28 October 2010
EMA/CHMP/656448/2010

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

18 – 21 October 2010

Centralised procedure

Initial applications for marketing authorisation

Positive opinion for a new medicine adopted

The Committee adopted a positive opinion by consensus, recommending the granting of a marketing authorisation for **Fluenz** (influenza vaccine (live attenuated, nasal)), from MedImmune LLC, intended for the prophylaxis of influenza in children from 24 months to less than 18 years of age. The review for Fluenz began on 17 December 2008 with an active review time of 210 days.

Generic medicinal products

The Committee adopted three positive opinions by consensus recommending the granting of marketing authorisations for:

- **Iasibon** (ibandronic acid), from Pharmathen S.A., for the prevention of skeletal events in patients with breast cancer and bone metastases, and for the treatment of tumour-induced hypercalcaemia with or without metastases. Iasibon is a generic of Bondronat.
- **Potactasol** (topotecan), from Actavis Group PTC ehf, for the treatment of metastatic carcinoma of the ovary, small cell lung cancer and carcinoma of the cervix. Potactasol is a generic of Hycamtin.
- **Docetaxel Teva Pharma** (docetaxel), from Teva Pharma B.V., for the treatment of locally advanced or metastatic breast cancer and small cell lung cancer, and of metastatic prostate cancer. Docetaxel Teva Pharma is a generic of Taxotere.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Withdrawals

Back in September, the European Medicines Agency (EMA) was formally notified by Warner Chilcott UK Ltd of its decision to withdraw its application for a change to the marketing authorisation for **Intrinsa** (testosterone) transdermal patch, to extend treatment to all postmenopausal women with hypoactive sexual desire disorder. A question-and-answer document with more information is now available.

Post-authorisation procedures

Extensions of indications and other recommendations

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

- **Lucentis** (ranibizumab), from Novartis Europharm Ltd, to include the treatment of visual impairment due to diabetic macular oedema.
- **Sprycel** (dasatinib), an orphan medicine from Bristol-Myers Squibb Pharma EEIG, to include the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukaemia in the chronic phase.
- **Sutent** (sunitinib), from Pfizer Ltd, to include the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.

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

Additional safety information

The CHMP adopted a positive opinion by consensus for a type II work sharing variation for **Puregon** from N.V. Organon and **Fertavid** from Schering-Plough Europe. Both products contain follitropin beta as active substance. Following a re-analysis of safety data the Summary of Product Characteristics (SmPC) was updated in section 4.4 with a warning regarding ovarian torsion and in section 4.8 to include further adverse events in women (abdominal discomfort, constipation, diarrhoea, metrorrhagia, ovarian cyst, ovarian torsion, uterine enlargement, vaginal haemorrhage (uncommon)) and men (headache, rash and injection site pain (common)). The package leaflet has been updated accordingly.

The CHMP adopted by consensus amendments to sections 4.4 and 4.8 of the SmPC of **Enbrel** (etanercept) from Wyeth Europa Ltd. Those sections were amended with information regarding reports of melanoma, Merkel cell carcinoma and peripheral demyelinating polyneuropathy in association with etanercept therapy. The package leaflet has been updated accordingly. This variation application was submitted following the CHMP assessment of the latest PSUR for Enbrel.

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Tamiflu** (oseltamivir) from Roche Registration Ltd. The update concerns section 4.2 of the SmPC to warn that Tamiflu 12mg/ml oral suspension formulation is not suitable for infants less than 1 year of age since the syringe provided in the pack does not allow for appropriate dose adjustments and commercially available syringes (with ml markings) may lead to unacceptable dosing inaccuracies. In the absence of a suitable formulation for infants less than 1 year of age, a pharmacy compounded preparation based on Tamiflu capsules should preferentially be used.

The CHMP recommended by consensus amendments to the SmPC and product information of **Tysabri** (natalizumab), from Elan Pharma International Ltd. A Type II variation was submitted by the marketing authorisation holder based on analysis performed on the data of 52 Tysabri treated patients with confirmed progressive multifocal leukoencephalopathy (PML) in respect of an association with prior immunosuppressant use. The presented data indicate that prior immunosuppressant use increases the risk of PML, independently of the duration of Tysabri therapy. Section 4.4 of the SmPC and section 2 of the package leaflet were updated accordingly to reflect those findings.

Following a class labelling review on thrombopoietin stimulating agents, the CHMP has adopted by consensus changes to the SmPC of **Nplate** (romiplostim) from Amgen Limited, in order to amend section 4.2 with regard to the platelet count cut-off levels for dose adjustment and treatment interruption. Furthermore sections 4.2, 4.4 and 4.8 were updated on the risk of thromboembolic events in patients with moderate to severe hepatic impairment. The CHMP has endorsed a Direct Healthcare Professional Communication (DHPC) informing healthcare professionals of the revised recommendations.

The Committee adopted by consensus amendments to the SmPC of **Sebivo** (telbivudine) from Novartis Europharm Ltd. The SmPC was updated with a new contraindication related to the combination of telivudine with standard or pegylated interferon alfa-2a due to an increased risk of developing peripheral neuropathy. The package leaflet has been updated accordingly.

Other information on the centralised procedure

Lists of Questions

The Committee adopted six Lists of Questions on initial applications (including four under the mandatory scope, and two under the optional scope as per Regulation (EC) No. 726/2004), together with three Lists of Questions on “line extension” applications (in accordance with Annex I of Commission Regulation (EC) No. 1234/2008).

Review of treatment recommendations for Fabrazyme

The Committee has reviewed its previous recommendations on the use of Fabrazyme (agalsidase beta) during the ongoing supply shortage. This was triggered by an increase in reported adverse events in patients treated with the lower dose of Fabrazyme that has been introduced during the shortage.

Fabrazyme is used to treat the rare, inherited enzyme-deficiency disorder, Fabry disease. Temporary treatment recommendations to manage patients relying on this medicine have been in place since the start of the supply shortage and have been regularly updated.

The CHMP is now recommending that physicians switch back to prescribing the full dose of Fabrazyme according to the authorised product information, depending on the availability of enzyme replacement therapy and the severity of the disease.

More information about the review of the treatment Fabrazyme is available in a separate press release document on the Agency’s website.

Review of Invirase concluded[1]

The Committee finalised a review of **Invirase** (saquinavir), from Roche Registration Ltd, following the detection of QT and PR interval prolongation in healthy volunteers. The Committee concluded by consensus that ritonavir-boosted Invirase combination treatment for HIV-1 infected adult patients continues to have a positive benefit-risk balance. However, the Committee recommended that treatment-naïve patients should take a reduced dose of Invirase during the first week of treatment, as a precautionary measure. Also, the CHMP asked Roche to investigate the potential risk of arrhythmia in treatment-naïve patients receiving the reduced dose of Invirase in combination with other antiretroviral medicines in a new study.

More information about the review of Invirase is available in a separate press release and a question-and-answer document on the Agency's website.

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 September 2010 is provided in **Annex 2**.

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 2010 CHMP plenary meeting are 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

Review of fibrates concluded[2]

The Committee finalised a review of the four **fibrates** bezafibrate, ciprofibrate, fenofibrate and gemfibrozil, and concluded by majority that their benefits continue to outweigh their risks in the treatment of patients with blood lipid disorders. However, doctors should not prescribe them to newly diagnosed patients with blood lipid disorders as first-line treatment, except for patients with severe hypertriglyceridaemia or patients who cannot take statins. For fenofibrate, the Committee noted additional new data and recommended that it can also be used together with a statin in some circumstances when a statin on its own has not been enough to completely control blood lipid levels.

Fibrates are a class of medicines that have been in use for many years to control levels of lipids such as cholesterol and triglycerides in the blood.

[1] The review of Invirase was conducted under Article 20 of Regulation (EC) No 726/2004
[2] The review of fibrates was conducted under Article 31 of Directive 2001/83/EC, as amended.

More information about the review of fibrates is available in a separate press release and a question-and-answer document on the Agency's website.

Harmonisation referrals concluded

The Committee recommended by consensus harmonisation of the prescribing information for three medicines. The reviews were initiated because of differences in the SmPCs, labelling and package leaflets in the countries where the products are marketed. The medicines reviewed are:

- **Fortum**[3] (ceftazidime), from GSK and associated companies. The medicine is an antibiotic authorised for treatment of infections such as hospital acquired pneumonia, complicated skin and soft tissue infections, bone and joint infections, chronic otitis media, complicated intra-abdominal infections, meningitis and complicated urinary tract infections, and bacteraemia that is associated with these infections.
- **Tazocin**[4] (piperacillin/tazobactam), from Pfizer and associated companies. The medicine is an antibiotic authorised for treatment of infections such as severe pneumonia, complicated urinary tract infections, complicated intra-abdominal infections, complicated skin and soft tissue infections and bacteraemia that is associated with these infections.
- **Vascace Plus**[5] and associated names (cilazapril/hydochlorothiazide), from Roche and associated companies. The medicine is authorised for treatment of hypertension in patients whose blood pressure is not adequately controlled with cilazapril alone.

Question-and-answer documents with more information about these referrals can be found on the Agency's website.

Follow-up on escitalopram suspension

The Committee recommended by consensus in February 2010 that the marketing authorisations of generic **escitalopram-containing medicinal products** from Alfred E. Tiefenbacher GmbH & Co KG and associated companies should be suspended in Member States where these medicines were authorised. These medicines are used to treat major depressive episodes. The review was initiated[6] because of disagreements on whether to maintain or suspend the marketing authorisations in the countries where they were authorised. After the adoption of the CHMP opinion, the Member State that had suspended the marketing authorisation reversed its decision and, as a result, there is no longer disagreement on whether to maintain or suspend the marketing authorisation between Member States.

The CHMP has now been informed that a European Commission decision on this opinion will not be issued as there are currently no divergent decisions across the EU.

Review of Octagam started

The Committee has begun a review[7] of **Octagam** and associated names (human normal immunoglobulin). This follows the recommendation for the suspension of the marketing authorisations of Octagam at the September 2010 CHMP meeting, due to an increased risk of thromboembolic events in patients receiving this medicine.

[3] The harmonisation referral of Fortum was conducted under Article 30 of Directive 2001/83/EC, as amended.
[4] The harmonisation referral of Tazocin was conducted under Article 30 of Directive 2001/83/EC, as amended.
[5] The harmonisation referral of Vascace was conducted under Article 30 of Directive 2001/83/EC, as amended.
[6] The review of escitalopram was conducted under Article 30 of Directive 2001/83/EC, as amended.
[7] The review of Octagam is being conducted in the context of a formal review, initiated by Germany under Article 31 of Directive 2001/83/EC, as amended. The Committee will make recommendations on whether the marketing authorisations for Octagam should be maintained, changed, suspended or revoked.

Octagam is an intravenous solution used to strengthen the body's immune system to lower the risk of infection in patients with a weakened immune system.

This review will allow for a scientific assessment of all available data on the safety and quality issues, identified previously. This includes the manufacturing process and the identification of appropriate corrective measures, and will allow for a coordinated approach on the resulting actions.

Mutual-recognition and decentralised procedures - Human

The CHMP noted the report from the 55th CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 18-19 October 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 27-28 September 2010. For further details, please see **Annex 5**.

Documents adopted during the October 2010 CHMP meeting are listed in **Annex 6**.

Upcoming meetings following the October 2010 CHMP plenary meeting

- The 71st meeting of the CHMP will be held at the Agency on 15-18 November 2010.
- The Name Review Group meeting will be held at the Agency on 23 November 2010.
- The 56th CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 15-16 November 2010.

Organisational matters

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

- The re-organisation of the CHMP meeting. In order to allow more time for scientific discussion on product related issues during the CHMP plenary meetings, it was decided to discuss all organisational matters in a separate ORGAM meeting scheduled as a web conference the week before CHMP plenary. The first ORGAM web conference was held on 11 October 2010.
- The election of Mr Robert Hemmings as Chair and Dr Bertil Johnsson as Vice Chair of the Scientific Advice Working Party (SAWP). The current Chair of the SAWP, Pr Bruno Flamion, will remain Chair until December 2010. Furthermore the CHMP nominated Prof Luca Pani as new member of the SAWP and Dr Caroline Auriche as his alternate.
- The updated policy on conflicts of interests of EMA's scientific experts. On 7 October 2010 the Management Board endorsed new rules on how the Agency will be handling potential conflicts of interests of its scientific experts. The new rules aim at balancing out the need to secure Europe's best scientific experts for the evaluation and supervision of medicines while ensuring that these

experts have no financial or other interests in the pharmaceutical industry that could affect their impartiality. The policy is published on the Agency's website.

Procedural Announcement

Submission of Type IA, Type IAin and Type IB variations in December 2010

Please note that the EMA will be closed between 23 December 2010 and 2 January 2011 (inclusive).

Marketing Authorisation Holders are therefore advised not to submit Type IA and Type IAin variation applications to the EMA after 26 November 2010 because the 30-day timeframe for the Agency to acknowledge the validity of the submitted Type IA and Type IAin variation(s) (see article 14 of Commission Regulation (EC) No 1234/2008) would coincide with the official closure of the EMA.

Type IA variation applications submitted by no later than 26 November 2010 will be finalised before the EMA Christmas break. Any Type IA variation application submitted to the EMA between 29 November 2010 and 2 January 2011 will be finalised in January 2011.

Marketing Authorisation Holders intending to apply for Type IB variations in December 2010 are encouraged to liaise with the EMA prior to their submission.

Deletion of version number of the detailed description of the pharmacovigilance system (DDPS) from Annex II.B of the Marketing Authorisation

Further to the entry into force of the Variations Regulation (EC) No 1234/2008 and the experience gained with the processing of changes to an existing pharmacovigilance system, as described in the detailed description of the pharmacovigilance system (DDPS), it has been agreed to delete the version number of the DDPS from Annex II.B of the marketing authorisation, in order to reduce the administrative work associated with the update of this version number with every change to the DDPS.

The following change to Annex II.B will be implemented in the next revision of the QRD Templates:

Annex II.B, Conditions of the marketing authorisation, other conditions

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance, ~~as described in version {insert version reference}~~ presented in Module 1.8.1 of the Marketing Authorisation ~~<Application>~~, is in place and functioning before and whilst the product is on the market.

Until the revision of the QRD templates the following timeframe should be followed for implementation of the revised Annex II.B for medicinal products with regulatory activity affecting the product information annexes:

- **On-going procedures**

All opinions on **new applications for marketing authorisation, extensions and Type II variations** affecting the annexes adopted as of November 2010 should include the revised annex II.B; the revised annexes in all other languages should be submitted on day +5 after CHMP opinion, as part of the linguistic review process of product information in the centralised procedure.

- **New procedures**

All **new applications for marketing authorisation, extensions and variation applications (Type IA, IB and II)** affecting the annexes submitted as of 1st November 2010 should include the revised annex II.B; this requirement is also applicable if the variation concerns the introduction of a new pharmacovigilance system (C.I.8) or a change to an existing pharmacovigilance system as described in the DDPS (C.I.9)

Noël Wathion

Head of Unit

Patient Health Protection, Tel. +44(0)20 74 18 85 92

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 October 2010

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Macugen *(pegaptanib sodium), Pfizer Ltd.*	Positive opinion	Recommending additional renewal
Rapamune *(EMEA/H/C/000273/R/0120), (sirolimus), Wyeth Europa Ltd*	Positive opinion	Unlimited validity

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Annex 2 to CHMP Monthly Report October 2010

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

Invented name	**Telmisartan Actavis**
INN	telmisartan
Marketing Authorisation Holder	Actavis Group PTC ehf.
Proposed ATC code	C09CA07
Indication	Hypertension Treatment of essential hypertension in adults. Cardiovascular prevention Reduction of cardiovascular morbidity in patients with: i) manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or ii) type 2 diabetes mellitus with documented target organ damage.
CHMP Opinion date	24.06.2010
Marketing Authorisation Date	30.09.2010

Invented name	**Myclausen**
INN	mycophenolate mofetil
Marketing Authorisation Holder	Herbert J. Passauer GmbH & Co. KG
Proposed ATC code	L04AA06
Indication	In combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants
CHMP Opinion date	22.07.2010
Marketing Authorisation Date	07.10.2010

Invented name	**Twynsta**
INN	telmisartan and amlodipine
Marketing Authorisation Holder	Boehringer Ingelheim International GmbH
Proposed ATC code	C09DB04
Indication	Treatment of essential hypertension in adults: *Add on therapy* TWYNSTA is indicated in adults whose blood pressure is not adequately controlled on amlodipine. *Replacement therapy* Adult patients receiving telmisartan and amlodipine from separate tablets can instead receive tablets of TWYNSTA containing the same component doses.
CHMP Opinion date	22.07.2010
Marketing Authorisation Date	07.10.2010

Annex 3 to CHMP Monthly Report October 2010

Overview of designated orphan medicinal products that have been the subject of a centralised application for marketing authorisation:

Update since the September 2010 CHMP meeting

Active substance	Sponsor/applicant	EU designation number & Date of orphan designation	Designated orphan indication
N-methyl D-(2,3,4,5,6-pentahydroxy-hexyl)-ammonium; 2-(3,5-dichloro-phenyl)-benzoxazole-6-carboxylate	FoldRx Pharmaceuticals Limited	EU/3/06/401	Treatment of familial amyloid polyneuropathy

ANNEX 4 TO CHMP MONTHLY REPORT October 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 Oct 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	50	69	59	65			**158**	**191**
Justification for retention of invented name *	***1***	***6***	2	4	3	3	2	4	0	3			**8**	**17**

*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 2009		NRG meeting 6 Oct 2009		NRG meeting 23 Nov 2009		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	139	85	144	45			**422**	**231**
Criterion - Safety concerns														
Similarity with other Invented name	73	21	90	31	90	62	98	59	128	38			**351**	**173**
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	1	0	0	8	2	1	1			**10**	**3**
Misleading with respect to composition	0	0	0	1	0	0	6	0	2	0			**6**	**1**
Criterion - INN concerns														
Similarity with INN	5	3	6	8	5	3	4	3	7	3			**20**	**17**
Inclusion of INN stem	3	6	3	1	2	3	2	6	5	3			**10**	**16**
Criterion - Other public health concerns														
Unacceptable qualifiers	0	1	0	2	0	0	5	2	0	0			**5**	**5**
Conveys a promotional message	0	1	1	4	0	0	10	9	1	0			**11**	**14**
Appears offensive or has a bad connotation	0	0	1	1	0	0	3	1	0	0			**4**	**2**
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	0	0	0	0	1	1	0	0			**2**	**1**
Similarity between name of prodrug and related active substance	0	0	0	0	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 5 to CHMP Monthly Report October 2010

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

	1995 - 2009	2010	Overall total
Scientific Advice	1134	189	1323
Follow-up to Scientific Advice	232	73	305
Protocol Assistance	245	40	285
Follow-up to Protocol Assistance	109	20	129
	1720	**322**	**2042**

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 October 2010 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 acute liver failure.		*x*				*x*	*x*	
Chemical	Treatment of type 2 diabetes.	*x*						*x*	
Chemical	Treatment of relapsing multiple sclerosis.	*x*					*x*	*x*	
Chemical	Treatment of acute myeloid leukaemia.				*x*			*x*	
Chemical	Treatment of metastatic melanoma.	*x*						*x*	
Chemical	Treatment of metastatic melanoma.	*x*						*x*	
Biological	Treatment of operable primary breast cancer.	*x*					*x*	*x*	
Biological	Biosimilar for the same indications as MabThera.	*x*						*x*	
Chemical	Treatment of advanced GIST.	*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 haematological malignancies.			*x*			*x*		
Biological	Treatment of follicular non-Hodgkin's lymphoma.			*x*				*x*	
Biological	Treatment of diffuse large B-cell lymphoma.	*x*						*x*	
Chemical	Treatment of advanced gastric cancer.	*x*					*x*	*x*	
Chemical	Treatment of non-small cell lung cancer.	*x*					*x*	*x*	
Advanced therapy	Prevention of acute GvHD following allogeneic stem cell transplantation.				*x*		*x*		
Chemical	Treatment of familial hypercholesterolemia.	*x*				*x*	*x*	*x*	
Advanced therapy	Treatment of neuropathic diabetic foot ulcers.			*x*				*x*	
Advanced therapy	Treatment of venous leg ulcers.	*x*				*x*	*x*	*x*	
Biological	Prevention of gastro-enteritis due to rotavirus infection.			*x*		*x*		*x*	
Biological	Prevention of influenza infection.	*x*				*x*	*x*	*x*	
Chemical	Treatment of Orthopoxvirus disease			*x*			*x*	*x*	
Chemical	Treatment of chronic kidney disease.	*x*				*x*	*x*	*x*	
Chemical	Treatment of epilepsy.	*x*					*x*	*x*	
Chemical	Treatment of epilepsy in children.	*x*					*x*	*x*	
Chemical	Treatment of moderate-to-severe pain.	*x*				*x*	*x*	*x*	
Chemical	Maintenance treatment of schizophrenia.	*x*					*x*	*x*	
Biological	Treatment of *P. aeruginosa* pulmonary infection.				*x*			*x*	
Chemical	Treatment of COPD and asthma.			*x*		*x*	*x*	*x*	
Chemical	Treatment of post-operative ocular inflammation.	*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				
Chemical	Diagnosis of gastric motility disorders.			*x*				*x*	
Chemical	Treatment of hyperphosphataemia.	*x*						*x*	

SA: scientific advice
PA: protocol assistance

The above-mentioned 21 Scientific Advice letters, 1 Protocol Assistance letters, 7 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 18 - 21 October 2010 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 41 new Requests for which the procedure started at the SAWP meeting held on 27 – 29 September 2010. The new requests are divided as follows: 21 Initial Scientific Advice, 7 Follow-up Scientific Advice, 10 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

Annex 6 to CHMP Monthly Report October 2010

Documents adopted during the October 2010 CHMP meeting

Blood Product Working Party (BPWP)

Reference number	Document	Status [8]
EMA/CHMP/BPWP/94038/2007 rev. 3	Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg) • Overview of comments	**adopted**
EMA/CHMP/BPWP/315244/2010	BPWP Work Programme 2010	**adopted**

EMA Human Scientific Committees Working Party with Patients and Consumer Organisations (PCWP)

Reference number	Document	Status[8]
EMA/458343/2010	PCWP Work Programme 2010	**adopted**

EMA

Reference number	Document	Status[8]
EMA/CHMP/578661/2010 Rev 1	Revision of the EMA recommendation on the procedural aspects and dossier requirements for the consultation to the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device or active implantable medical device	**Adopted for 3-month public consultation**

[8] Adopted or release for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").