European Medicines Agency
Evaluation of Medicines for Human Use

London, 27 October 2006
EMEA/410526/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
OCTOBER 2006 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its October plenary meeting from 16-18 October 2006.

Centralised procedure

Initial applications for marketing authorisation

The Committee gave four positive opinions on initial marketing authorisation applications, including two opinions for medicinal products that are intended for the treatment of patients suffering from rare diseases:

- The Committee recommended by consensus the granting of a conditional marketing authorisation for **Diacomit** (stiripentol), from Laboratoires Biocodex, for the treatment of refractory severe myoclonic epilepsy in infants in conjunction with clobazam and valproate. Conditional marketing authorisation has been recommended on the condition that further evidence regarding efficacy of stiripentol in combination with maximum safe doses of clobazam and valproate, and on the bioavailability of Diacomit sachets compared to capsules is provided at a later stage. The EMEA will re-assess Diacomit annually to confirm that the benefit-risk balance remains positive. Diacomit is the **32nd orphan medicinal product** to receive a positive CHMP opinion. EMEA review began on 18 May 2005 with an active review time of 201 days.
- The Committee recommended by consensus the granting of a marketing authorisation under exceptional circumstances for **Elaprase** (idursulfase), from Shire Human Genetics Therapies AB, for the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase is the **33rd orphan medicinal product** to receive a positive CHMP opinion. EMEA review began on 28 December 2005 with an active review time of 207 days. Marketing authorisation under exceptional circumstances may be granted subject to certain specific obligations, to be reviewed annually. In the case of Elaprase, this relates to the fact that the indication applied for is so rare that the applicant cannot reasonably be expected to provide comprehensive data on the safety and efficacy of the medicinal product.
- The Committee recommended by majority the granting of a marketing authorisation for **Tandemact** (pioglitazone hydrochloride/glimepiride), from Takeda Europe R & D Centre Ltd, for the treatment of patients with type-2 diabetes mellitus who show intolerance to metformine or for whom metformin is contraindicated and who are already treated with a combination of pioglitazone and glimepiride. EMEA review began on 17 August 2005 with an active review time of 196 days.
- The Committee recommended by consensus the granting of a marketing authorisation for **Adrovance** (alendronic acid and colecalciferol), from Merck Sharp & Dohme Ltd, for the treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. Adrovance is the same medicinal product as Fosavance, also from Merck Sharp & Dohme Ltd, which is already authorised in the European Union. EMEA review began on 21 July 2006 with an active review time of 89 days.

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Lifting of conditional marketing authorisation

Sutent (sunitinib malate), from Pfizer Ltd., is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumours after failure of imatinib mesylate treatment due to resistance or intolerance, and advanced and/or metastatic renal cell carcinoma (MRCC) after failure of interferon alfa or interleukin-2 therapy. Sutent was the first medicinal product to be granted a conditional marketing authorisation in the European Union. The marketing authorisation was granted under the condition that the marketing authorisation holder would provide further comprehensive data on Sutent's effect in terms of relevant clinical endpoints such as progression-free survival in patients with MRCC.
Following evaluation of clinical data submitted by the marketing authorisation holder as part of a Type II variation for an extension of indication, the Committee recommended by consensus a switch from the conditional marketing authorisation to a full marketing authorisation. It also recommended extending the indication in MRCC to first-line treatment.

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.

Extensions of indication and other recommendations

In addition to the extension of indication for Sutent, the Committee gave another four positive opinions for applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Aldara** (imiquimod), from Laboratoires 3M Santé, received a positive opinion by consensus to include topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis in adults. Aldara was first granted a marketing authorisation in the European Union on 18 September 1998 and is currently indicated for the topical treatment of external genital and perianal warts and small superficial basal cell carcinomas in adults.
- **Glivec** (imatinib mesylate), from Novartis Europharm Ltd, received two positive opinions by consensus to include treatment of myelodysplastic syndromes and myeloproliferative diseases (MDS/MPD) as well as treatment of adult patients with hypereosinophilic syndrome and chronic eosinophilic leukaemia (HES/CEL). Glivec was first granted a marketing authorisation in the European Union on 7 November 2001 and is currently indicated for the treatment of adult and paediatric patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia, adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST) and adult patients with dermatofibrosarcoma protuberans (DFSP).
- **Hycamtin** (topotecan), from SmithKline Beecham Plc, received a positive opinion by consensus to include treatment, in combination with cisplatin, of patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment-free interval to justify treatment with the combination. Hycamtin was first granted a marketing authorisation in the European Union on 12 November 1996 and is currently indicated as monotherapy for second-line treatment of patients with metastatic carcinoma of the ovary and patients with relapsed small cell lung cancer.
- **Rotarix** (live human rotavirus RIX4414), an oral vaccine from GlaxoSmithKline Biologicals, received a positive opinion by consensus to extend the therapeutic indication to include new information that protection against rotavirus serotypes G4P[8] and G2P[4] has also been demonstrated. Rotarix was first granted a marketing authorisation in the European Union on 21 February 2006 and is indicated for the prevention of gastro-enteritis caused by Rotavirus of types G1P[8], G3P[8] and G9P[8].
- **Sutent (**sunitinib malate) – see above under "Lifting of conditional marketing authorisation"

Summaries of opinions for these five products including the detailed therapeutic indications are available and can be found here.

New contraindications

The Committee recommended adding new contraindications for four medicinal products that contain duloxetine as active substance. For all four products, namely **Ariclaim** and **Xeristar**, from Boehringer Ingelheim International GmbH, and **Yentreve** and **Cymbalta**, from Eli Lilly Nederland B.V., the Committee recommended that treatment should not be initiated in patients with uncontrolled hypertension that could expose patients to a potential risk of hypertensive crisis.
In addition, for Ariclaim and Yentreve, the Committee also recommended that these two products should not be used in patients with severe renal impairment. This contraindication is already included in the product information for Cymbalta and Xeristar.
Ariclaim and Yentreve were first granted marketing authorisations on 11 August 2004 and are currently authorised for the treatment of moderate to severe stress urinary incontinence in women. Cymbalta and Xeristar were first granted marketing authorisations on 17 December 2004 and are currently authorised for the treatment of major depressive episodes and the treatment of diabetic peripheral neuropathic pain in adults.

Summaries of opinions, including more detailed information on the contraindications for all products mentioned above are available and can be found here.

Lists of Questions

The Committee adopted four Lists of Questions on initial applications (three under the mandatory scope and one under the optional scope).

Withdrawals

The European Medicines Agency has been formally notified by La Jolla Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product **Riquent** (abetimus sodium).

The indication applied for was treatment of lupus nephritis, an inflammation of the kidneys, in patients with systemic lupus erythematosus (an auto-immune disease caused by the body's own defence system attacking normal tissue) who have a history of kidney disease. Riquent was expected to delay and to reduce the incidence of 'flares' (increased signs of kidney disease). Abetimus sodium was designated as an orphan medicinal product for the treatment of lupus nephritis on 20 November 2001. The application for marketing authorisation for Riquent was submitted to the EMEA on 31 March 2006. At the time of the withdrawal, it was under review by the CHMP. In its official letter, the company stated that the withdrawal of Riquent was due to the fact that the additional clinical data requested by the CHMP to support the application cannot be provided within the timeframe of the current application procedure. More information about Riquent and the current state of the scientific assessment at the time of withdrawal will be made available in a question and answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website http://www.emea.europa.eu/htms/human/withdraw/withdrawapp.htm, in the very near future.

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in September 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 September 2006 CHMP plenary meeting are provided in **Annex 4**.

Referral procedures

- The Committee concluded a referral procedure for **Alendros 70** (alendronate sodium trihydricum), from Zentiva a.s., intended for the treatment of osteoporosis in postmenopausal women. The CHMP recommended by majority the refusal of a marketing authorisation and a suspension of the marketing authorisation for Alendros 70 mg tablets where appropriate because bioequivalence with the reference product (Fosamax 70 mg tablets) has not been demonstrated by appropriate bioavailability study. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) by the Czech Republic because of disagreement among the Member States in the context of the mutual recognition procedure.

- The Committee concluded a referral procedure recommending by consensus the suspension of a generic medicinal product called **Simvastatine** (simvastatine), from Neo Pharma Ltd, because of non-compliance with good clinical practice (GCP) in the conduct of the study used to demonstrate bioequivalence with the originator product. The procedure was initiated by the Netherlands under Article 36 of the Community code on human medicinal products (Directive 2001/83/EC as amended). This procedure is initiated where a Member State considers that there are public health concerns relating to a product that may require regulatory action in all Member States where the product is authorised.

The Committee started referral procedures for two generic medicinal products under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended) because of disagreement among the Member States in the context of the mutual recognition procedure:

- The referral for **Cefuroximaxetil** 125 omhulde tabletten 125 mg, Cefuroximaxetil 250 omhulde tabletten 250 mg, Cefuroximaxetil 500 omhulde tabletten 500 mg, (cefuroxim (as axetil)), from Sandoz B.V., was initiated because of disagreements on whether the medicinal product should be indicated for the treatment of uncomplicated gonorrhoea (urethritis and cervicitis).
- The referral for **Fexofenadinhydrochlorid "Teva"** 120 mg and 180 mg film-coated tablets (fexofenadine hydrochloride), from Teva UK Ltd, was initiated because of disagreements regarding bioequivalence with the originator product.

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

The European Medicines Agency has been formally requested by Roche Registration Limited, to re-examine the negative opinion for the extension of indication for **Tarceva** (erlotinib) adopted during the CHMP meeting that took place on 24-27 July 2006.

Other procedures

- **Review of NSAIDs**

  The European Medicines Agency has concluded that the benefit-risk balance for non-selective non-steroidal anti-inflammatory drugs (NSAIDs) remains favourable. This conclusion was drawn following a review announced in September 2006 of new thrombotic cardiovascular safety data. This review procedure has been initiated under Article 5(3) of Regulation (EC) No 726/2004 and has resulted in a CHMP scientific opinion, which can be found here.

  A separate Press Release and question and answers document with more detailed information about the review of NSAIDs is available.

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 25-27 September 2006. For further details, please see **Annex 5**.

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

Invented 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 7.**

Mutual Recognition procedure and Decentralised procedures-Human

The CHMP noted the report from the 11th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-17 October 2006. For further details, please see the relevant press release on the CMD(h) website under the heading Press Releases: http://heads.medagencies.org/

Upcoming meetings following the October 2006 CHMP plenary meeting:

- The 27th meeting of the CHMP will be held at the EMEA on 13-16 November 2006.
- The next Invented Name Review Group meeting will be held at the EMEA on 13 November 2006.
- The 12th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 16-18 October 2006.
- A SAG Anti-Infectives "kick-off" meeting will take place on the 7th December 2006.

Organisational matters

The main topics addressed during the October 2006 CHMP meeting related to:

- Discussions with regard to the Draft Core Risk Management plan for the Pandemic Influenza Vaccines.
- Discussions with regard to the Draft Guideline on the use of statistical signal detection methods in the EudraVigilance data analysis system.
- Update on public consultation phase and final discussion on concepts for CHMP opinions on Compassionate Use.
- The adoption of revised draft work plans for some CHMP Working Parties.
- The nomination of CHMP representatives/experts for the EMEA Human Scientific Committees Working Party with Patients and Consumer Organisations (PCWP).
- The nomination of CHMP representatives/experts for the EMEA/CHMP Working Group with Health Care Professionals Organisations.

PROCEDURAL ANNOUNCEMENT

- Submission of product information in Maltese

On 1st May 2007 the derogation regarding the status of the Maltese language as part of a Commission decision issued in the context of the centralised procedure will most likely come to an end. EMEA in collaboration with the Maltese National Competent Authorities are therefore organising a continuation of the "pre-accession linguistic check (PALC)" for all Centrally Authorised Products which were authorised after 1st May 2004 as these were not reviewed by the Maltese authorities as part of the previous PALC.
As Maltese will be required for all procedures with product information annexes, which will receive a CHMP opinion as of February/March 2007, and in an effort to anticipate any possible delays in the decision-making process, we would strongly advise companies with planned regulatory activity in the first quarter of 2007 to initiate the translation process for their products in Maltese as soon as possible.
EMEA will publish detailed guidance on the handling of Maltese translations together with specific timeframes, in November 2006.

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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

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	Dec 2005/2006[1]							1995 onwards	
	Optional Scope				Mandatory scope				
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans	Total	Overall total
Applications for MA submitted[2]	26	6	0	2	14	8	14	70	605
Positive opinions[3]	19	2	0	0	6	0	9	36	362[4]
Negative opinions[5]	3	0	0		2	0	0	5	12[6]
Withdrawals prior to opinion	2	1	0		1	0	4	8	107
Marketing authorisation granted by the Commission	20	1	0		10	0	8	39	350

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	Dec 2005/2006	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	1	3
Consultation for medical devices[6]	1	5
PMF	3	10
VAMF	0	0

[1] Starting point for operation of the new eligibility criteria to the centralised procedure
[2] Number of accelerated reviews requested and number of accelerated reviews granted (3/0)
[3] Subdivided by conditional and exceptional (0/0)
[4] 362 positive Opinions corresponding to 288 substances
[5] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[6] Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/104/EC

OUTCOME OF THE OCTOBER 2006 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
N/A	N/A	N/A	N/A

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ANNEX 2 TO CHMP MONTHLY REPORT OCTOBER 2006

POST-AUTHORISATION: TYPE I AND II VARIATIONS, ANNEX II, RENEWALS AND ANNUAL RE-ASSESSMENT APPLICATIONS

Activity	2006	Overall total 1995 onwards
Type I Variations (positive notifications)	583	4023
Type II Variations (positive opinions)	550	2732
Type II Variations (negative opinions)	1	8
Annex II Applications (positive opinions)	14	141
Annual Re-assessment (positive opinions)	18	-
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	46	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
6 Extensions of indication	6 Positive opinions
38 SPC changes	38 Positive opinions
18 Quality changes	18 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Velcade (bortezomib) Janssen-Cilag International N.V	Positive Opinion	The Marketing Authorisation will remain 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**
Viread (tenofovir) Gilead Science International Limited	Positive Opinion adopted	The Committee agreed that one further renewal would be required in 5 years time due to safety issues

ANNEX 3 TO CHMP MONTHLY REPORT OCTOBER 2006

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE SEPTEMBER 2006 CHMP MONTHLY REPORT

Invented Name	Champix
INN	varenicline tartrate
Marketing Authorisation Holder	Pfizer Limited
Proposed ATC code	N07BA03
Indication	CHAMPIX is indicated for smoking cessation in adults
CHMP Opinion date	27.07.2006
Marketing Authorisation Date	26.09.2006

Invented Name	Suboxone
INN	buprenorphine / naloxone
Marketing Authorisation Holder	Schering Plough Europe
Proposed ATC code	N07BC51
Indication	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment.. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction.
CHMP Opinion date	27.07.2006
Marketing Authorisation Date	26.09.2006

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE SEPTEMBER 2006 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
1,3-Propanedisulfonic acid, disodium salt (Kiacta)	Neurochem Luxco II SARL	EU/3/01/051 31/07/2001	Treatment of systemic secondary amyloidosis
Fluocinolone acetonide (prolonged-release intravitreal implant) (Retisert 590 microgram intravitreal implant)	Bausch and Lomb (UK) Ltd	EU/3/05/261 07/03/2005	Treatment of non-infectious uveitis affecting the posterior segment of the eye
Mecasermin (Increlex)	Tercica Europe Limited - Ireland	EU/3/06/373 22/05/2006	Treatment of primary insulin-like growth factor-1 deficiency due to molecular or genetic defects

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

	1995 - 2005	2006	Overall Total
Scientific Advice	558	129	687
Follow-up to Scientific Advice	94	31	125
Protocol Assistance	107	45	152
Follow-up to Protocol Assistance	26	12	38
	785	**217**	**1002**

OUTCOME OF THE OCTOBER 2006 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 diabetes	X					X	X	
Chemical	Treatment of nephrotic syndrome				X	X		X	X
Chemical	Treatment of breast cancer								
Biological	Treatment of of ulcerative colitis	X				X	X	X	
Biological	Treatment of primary hyperoxaluria		X				X	X	
Chemical	Secondary Prevention in percutaneous coronary interventions (PCI) and coronary artery bypass (CABG) surgery settings	X					X	X	
Biological	Treatment of short bowel syndrome		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 melanoma			X		X	X	X	
Chemical	Treatment of non small cell lung cancer			X				X	
Biological	Treatment of neutropenias	X					X	X	
Chemical	Treatment of Wegener's granulomatosis				X			X	
Chemical	Treatment of breast cancer			X				X	
Chemical	Treatment of multiple myeloma	X						X	
Chemical	Treatment of acute myelogenous leukaemia		X				X	X	
Biological	Treatment of Cutaneous T-cell Lymphoma				X			X	X
Chemical	Treatment of atrial fibrillation			X				X	
Chemical	Treatment of Traumatic Brain Injury		X				X	X	
Chemical	Treatment of bipolar I disorder	X						X	
Chemical	Treatment of 5q spinal muscular atrophy		X				X	X	
Chemical	Treatment of HIV-1 infection			X				X	
Biological	Prevention of gastrointestinal side effects related to antibiotherapy	X				X	X	X	
Chemical	Treatment of rheumatoid arthritis	X						X	
Chemical	Treatment of psoriasis	X						X	
Chemical	Treatment ofhand eczema	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 psoriasis	X				X		X	
Biological	Treatment of immunglobulin-E (Ig E) mediated allergic diseases	X				X	X	X	
Biological	Avian influenza vaccine	X					X	X	
Biological	Pandemic influenza vaccine	X				X	X	X	
Chemical	Treatment of congenital ichthyoses		X				X	X	X
Chemical	Treatment of cystic fibrosis				X			X	X
Biological	Pandemic influenza vaccine	X				X	X	X	
Chemical	Treatment and prevention of Venous Thromboembolic events			X				X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 15 Scientific Advice letters, 6 Protocol Assistance letters, 6 Follow-up Scientific Advice letters and 4 Follow-up Protocol Assistance letters were adopted at the 16-18 October CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 16 new Requests for which the procedure started at the SAWP meeting held on 25-27 September. The new requests are divided as follows: 14 Initial Scientific Advice, 1 Follow-up Scientific Advice and 1 Initial Protocol Assistance.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE OCTOBER 2006 CHMP MEETING

CHMP PHARMACOGENETICS WORKING PARTY

Reference number	Document	Status[7]
EMEA/201914/2006	Reflection Paper on Pharmacogenomic Samples, Testing and Data Handling.	Release for 3 months consultation

QUALITY WORKING PARTY

Reference number	Document	Status
CHMP/QWP/396951/2006	Guideline on Excipients in the Dossier for application for Marketing Authorisation of a Medicinal Product.	For release for 3 months consultation

SAFETY WORKING PARTY

Reference number	Document	Status
EMEA/341972/2006	Reflection paper on PPARs (Peroxisome Proliferator Activated Receptors)	Adopted

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/422/04	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Juvenile Idiopathic Arthritis	Adopted
EMEA/EWP/24400/2005	Revised version of Concept paper on the need for regulatory for the revision of the guidance on fixed combination medicinal products in the treatment of hypertension	Adopted

[7] 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").

PAEDIATRIC WORKING PARTY

Reference number	Document	Status
EMEA/381922/2006	Assessment of the Paediatric Needs Immunology	Adopted
EMEA/381452/2006	Overview of Comments received on List of Paediatric Needs Immunology	Adopted
EMEA/377174/2006	Assessment of the Paediatric Needs Epilepsy	Adopted
EMEA/377231/2006	Overview of Comments received on List of Paediatric Needs Epilepsy	Adopted
EMEA/384641/2006	Assessment of the Paediatric Needs Chemotherapy Products (Part I)	Adopted
EMEA/384188/2006	Overview of Comments received on List of Paediatric Needs Oncology I (Cytotoxis Therapy)	Adopted

PHARMACOVIGILANCE WORKING PARTY (PhVWP)

Reference number	Document	Status
Volume 9A of the Rules Medicinal Governing Medicinal Products in the European Union	Guidelines on Pharmacovigilance for Medicinal Products for Human Use	Adopted

INVENTED NAME REVIEW GROUP (NRG)

	October 2006			2006	
	Accepted	Rejected	Pending	Accepted	Rejected
Proposed invented names	53	25	21	136	134
Justification for retention of invented name *	3	2	3	16	23

*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.