A..

The Committee also adopted a positive opinion by consensus for **Topotecan Actavis** (topotecan), from Actavis Group PTC ehf. The reference medicine for this generic product is Hycamtin.

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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.

Withdrawals

The EMEA has been formally notified by Sepracor Pharmaceuticals Ltd of its decision to withdraw its application for a centralised marketing authorisation for **Lunivia** (eszopiclone). Lunivia had received a positive opinion in October 2008, but the CHMP recommended that the medicine should not be granted 'new active substance' status. Following a re-examination procedure under Article 9(2) of Regulation (EC) No. 726/2004 at the request of the applicant, the CHMP confirmed its previous opinion in February 2009. At the time of withdrawal, the application was pending the adoption of a marketing authorisation decision by the European Commission. A separate press release and a question-and-answer document with more information are available.

The EMEA has been formally notified by BioPartners GmbH of its decision to withdraw its application for a centralised marketing authorisation for **Biferonex** (interferon-beta-1a). Biferonex was in a re-examination procedure under Article 9(2) of Regulation (EC) No. 726/2004 and was intended for the treatment of adult patients with relapsing remitting multiple sclerosis characterised by two or more exacerbations in the previous two years. A separate press release document with more information is available and a question-and-answer document will be available after the June 2009 CHMP plenary meeting.

The question-and-answer document on the withdrawal of application for **Clopidogrel Teva Pharma** (clopidogrel hydrobromide), which was originally announced in the April CHMP monthly report, is now available on the EMEA website.

Post-authorisation procedures

Extensions of indication and other recommendations

The Committee gave five positive opinions by consensus for applications for the extension of indication, adding a new treatment option, for the following medicines:

- **Alimta (**pemetrexed), from Eli Lilly Nederland B.V., to extend the indication to include monotherapy maintenance treatment of locally advanced or metastatic non-small cell lung cancer in patients whose disease has not progressed immediately following platinum-based chemotherapy. Alimta is already authorised in this indication as monotherapy for second-line treatment after prior chemotherapy, and as first line treatment in combination with cisplatin. It is also authorised as combination therapy for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.
- **Pandemrix (**H5N1) (split virion, inactivated, adjuvanted), **PrePandrix** (H5N1) (split virion, inactivated, adjuvanted), and **Prepandemic influenza vaccine** (H5N1) (split virion, inactivated, adjuvanted), all from GlaxoSmithKlineBiologicals S.A., to extend the use of these vaccines to include subjects aged 61 years and older based on clinical trial data. Pandemrix is a mock-up pandemic influenza vaccine, intended for the prevention of influenza during an officially declared pandemic influenza situation, once the pandemic viral strain has been included. Prepandrix and Prepandemic influenza vaccine are pre-pandemic vaccines intended to trigger an immune response against the H5N1 strain of the influenza virus before or during an officially declared influenza pandemic.
- **Revatio (**sildenafil), from Pfizer Limited, to extend the indication to include the treatment of patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II. Revatio is currently authorised for the treatment of PAH classified as WHO functional class III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.

Summaries of opinion for these extensions of indication are available here. Further information will be included in the EPARs once the European Commission has granted final approval.

Re-examination procedure under Article 6(9) of Regulation (EC) No. 1085/2003 started

The EMEA has been formally requested by Pfizer Limited to re-examine the negative opinion adopted during the CHMP meeting on 20–23 April 2009 on **Lyrica** (pregabalin), for an extension of the indication to the treatment of fibromyalgia in adults experiencing moderate to severe pain, for **Lyrica** (pregabalin), from Pfizer Ltd. Lyrica is currently authorised for the treatment of neuropathic pain, epilepsy and generalised anxiety disorder in adults.

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

Following re-examination of its negative opinion adopted in January 2009, the Committee adopted a final positive opinion by consensus under exceptional circumstances, subject to certain specific obligations to be reviewed annually, for **Vedrop** (tocofersolan), from Orphan Europe S.A.R.L., intended for the treatment of vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis. A question-and-answer document with more information about the re-examination is available.

Special warning and precaution for use

The CHMP adopted an amendment to update sections 4.4 and 4.8 of the Summary of Product Characteristics (SPC) for **Tygacil** (tigecycline) from Wyeth Europa Ltd to include precautionary language regarding isolated cases of significant hepatic dysfunction and hepatic failure following the assessment of the fifth Periodic Safety Update Report (PSUR) covering the period from 15 December 2007 to 14 June 2008. A review of all cases of severe hepatic injury and hepatic failure associated with tigecycline has been assessed and the conclusion was that cases of liver injury with a predominantly cholestatic pattern have been reported in patients receiving Tygacil treatment, including some cases of hepatic failure with a fatal outcome. Although hepatic failure may occur in patients treated with Tygacil due to underlying conditions or concomitant medications, a possible contribution of Tygacil should be considered.

Other information

The CHMP revised the posology and adverse events sections of the SPC regarding re-administration of **Remicade** (infliximab) from Centocor B.V. Limited experience from re-treatment following disease flare by a re-induction regimen suggested a higher incidence of infusion reactions when compared to maintenance treatment for psoriasis. The product information was amended to alert prescribers that, in case maintenance therapy is interrupted across all indications, and the need exists to restart treatment, the use of a re-induction regimen is not recommended. Remicade should be re-initiated as a single dose followed by the appropriate maintenance dose recommendations.

Lifting of supply and treatment restrictions for Neupro

The Committee recommended that the supply and treatment restrictions for Neupro (rotigotine transdermal patch), from Schwarz Pharma Ltd, be lifted. Once this recommendation is endorsed by the European Commission, the ban on prescribing Neupro to patients not yet taking the medicine will be reversed. Doctors in the European Union will then be able to prescribe Neupro to all patients in accordance with the approved product information and prescriptions will no longer be limited to one month. A separate press release with more detailed information is available here.

Expiry of licence

The EMEA has been formally notified by Sanofi Pasteur MSH of its decision not to renew its application for a centralised marketing authorisation for **Procomvax** (haemophilus b conjugate (Meningoccocal Protein conjugate) and hepatitis B (recombinant) vaccine) for commercial reasons. Procomvax was developed for vaccination against invasive disease caused by *Haemophilus influenzae* type b and against infection caused by all known subtypes of hepatitis B virus in infants 6 weeks to 15 months of age. A separate public statement document is available. A separate public statement with more detailed information is available here.

Article 5(3) of Regulation (EC) No 726/2004 and follow-up recommendations on use of antiviral medicines in the event of an influenza A/H1N1 pandemic

The Committee has adopted a set of follow-up recommendations to its guidance on the use of Tamiflu (oseltamivir) in children under one year of age and the use of Tamiflu and Relenza (zanamivir) in pregnant and breast feeding women in the case of a declared influenza A/H1N1 published on 8 May 2009. The detailed follow-up recommendations are available here.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (including one under the mandatory scope and two under the optional scope) and one List of Questions on "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 April 2009 is provided in **Annex 3.**

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 4**.

REFERRAL PROCEDURES

Referral procedures concluded

The CHMP concluded one referral procedure 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 medicinal product concerned is:

Loratadine Sandoz 10 and associated names (loratadine), 10 mg tablets 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. The CHMP concluded that bioequivalence had not been adequately demonstrated. The CHMP recommended the refusal of the granting of the Marketing Authorisation in the Concerned Member States and the suspension of the Marketing Authorisation for Loratadine Sandoz 10 in the Member States where the product is currently authorised. A separate question-and-answer document with more information about the above mentioned procedure is available here.

Referral procedures started

The CHMP started a referral procedure under **Article 31** of Regulation (EC) 83/2001, as amended for **modafinil-containing medicines**, on the request of the United Kingdom, because of concerns related to skin and hypersensitivity reactions and psychiatric disorders. Modafinil-containing medicines are wakefulness promoting stimulants authorised for the symptomatic relief of excessive sleepiness associated with narcolepsy and in some Member States also for use in obstructive sleep apnoea/hypopnoea syndrome and/or moderate to sever chronic shift work sleep disorder.

The CHMP started a referral procedure under **Article 6(13)** of Commission Regulation EC No 1084/2003. This type of referral procedure is triggered by a Marketing Authorisation Holder when a Type II variation is refused in the context of the mutual recognition procedure or the decentralised procedure. The medicinal product concerned is:

Seroquel XR and associated names (quetiapine fumarate), from AstraZeneca AB. The procedure was initiated because of the refusal of a Type II variation application for the extension of the indication of the prolonged release formulation of Seroquel to the treatment of major depressive disorders.

The CHMP started a number of 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 medicinal products concerned are:

- **Fentrix** (fentanyl), 25, 50, 75 and 100 µg/h transdermal patches from Helm Pharmaceuticals GmbH, indicated for severe chronic pain. The procedure was initiated because of disagreements regarding the safety of the product.
- **Pantoprazole Olinka 1169 (**pantoprazole sodium sesquihydrate), 20 mg, 40 mg gastro resistant tablets from Olinka (UK) Ltd, indicated for the treatment of gastrointestinal diseases associated with acid hypersecretion. The procedure was initiated because of disagreements regarding bioequivalence.
- **Pantoprazole Olinka 1170** (pantoprazole sodium sesquihydrate), 20 mg, 40 mg gastro resistant tablets from Olinka (UK) Ltd, indicated for the treatment of gastrointestinal diseases associated with acid hypersecretion. The procedure was initiated because of disagreements regarding bioequivalence.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended. This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level. The medicinal product concerned is:

- **Tienam and associated names** (imipenem monohydrate and cilastatin sodium), from Merck Sharp & Dohme group of companies and associated companies, used as a broad-spectrum antibiotic.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 40th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 26-27 May 2009. For further details, please see the relevant press release on the CMD(h) website under the heading 'Press Releases': http://www.hma.eu/

Extension of shelf-life of Relenza

The CHMP noted the approval via mutual recognition procedure of a variation to extend the shelf life of Relenza (zanamivir), inhalation powder from five to seven years. For further information, including recommendations on the use of Relenza in case of a shortage, please refer to the CMD(h) press release from the May 2009 meeting.

CHMP WORKING PARTIES

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Party (SAWP) meeting, which was held on 4-6 May 2009. For further details, please see **Annex 5**.

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

UPCOMING MEETINGS FOLLOWING THE MAY 2009 CHMP PLENARY MEETING

- The 56th meeting of the CHMP will be held at the EMEA on 22-25 June 2009.
- The next Name Review Group meeting will be held at the EMEA on 28 July 2009.
- The 41st CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 22-23 June 2009.

ORGANISATIONAL MATTERS

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

- The latest development regarding activities at EMEA concerning the Novel Influenza Virus (swine flu). The Committee was informed of the current information from WHO and the Committee adopted EMEA interim considerations on data requirements for a novel Influenza (swine) Vaccine following consultation of the VWP, BWP, PDCO and PhVWP.
- The adoption of minor revision regarding the guideline on the Scientific Application and the Practical Arrangements necessary to Implement Commission Regulation (EC) No 507/2006 on the Conditional Marketing Authorisation for Medicinal Products for Human Use falling within the Scope of Regulation (EC) No 726/2004 (EMEA/509951/2006) together with the overview of comments received.
- Follow-up discussion on the experience obtained following the recent suspension / withdrawal of marketing authorisations.
- Discussion on action plan and steps forward to be taken in the context of radiopharmaceuticals used in clinical practice in the EU following the supply shortage in September 2008. A specific workshop will be planned towards the end of 2009.
- The election of Dr. Robert and Dr. Berchem as his alternate as CHMP representative on the Committee on Advanced Therapy.
- The re-election of Pr. Weller as Chair of the SAG HIV/Viral diseases and Dr. Vittecoq as Vice-Chair.
- The adoption of the report from EMEA - EFPIA Pharmacogenetics Workshop on Integrating Pharmacogenetics Early into Drug Development held on 19th December 2008 (EMEA/151623/2009). The report focused on the application of Pharmacogenomic biomarkers in early clinical drug development (from Phase I to Phase IIa) and will be published on the EMEA website shortly.

PROCEDURAL ANNOUNCEMENT

Use of 2D Matrix codes on Outer Cartons for Centralised Products

The EMEA has been made aware that the French Agency for the Safety of Health products (AFSSAPS) is switching the CIP codes from 7 characters to 13 characters and from barcode 39 to EAN 128 (combined with ECC.200 data matrix marking) as per the EAN.UCC system.

http://www.afssaps.fr/var/afssaps_site/storage/original/application/b02d12c20a61ec4c6119974c92c0d15f.pdf

According to the Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community, the information described above is considered additional labelling information required by a Member State. Such information should normally be accommodated in the blue-box area, to appear on one side of the pack. However, Marketing Authorisation Holders have informed the EMEA of the technical difficulties in fitting the 2D Matrix codes in the blue-box area. In such cases, the 2D Matrix codes may be displayed outside the blue-box.

Please note that the 13 characters CIP code should still be printed within the blue-box.

PROCEDURAL ANNOUNCEMENT

Handling changes to the Detailed Description of Pharmacovigilance System

The EMEA is applying a new policy to facilitate the handling of submission of changes to the Detailed Description of Pharmacovigilance System (DDPS) module 1.8.1 of the CTD, which affects different products of the same Marketing Authorisation Holder (MAH).

The MAH should submit at the same time a Type II variation for each concerned product but there will be a joint assessment of the DDPS. One lead PTL and one lead Rapporteur will be appointed to coordinate this exercise. Nevertheless, the individual PTLs and Rapporteurs will still be involved as usual. If necessary, one lead contact person from the company can be nominated to coordinate this exercise.
Only one reduced fee will apply (please refer to the explanatory note on the fees payable to the EMEA: http://www.emea.europa.eu/pdfs/general/admin/fees/explanatory_note.pdf).

The MAH should submit a letter of intent one month before the submission date to CIG with copy to all concerned PTLs along with the following information:
- A table listing all the products concerned by the work sharing exercise indicating if there are any changes to the product specific annexes (only applicable when the changes are linked to the DDPS only);
- Confirmation that the core DDPS is the same for all the products.
- Summary of the change(s) in the DDPS;
- Version number of the updated DDPS;

The EMEA will then decide on the appropriateness of the proposal and confirm the Lead Rapporteur appointment to the applicant as well as the lead PTL.

At the time of the submission, the applicant will need to re-submit the above mentioned information to the lead Rapporteur with copy to the lead PTL but also to all the individual Rapporteurs and PTLs concerned by the variation application.
A version highlighting the changes to the DDPS should be part of the variation application. If extensive changes to the DDPS are proposed, an addendum to the clinical overview and a clinical expert signature and CV (M.1.4.3) should also be provided.

The timetable is 30 days for a change in QPPV and 60 days for any other change(s).

The Post-authorisation procedural advice will be updated shortly to reflect these measures. Please note however that this is an interim measure and may change when the Variation Regulation (Regulation (EC) No 1234/2008) comes into force.

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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 MAY 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	8	2	0	28	2	1	3	44	842
Positive opinions	7	9	0	12	3	1	3	35	528
Negative opinions[1]	0	0	0	0	1	0	1	2	23
Withdrawals prior to opinion	1	0	0	1	2	2	1	7	146
Marketing authorisation granted by the Commission	10	4	0	3	8	1	4	30	515

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2009	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	6
PMF (Click here for a list of PMF certifications)	0	13
VAMF	0	0

[1] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[2] Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/104/EC

OUTCOME OF THE MAY 2009 CHMP MEETING IN RELATION TO ACCELERATED ASSESSMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Chemical	Treatment of chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis		X
Biological	N/A	N/A	N/A

ANNEX 2 TO CHMP MONTHLY REPORT MAY 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)	465	6834
Type II Variations (positive opinions)	446	4989
Type II Variations (negative opinions)	1	17
Annex II Applications (positive opinions)	31	214
Annual Re-assessments (positive opinions)	7	-
Opinions for renewals of conditional MA's (positive opinions)	2	8
5-year Renewals (positive opinions)	33	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
5 Extension of indication	5 Positive opinions
51 SPC changes	51 Positive opinions
35 Quality changes	35 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	**N/A**	**N/A**

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
INTELENCE (etravirine), Janssen-Cilag International NV	Positive Opinion adopted	N/A

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Apidra (insulin glulisine) sanofi-aventis Deutschland GmbH	Positive Opinion adopted	Unlimited validity
Pedea (ibuprofen) Orphan Europe S.A.R.L.,	Positive Opinion adopted	Unlimited validity
Synagis (palivizumab) Abbott Laboratories Ltd	Positive Opinion adopted	Unlimited validity
Zeffix (lamivudine) Glaxo Group Limited	Positive Opinion adopted	Recommending additional renewal

ANNEX 3 TO CHMP MONTHLY REPORT MAY 2009

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

Invented Name	Qutenza
INN	capsaicin
Marketing Authorisation Holder	NeurogesX UK Ltd
Proposed ATC code	N01BX04
Indication	Qutenza is indicated for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain.
CHMP Opinion date	19.03.2009
Marketing Authorisation Date	15.05.2009

Invented Name	Modigraf
INN	tacrolimus
Marketing Authorisation Holder	Astellas Pharma Europe B.V.
Proposed ATC code	L04AD02
Indication	Prophylaxis of transplant rejection in adult and paediatric, kidney, liver or heart allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult and paediatric patients.
CHMP Opinion date	19.03.2009
Marketing Authorisation Date	15.05.2009

Invented Name	Ellaone
INN	ulipristal acetate
Marketing Authorisation Holder	Laboratoire HRA Pharma
Proposed ATC code	Not yet assigned
Indication	Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.
CHMP Opinion date	19.03.2009
Marketing Authorisation Date	15.05.2009

Invented Name	Nimvastid
INN	rivastigmine
Marketing Authorisation Holder	Krka, d.d., Novo mesto
Proposed ATC code	N06DA03
Indication	Symptomatic treatment of mild to moderately severe Alzheimer's dementia. Symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease.
CHMP Opinion date	19.03.2009
Marketing Authorisation Date	11.05.2009

ANNEX 4 TO CHMP MONTHLY REPORT MAY 2009
INVENTED NAME REVIEW GROUP (NRG)

	NRG meeting; 27 Jan 2009		**NRG meeting; 17 Mar 2009**		**NRG meeting; 12 May 2009**		**2009**	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	47	52	30	36	27	28	104	116
Justification for retention of invented name *	5	1	3	1	2	1	10	3

*In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the EMEA website.

	NRG meeting; 27 January 2009		**NRG meeting; 17 March 2009**		**NRG meeting; 12 May 2009**		**2009**	
Objections	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	120	65	79	40	56	46	255	151
Criterion - Safety concerns								
Similarity with other Invented name	100	56	67	36	51	39	218	131
Conveys misleading therapeutic/pharmaceutical connotations	6	0	1	1	0	0	7	1
Misleading with respect to composition	0	0	3	0	0	2	3	2
Criterion - INN concerns								
Similarity with INN	2	3	1	1	1	4	4	8
Inclusion of INN stem	3	0	0	1	0	1	3	2
Criterion - Other public health concerns								
Unacceptable qualifiers	4	1	0	1	0	0	4	2
Conveys a promotional message	1	0	5	0	0	0	6	0
Appears offensive or has a bad connotation	1	1	0	0	1	0	2	1
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	3	4	2	0	3	0	8	4
Similarity between name of prodrug and related active substance	0	0	0	0	0	0	0	0

See *Guideline on the Acceptability of Invented names for human medicinal products processed through the Centralised procedure (CPMP/328/98)* for detailed explanations of criteria used.

ANNEX 5 TO CHMP MONTHLY REPORT MAY 2009

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

	1995 - 2008	2009	Overall Total
Scientific Advice	887	**86**	**973**
Follow-up to Scientific Advice	171	**19**	**190**
Protocol Assistance	198	**14**	**212**
Follow-up to Protocol Assistance	90	**6**	**96**
	1346	**125**	**1471**

OUTCOME OF THE MAY 2009 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Final Scientific Advice Procedures

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	treatment of graft versus host disease		X					X	X
Chemical	treatment of Fabry disease				X			X	
Chemical	treatment of colorectal cancer, gastric cancer and breast cancer	X						X	
Chemical	treatment of multiple myeloma		X				X	X	
Chemical	treatment breast cancer			X				X	
Biological	treatment of asthma	X					X	X	
Biological	treatment of chronic lymphocytic leukemia	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 non Hodgkin's lymphoma	X						X	
Biological	treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis	X				X	X	X	
Biological	treatment of breast cancer	X						X	
Biological	treatment of bleeding episodes in haemophilia A patients	X						X	
Chemical	maintenance of patients with severe cardiac failure until cardiac transplant	X					X	X	
Chemical	treatment of atopic dermatitis	X					X	X	
Chemical	treatment of congenital ichthyoses				X			X	X
Biological	prevention of hepatitis B infection in end-stage renal disease	X					X	X	
Biological	prevention of Neisseria meningitides infection			X			X	X	
Biological	prevention of N. meningoccal serogroup B infection			X		X		X	
Biological	prevention of N. meningoccal serogroup B infection	X					X		
Chemical	prevention of skeletal related events	X						X	
Biological	treatment of Alzheimer's disease	X				X			

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	treatment of partial epilepsy	X				X		X	
Chemical	treatment of Parkinson's Disease	X				X	X	X	
Chemical	treatment of Huntington's disease	X					X	X	
Biological	treatment of emphysema		X				X	X	
Chemical	treatment of asthma			X			X	X	
Biological	treatment of asthma			X				X	
Chemical	treatment of seasonal allergic rhinitis and perennial allergic rhinitis	X						X	
Biological	treatment of osteoporosis	X							
Biological	broad advice on developmental and reproductive toxicology studies	X					X		
Chemical	treatment of hyper-phosphataemia associated with chronic kidney disease	X						X	
Chemical	treatment of hyper-phosphataemia	X				X		X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 21 Scientific Advice letters, 3 Protocol Assistance letters, 5 Follow-up Scientific Advice and 2 Follow-up Protocol Assistance letters were adopted at the 26-29 May 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 52 new Requests for which the procedure started at the SAWP meeting held on 4-6 May 2009. The new requests are divided as follows: 37 Initial Scientific Advice, 4 Follow-up Scientific Advice, 8 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

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

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CPMP/BWP/ 125/04/Rev 1	Guideline on Epidemiological Data on Blood Transmissible Infections	Adopted for 3-month public consultation

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CPMP/EWP/1343/01 Rev. 1	Guideline on the Clinical Evaluation of Antifungal Agents for the Treatment and Prophylaxis of Invasive Fungal Disease	Adopted for 6-month public consultation