02 July 2010
EMA/CHMP/410431/2010

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

21-24 June 2010

The Committee re-elected on Monday 21st June 2010 Dr Eric Abadie as its Chair and Dr Tomas Salmonson as its Vice-Chair for a 2nd 3-year mandate.

Furthermore the Committee noted the following changes in the membership of the CHMP:

- Prof Piotr Fiedor replaces Prof Michal Pirozynski as the new Polish CHMP member.
- Dr Agnes Gyurasics became the new Hungarian CHMP member replacing Prof János Borvendég who became the Hungarian alternate.
- Prof Kinga Borowicz replaces Dr Piotr Siedlecki as the new Polish CHMP alternate.
- Dr Vlasta Kákošová is appointed as the new Slovakian CHMP alternate.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

New medicinal product

The Committee adopted four positive opinions by consensus and one by majority (Sycrest) recommending the granting of marketing authorisations for the following new medicines:

- **Brinavess** (vernakalant), from Merck Sharp & Dohme Ltd, intended for the rapid conversion of recent onset of atrial fibrillation to sinus rhythm in adults. The review for Brinavess began on 19 August 2009 with an active review time of 209 days.
- **Rapiscan** (regadenoson), from Gilead Sciences International Ltd, intended as pharmacological stress agent for radionuclide myocardial perfusion imaging. The review for Rapiscan began on 27 May 2009 with an active review time of 209 days.

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- **Ruconest** (conestat alfa), previously known as Rhucin, from Pharming Group N.V., an orphan medicine intended for the treatment of angioedema attacks. The active substance in Ruconest, conestat alfa, is produced using 'recombinant DNA technology'. It is extracted from the milk of rabbits that have had a gene (DNA) inserted, which makes them able to produce the human protein in their milk. The review for Ruconest began on 23 September 2009 with an active review time of 210 days. This was a resubmission of an application for a marketing authorisation following a negative opinion by the CHMP in December 2007.
- **Sycrest** (asenapine), from N.V. Organon, intended for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults. The review for Sycrest began on 27 May 2009 with an active review time of 210 days.
- **Vpriv** (velaglucerase alfa), from Shire Pharmaceutical Ireland Ltd, an orphan medicine intended for the treatment of Gaucher disease. The review for Vpriv began on 23 December 2009 with an active review time of 150 days. The Committee carried out an accelerated assessment of this medicine, due to a major public health interest. In the light of the ongoing shortage of the authorised medicine for the treatment of Gaucher disease, the CHMP found that Vpriv might constitute an alternative treatment option for this condition.

The summary of opinion for all above mentioned medicines, including their full indication, can be found here.

'Hybrid generic' medicine

The Committee adopted a positive opinion by consensus recommending the granting of a marketing authorisation for **PecFent** (fentanyl), from Archimedes Development Ltd, intended for the treatment of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. PecFent is a 'hybrid generic' medicine. This means that this medicine contains a known active substance, but is presented in a new pharmaceutical form (nasal spray). The medicines Actiq lozenges and Effentora buccal tablets are the reference products. The review for PecFent began on 27 May 2009 with an active review time of 203 days.

Generic medicinal products

The Committee adopted two positive opinions by consensus recommending the granting of marketing authorisations for the following generic medicines:

- **Ibandronic Acid Teva** (ibandronic acid), from Teva Pharma B.V. The 50-mg tablets are intended for the prevention of skeletal events in patients with breast cancer and bone metastases, and the 150-mg tablets are intended for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. Ibandronic Acid Teva 50 mg is a generic of Bondronat, and Ibandronic Acid Teva 150 mg is a generic of Bonviva.
- **Telmisartan Actavis** (telmisartan), from Actavis Group PTC ehf, intended for the treatment of essential hypertension and reduction of cardiovascular morbidity. Telmisartan Actavis is a generic of Micardis.

The summary of opinion for all above mentioned medicines, including their full indication, can be found here.

Withdrawals

The European Medicines Agency has been formally notified by Wyeth Europa Limited of it decision to withdraw its application for a centralised marketing authorisation for the medicine **Brilence** (bazedoxifene) 20 mg film-coated tablets. Brilence was submitted as an informed consent application to the already authorised medicinal product Conbriza and was intended to be used for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. A separate press release and question-and-answer document with more information are available.

Post-authorisation procedures

Extensions of indications and other recommendations

The Committee gave three positive opinions by consensus for applications for extension of the therapeutic indications, adding new treatment options for medicines that are already authorised in the European Union:

- **Byetta** (exenatide), from Eli Lilly Nederland B.V., to include treatment of type 2 diabetes mellitus in combination with thiazolidinedione (with or without metformin).
- **Gardasil** and **Silgard** (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)), from Sanofi Pasteur MSD SNC and Merck Sharp & Dohme Ltd, to include the prevention of premalignant genital lesions, cervical cancer and external genital warts in mid-adult women, from the age of 26 to 45 years.

Summaries of opinion for all mentioned medicines, including their full indication, can be found here.

Re-examination procedure on Zeftera concluded

The Committee confirmed its previous negative opinion and adopted a final negative opinion by majority, recommending that **Zeftera** (ceftobiprole medocaril), from Janssen-Cilag International NV, should not be granted a marketing authorisation. Zeftera is an antibiotic, intended for the treatment of complicated skin and soft-tissue infections.

More information about this re-examination procedure is available in a separate question-and-answer document here.

Additional safety information

Several cases of air embolism, including two fatal cases, have been reported following the application of **Evicel** and **Quixil** (another fibrin sealant) using spray application device with pressurised gas or air in conjunction with a pressure regulator. Following the assessment of the two Evicel PSURs, the Marketing Authorisation Holder (MAH) committed to submit a type II variation to update sections 4.4 and 6.6 of the Summary of Product Characteristics (SmPC) and the risk-management plan regarding to the risk of air embolism associated with use of a spray applicator. The CHMP considered this type II variation acceptable and agreed on amendments to be introduced in the SmPC and the Package Leaflet, together with a revised risk-management plan.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (including two under the mandatory scope, and one under the optional scope) as per Regulation (EC) No. 726/2004.

Detailed information on the centralised procedure

Monthly figures related to the centralised procedure activities are published independently on the Agency's website within two weeks following the end of the CHMP meeting and can be found here. The overview of opinions for annual re-assessments and renewals is provided in **Annex 1**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in May 2010 is provided in **Annex 2**.

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 3**.

REFERRAL PROCEDURES

Arbitration procedures concluded

The Committee completed arbitration procedures initiated because of disagreement among EU Member States[1] regarding the authorisation of **Fortipan Combi D** and **Norsed Combi D** (risedronate sodium, calcium carbonate and colecalciferol) and associated names, from Warner Chilcott UK Ltd and Sanofi-Aventis S.p.A. These medicines are indicated for the treatment of post-menopausal osteoporosis. The procedures were initiated because of concerns regarding the efficacy of these medicines, in particular regarding claims of improved benefit of the combination pack as compared to the individual active substances and improved compliance compared with the standard treatment. The Committee concluded that the combination pack will simplify the correct dosage regimen and did not consider the demonstration of improved compliance to be an absolute requirement for the approval of these combination products. Therefore, the Committee concluded by majority that the benefit-risk profile of these medicines was positive and recommended that marketing authorisations should be granted.

The Committee completed an arbitration procedure initiated because of disagreement among EU Member States[2] regarding the extension of the therapeutic indications for **Genotropin** (somatropin) and associated names, from Pfizer ApS. These medicines are indicated for treatment of children with growth disturbances and adults with growth hormone deficiency. This procedure was initiated because of concerns regarding the efficacy of these medicines in children with severe forms of juvenile idiopathic arthritis (JIA) requiring long-term glucocorticoid treatment. The Committee concluded by majority that the benefit-risk profile of these medicines was negative in children with JIA requiring long term glucocorticoid treatment and recommended that the therapeutic indications should not be extended.

Question-and-answer documents with more information about these arbitration procedures can be found here.

[1] The arbitration procedures for Fortipan Comb and Norsed Combi were conducted under Article 29(4) of Directive 2001/83/EC.
[2] The arbitration procedure for Genotropin was conducted under article 6(12) of Commission Regulation (EC) no 1084/2003.

Harmonisation referral on candesartan & hydrochlorothiazide concluded

The Committee recommended by consensus the harmonisation of the prescribing information for **Atacand Plus** (candesartan/hydrochlorothiazide) and associated names, from AstraZeneca group of companies. The review was initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where the products are marketed[3]. These medicines are authorised to treat essential hypertension in patients whose blood pressure is not optimally controlled with candesartan or hydrochlorothiazide monotherapy.

A question-and-answer document with more information about this referral can be found here.

Review of benefits and risks for Invirase started

The Committee started a review[4] of the benefits and risks of **Invirase** (saquinavir), in view of the results of a study conducted by the marketing authorisation holder, Roche Registration Ltd, investigating the proarrhythmic effect of ritonavir-boosted saquinavir in healthy volunteers. The study showed that Invirase had a marked effect on QT interval prolongation and PR prolongation. These findings have been included in the product information of Invirase and the use of Invirase has been contra-indicated in patients at high risk of arrhythmia and in patients using other medicines that may cause QT or PR prolongation. Warnings over its use in patients at moderate risk of arrhythmia, together with recommendations for ECG monitoring, have also been included in the product information. The review of the medicine's benefits and risks has been initiated to discuss any additional measures necessary to ensure the safe and effective use of Invirase and to determine how to balance the risks and benefits of the medicine. Ritonavir-boosted Invirase is indicated as combination treatment of HIV-infected adult patients.

Review of angiotensin II receptor inhibitors started

The Committee has begun looking at the possible risk of cancer in patients taking angiotensin II receptor inhibitors[5,6]. This follows the publication of a meta-analysis[7] reviewing nine randomised controlled trials involving almost 95,000 patients, which suggests that these medicines may be linked with a modestly increased risk of new diagnoses of cancer when compared with placebo or other heart medicines.

The CHMP will review the meta-analysis thoroughly, together with any other available non-clinical and clinical data (including data from clinical trials and epidemiological studies) on angiotensin II receptor inhibitors, to clarify whether there is an increased risk of cancer in patients taking these medicines. The Committee will also issue an opinion on whether a future change to the product information or risk-management plans for these medicines might be necessary.

[3] The harmonisation referral of Atacand Plus was conducted under Article 30 of Directive 2001/83/EC, as amended.
[4] The review of Invirase is being conducted in the context of a formal review, initiated by the European Commission under Article 20 of Regulation (EC) No 726/2004/EC. The Committee will make recommendations on whether the marketing authorisation for Invirase should be maintained, changed, suspended or withdrawn.
[5] The review of angiotensin inhibitors was started at the request of Italy under Article 5(3) of Council Regulation (EC) No 726/2004.
[6] Angiotensin receptor blockers are used to reduce blood pressure and have been available in the EU since the mid-1990s. The authorised angiotensin receptor blockers are candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan and valsartan.
[7] The reference for the meta-analysis of angiotensin receptor blockers is as follows: Sipahi I et al. Angiotensin-receptor blockade and risk of cancer: meta analysis of randomised controlled trials. Lancet Oncol doi:10.1016/S0140-6736(08)61345-8.

MUTUAL-RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 52nd CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 21-22 June 2010. For further details, please see the relevant press release on the CMDh website under the heading Press Releases: http://www.hma.eu/

CHMP WORKING PARTIES

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Party (SAWP) meeting, which was held on 25-27 May 2010. For further details, please see **Annex 4**.

Documents prepared by the CHMP Working Parties adopted during the June 2010 CHMP meeting are listed in **Annex 5**.

UPCOMING MEETINGS FOLLOWING THE JUNE 2010 CHMP PLENARY MEETING

- The 68th meeting of the CHMP will be held at the Agency on 19-22 July 2010.
- The next Name Review Group meeting will be held at the Agency on 27 July 2010.
- The 53rd CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 19-20 July 2010.

ORGANISATIONAL MATTERS

The main topics addressed during the June 2010 CHMP meeting related to:

- A discussion on CHMP representation to the PDCO with CHMP members from Lithuania and Romania being confirmed as representatives for another 3 year term.
- Discussion on patient participation in Scientific Advisory Group (SAG) meetings. The Committee agreed to the benefit of patients' involvement in SAGs meetings and discussed the need to provide training and specific support to facilitate patient participation. The Committee will follow-up on this issue in future ORGAM meetings.
- Follow-up discussion on proposals to increase the CHMP meeting efficiency due to heavy workload. Several proposals were agreed by the Committee including changes to meeting starting times and removal of organisational matters discussion into a separate meeting held outside the plenary week. The agreed changes will be implemented from Q4 2010.
- The announcement of the informal meeting in Antwerp from 30th September to 1st October 2010 that will be held under the Belgian EU presidency.
- The adoption for 3-month public consultation of the ICH Impurities Guideline for Residual Solvents PDE for Cumene (EMA/CHMP/ICH/404855/2010).

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This CHMP Monthly Report and other documents are available on the Internet at the following address: http://www.ema.europa.eu

ANNEX 1 TO CHMP MONTHLY REPORT JUNE 2010

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Elaprase *(idursulfase), Shire Human Genetic Therapies AB*	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

Opinion for renewals of conditional MA's		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Cayston *(aztreonam), Gilead Sciences International Ltd*	Positive Opinion	Marketing Authorisation remains under conditional circumstances

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Actos *(pioglitazone), Takeda Global Research and Development Centre (Europe) Ltd.*	Positive Opinion	Unlimited validity
Corlentor *(ivabradine), Les Laboratoires Servier*	Positive Opinion	Unlimited validity
Glustin *(pioglitazone), Takeda Global Research and Development Centre (Europe) Ltd.*	Positive Opinion	Unlimited validity
Helixate NexGen *(octocog alfa), Bayer Schering Pharma AG*	Positive Opinion	Unlimited validity
Infanrix hexa *(diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus type b (hib) conjugate vaccine (adsorbed)), GlaxoSmithKline Biologicals S.A.*	Positive Opinion	Unlimited validity
Infanrix penta *(diphtheria (d), tetanus (t), pertussis (acellular, component) (pa),*	Positive Opinion	Unlimited validity

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Opinions for 5-Year Renewal applications		
hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) vaccine (adsorbed)), GlaxoSmithKline Biologicals S.A.		
***Keppra** (levetiracetam), UCB Pharma SA*	Positive Opinion	Recommending additional renewal
***KOGENATE Bayer** (octocog alfa), Bayer Schering Pharma AG*	Positive Opinion	Unlimited validity
***Procoralan** (ivabradine), Les Laboratoires Servier*	Positive Opinion	Unlimited validity
***Xolair** (omalizumab), Novartis Europharm Ltd.*	Positive Opinion	Recommending additional renewal

ANNEX 2 TO CHMP MONTHLY REPORT JUNE 2010

Medicinal products granted a community marketing authorisation under the centralised procedure since the May 2010 CHMP Monthly Report

Invented name	**Prolia**
INN	denosumab
Marketing Authorisation Holder	Amgen Europe B.V.
Proposed ATC code	M05BX04
Indication	Treatment of osteoporosis in postmenopausal women at increased risk of fractures. Prolia significantly reduces the risk of vertebral, non vertebral and hip fractures. Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (see section 5.1). In men with prostate cancer receiving hormone ablation, Prolia significantly reduces the risk of vertebral fracture
CHMP Opinion date	18.03.2010
Marketing Authorisation Date	26.05.2010

Invented name	**Votrient**
INN	pazopanib
Marketing Authorisation Holder	Glaxo Group Limited
Proposed ATC code	L01XE11
Indication	First line treatment of advanced Renal Cell Carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.
CHMP Opinion date	22.04.2010
Marketing Authorisation Date	14.06.2010

Invented name	Nivestim
INN	filgrastim
Marketing Authorisation Holder	Hospira UK Limited
Proposed ATC code	L03AA02
Indication	Filgrastim is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. Filgrastim is indicated for the mobilisation of peripheral blood progenitor cells (PBPC). In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of $\leq 0.5 \times 10^9$ /l and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. Filgrastim is indicated for the treatment of persistent neutropenia (ANC less than or equal to 1.0×10^9 /l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate.
CHMP Opinion date	18.03.2010
Marketing Authorisation Date	08.06.2010

Invented name	Tolura
INN	telmisartan
Marketing Authorisation Holder	KRKA, d.d., Novo mesto
Proposed ATC code	C09CA07
Indication	Treatment of essential hypertension in adults
CHMP Opinion date	18.03.2010
Marketing Authorisation Date	04.06.2010

Invented name	Humenza
INN	Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)
Marketing Authorisation Holder	Sanofi Pasteur SA
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in an officially declared pandemic situation
CHMP Opinion date	18.02.2010
Marketing Authorisation Date	08.06.2010

ANNEX 3 TO CHMP MONTHLY REPORT June 2010

NAME REVIEW GROUP (NRG)

	NRG meeting 26 Jan 2010		NRG meeting 23 Mar 2010		NRG meeting 26 May 2010		NRG meeting 27 Jul 2010		NRG meeting 6 Sep 2010		NRG meeting 23 Nov 2010		2010	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	25	35	48	46	35	41							**108**	**122**
Justification for retention of invented name *	1	6	2	4	3	3							**6**	**13**

*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 26 Jan 2010		NRG meeting 23 Mar 2010		NRG meeting 25 May 2010		NRG meeting 27 Jul 2010		NRG meeting 6 Sep 2010		NRG meeting 23 Nov 2010		2010	
Objections	Accepted	Rejected	Accepted	Rejecte	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	83	32	102	45	98	69							**283**	**146**
Criterion - Safety concerns														
Similarity with other Invented name	73	21	90	31	90	62							**253**	**114**
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	1	0	0							**2**	**1**
Misleading with respect to composition	0	0	0	1	0	0							**0**	**1**
Criterion - INN concerns														
Similarity with INN	5	3	6	8	5	3							**16**	**14**
Inclusion of INN stem	3	6	3	1	2	3							**8**	**10**
Criterion - Other public health concerns														
Unacceptable qualifiers	0	1	0	2	0	0							**0**	**3**
Conveys a promotional message	0	1	1	4	0	0							**1**	**5**
Appears offensive or has a bad connotation	0	0	1	1	0	0							**1**	**1**
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	0	0	0	0							**1**	**0**
Similarity between name of prodrug and related active substance	0	0	0	0	0	0							**0**	**0**

See *Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure (CPMP/328/98 Rev. 5)* for detailed explanations of criteria used.

ANNEX 4 TO CHMP MONTHLY REPORT JUNE 2010

Pre-authorisation: scientific advice and protocol assistance
EMA centralised procedures

	1995 - 2009	2010	Overall total
Scientific Advice	1134	122	1256
Follow-up to Scientific Advice	232	52	284
Protocol Assistance	245	31	276
Follow-up to Protocol Assistance	109	13	122
	1720	**218**	**1938**

FDA Parallel Scientific Advice	2006 - 2009	2010	Overall total
Completed	7	2	9
Ongoing	0	1	1
Foreseen	0	1	1
	7	**4**	**11**

Outcome of the June 2010 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
Chemical	Treatment of type 2 diabetes.			*x*				*x*	
Chemical	Treatment of type 2 diabetes.	*x*				*x*	*x*		
Chemical	Treatment of gastro-oesophageal reflux oesophagitis, benign gastric and duodenal ulceration.	*x*				*x*	*x*	*x*	
Biological	Treatment of alpha-mannosidosis.		*x*				*x*	*x*	
Chemical	Treatment of type 2 diabetes.			*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 type 2 diabetes.	x					x		
Biological	Treatment of short bowel syndrome.		x			x	x	x	
Chemical	Treatment of chronic myeloid leukemia (CML).		x				x	x	x
Chemical	Treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).		x				x	x	x
Chemical	Treatment of active psoriatic arthritis.	x					x	x	
Chemical	Treatment of plaque psoriasis.	x					x	x	
Biological	Treatment of neutropenia in patients with malignancies.			x				x	
Biological	Treatment of colorectal cancer.			x				x	
Biological	Treatment of neutropenia in patients with malignancies.			x				x	
Advanced therapy	Treatment of hepatocellular carcinoma.		x			x		x	x
Chemical	Treatment of castrate-resistant prostate cancer.	x					x	x	
Chemical	Treatment of colorectal cancer.	x						x	
Biological	Treatment of castrate-resistant prostate cancer.			x		x	x		
Chemical	Treatment of castrate-resistant prostate cancer.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of the same indications as Herceptin.	*x*					*x*	x	
Biological	Treatment of melanoma.	*x*						*x*	
Chemical	Treatment of onchocerciasis.			*x*				*x*	
Chemical	Treatment of essential hypertension.	*x*				*x*	*x*	*x*	
Chemical	Prevention of cardiovascular events.			*x*				*x*	
Chemical	Treatment of HCV infection.	*x*					*x*	*x*	
Biological	Vaccines intended for active immunization.	*x*				*x*	*x*	*x*	
Biological	Treatment of HCV infection.	*x*				*x*		*x*	
Chemical	Treatment of influenza A infection.	*x*				*x*	*x*	*x*	
Chemical	Management of pulmonary infections in cystic fibrosis.		*x*				*x*	*x*	*x*
Chemical	Treatment of *P. aeruginosa* lung infection in cystic fibrosis.				*x*			*x*	
Chemical	Treatment of influenza A or B infection.	*x*					*x*	*x*	
Chemical	Treatment of endometriosis.	*x*					*x*		
Biological	Treatment of achondroplasia.	*x*					*x*	*x*	
Chemical	Treatment of perinatal asphyxia.		*x*					*x*	
Chemical	Treatment of the same indications as Abilify.	*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-onset seizures.	x						x	
Biological	Treatment of Alzheimer's disease.			x				x	
Advanced therapy	Treatment of Parkinson's disease.	x					x	x	
Chemical	Treatment of epilepsy.	x						x	
Chemical	Treatment of epilepsy.	x						x	
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of schizophrenia.	x					x		
Chemical	Treatment of alcohol dependence.	x						x	
Chemical	Treatment of major depressive disorder.	x						x	
Chemical	Treatment of progressive supranuclear palsy.		x			x	x	x	
Chemical	Treatment of asthma.	x				x		x	
Biological	Treatment of asthma.	x					x		
Biological	Treatment of diabetic macular edema.			x				x	
Chemical	Treatment of osteoporosis.	x					x	x	
Biological	Treatment of low-trauma hip fractures.	x						x	
Biological	Treatment of multinodular goitre.	x					x	x	
Biological	Treatment of Alzheimer's disease.			x				x	
Chemical	Treatment of hyperphosphataemia in chronic kidney disease patients.	x						x	

SA: scientific advice
PA: protocol assistance

The above-mentioned 32 Scientific Advice letters, 8 Protocol Assistance letters, 12 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letters were adopted at the 21 - 24 June 2010 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 32 new Requests for which the procedure started at the SAWP meeting held on 25 – 27 May 2010. The new requests are divided as follows: 24 Initial Scientific Advice, 5 Follow-up Scientific Advice, 1 Initial Protocol Assistance and 2 Follow-up Protocol Assistance.

ANNEX 5 TO CHMP MONTHLY REPORT JUNE 2010

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE JUNE 2010 CHMP MEETING

BIOLOGICS WORKING PARTY

Reference number	Document	Status [8]
EMA/CPMP/BWP/2879/2002/rev 2	Revision of the CHMP Position Statement on Creutzfeldt-Jakob Disease and Plasma-Derived and Urine-Derived Medicinal Products (rev 3)	**3-month public consultation**
EMA/CHMP/CAT/BWP/353632/2010	CHMP/CAT position statement on Creutzfeldt-Jakob disease and ATMPs	**3-month public consultation**

GENE THERAPY WORKING PARTY

Reference number	Document	Status [8]
EMA/CHMP/GTWP/587488/2007 rev1	Reflection Paper on Recombinant Adeno-Associated Viral Vectors Overview of comments received from public consultation (EMA/CHMP/GTWP/629733/2009)	**adopted**

PHARMACOGENOMICS WORKING PARTY

Reference number	Document	Status [8]
EMA/CHMP/641298/2008	Reflection Paper on Co-development of PG Biomarkers and Assays in the context of drug development	**6-month consultation**

QUALITY WORKING PARTY

Reference number	Document	Status [8]
EMA/CHMP/CVMP/QWP/199250/2009	Guideline on Setting Specifications for Related Impurities in Antibiotics	**6-month consultation**
EMA/CHMP/QWP/202350/2010	Concept Paper on the Revision of the note for guidance on quality of modified release oral dosage forms and transdermal dosage forms: Section I (quality)	**adopted**

[8] Adopted or release for consultation documents can be found at the European Medicines Agency website (under "What's new-recent publications" or under Human Medicines-Guidance documents").

SAFETY WORKING PARTY

Reference number	Document	Status [8]
EMA/CHMP/410486/2009	Reflection Paper on Non-clinical Evaluation of Drug-induced Liver Injury (DILI)	**adopted**
EMA/CHMP/81714/2010	Questions and Answers on the Withdrawal of the Note for Guidance on Single Dose Toxicity	**adopted**
EMA/CHMP/44609/2010	Questions and Answers on the Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use	**3-month consultation**
EMA/CHMP/336670/2010	Question and Answers on the Note for Guidance on Photosafety Testing	**3-month consultation**

EFFICACY WORKING PARTY

Reference number	Document	Status [8]
EMA/CHMP/213057/2010	Paediatric addendum for the Guidance on Clinical Investigation of Medicinal Products in the treatment of Lipid Disorders	**6-month consultation**