EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

16 – 19 May 2011

Centralised procedure

Initial applications for marketing authorisation

New medicinal products

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

- **Benlysta** (belimumab), from Glaxo Group Ltd, intended as add-on therapy in adult patients with active autoantibody-positive systemic lupus erythematosus with a high degree of disease activity. The review for Benlysta began on 23 June 2010 with an active review time of 210 days.
- **Vibativ** (telavancin), from Astellas Pharma Europe B.V., intended for the treatment of adults with nosocomial pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA). The review for Vibativ began on 18 November 2009 with an active review time of 210 days. This is the first antibacterial medicine to receive a positive CHMP opinion in two years, albeit in a restricted indication, addressing an increased need for new antibiotics.
- **Victrelis** (boceprevir), Merck Sharp & Dohme Ltd, intended for the treatment of chronic hepatitis-C genotype-1 infection, in combination with peginterferon alpha and ribavirin, in adult patients with compensated liver disease who are previously untreated or for whom previous therapy has failed. The review for Victrelis began on 15 December 2010 with an active review time of 120 days. The Committee carried out an accelerated assessment of this medicine, because it found that boceprevir could answer the unmet medical need to provide improved treatment options for chronic hepatitis-C genotype-1 naïve as well as pretreated patients. Boceprevir is the first of a new class of medicines for the treatment of chronic hepatitis that directly inhibit the replication of the hepatitis-C virus in hepatitis-C-virus-infected host cells.

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

- **Xgeva** (denosumab), from Amgen Europe B.V., intended for the prevention of skeletal-related events in adults with bone metastases from solid tumours. The review for Xgeva began on 23 June 2010 with an active review time of 210 days.
- **Yervoy** (ipilimumab), from Bristol-Myers Squibb Pharma EEIG, intended for the treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. The review for Yervoy began on 26 May 2010 with an active review time of 210 days.

Positive opinions for generic medicines adopted

The Committee adopted three positive opinions by consensus recommending the granting of a marketing authorisation for the following generic medicines:

- **Temozolomide SUN** (temozolomide), from Sun Pharmaceutical Industries Europe B.V., intended for the treatment of glioblastoma multiforme and malignant glioma. Temozolomide SUN is a generic of Temodal.
- **Levetiracetam ratiopharm** (levetiracetam), from ratiopharm GmbH, and **Levetiracetam Teva** (levetiracetam), from Teva Pharma B.V., intended for the treatment of epilepsy. Both medicines are generics of Keppra.

The summaries of opinion for all medicines, including their full therapeutic indications, can be found here.

Re-examination for Fampyra concluded

Following re-examination of its previous negative opinion, the Committee adopted a final positive opinion by majority, recommending the granting of a conditional marketing authorisation for **Fampyra** (fampridine), from Biogen Idec Ltd. Fampyra is intended to improve walking of adult patients suffering from multiple sclerosis with walking disability.

A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Fampyra this relates to a long-term efficacy and safety study to investigate a broader primary endpoint that is clinically meaningful in terms of walking ability and to further evaluate the early identification of responders in order to guide further treatment. The European Medicines Agency will review new information within one year and update the product information as necessary.

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

Withdrawals

The European Medicines Agency has been formally notified by NicOx S.A. of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Beprana** (naproxcinod), 375 mg hard capsules. Beprana was intended to be used for the relief of the signs and symptoms of osteoarthritis of knee and hip in adults. The application for the marketing authorisation for Beprana was submitted to the Agency on 21 December 2009. At the time of the withdrawal it was under review by the CHMP.

A separate question-and-answer document and press release with more information are available.

Post-authorisation procedures

Positive opinions for extensions of therapeutic indications adopted

The Committee adopted one positive opinion by consensus for an application for extension of the therapeutic indications, adding a new treatment option for a medicine that is already authorised in the EU, for **RoActemra** (tocilizumab), from Roche Registration Ltd, to include the treatment of active systemic juvenile idiopathic arthritis in patients from two years of age and older.

The summary of opinion for the above mentioned medicine, including its full therapeutic indications, can be found here.

Restrictions on use of Erbitux

The Committee recommended by consensus the restriction of indication for **Erbitux** (cetuximab) from Merck KGaA based on the results of a new clinical study showing lack of efficacy of cetuximab in combination with certain oxaliplatin-based chemotherapy regimens. The Committee recommended that the metastatic colorectal cancer indication in combination with chemotherapy should be restricted to use in combination with irinotecan-based chemotherapy or FOLFOX4 only.

The summary of opinion for the above mentioned medicine can be found on the Agency's website.

Removal of contraindication recommended

Further to the results of a study of **Velcade** (bortezomib) from Janssen-Cilag International NV in subjects with advanced malignancies and varying degrees of hepatic dysfunction, the Committee recommended by consensus that the contraindication for severe hepatic impairment should be removed from the product information for Velcade. Consequently, sections 4.2, 4.3, 4.4 and 5.2 of the Summary of Product Characteristics and the Package Leaflet have been updated.

The summary of opinion for the above mentioned medicine can be found on the Agency's website.

Additional safety information

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Aptivus** (tipranavir) from Boehringer Ingelheim International GmbH, to include contraindications with regard to co-administration with alfuzosin and co-administration with sildenafil used in the treatment of pulmonary arterial hypertension, due to pharmacokinetic interactions. In addition, co-administration of colchicine, salmeterol or bosentan is not recommended. Information concerning concomitant use with raltegravir, valaciclovir and PDE-5 inhibitors has also been included in the product information.

The CHMP adopted by consensus amendments to sections 4.4 and 5.2 of the SmPC for **Torisel** (temsirolimus) from Wyeth Europa Ltd. Those sections were amended with information regarding the treatment of patients with hepatic impairment, in particular with respect to an increased rate of fatal events observed in patients with moderate to severe hepatic impairment as well as reflecting the results of a phase I study for mild to moderate hepatic impaired patients.

The CHMP adopted by consensus amendments to sections 4.4 and 4.5 of the SmPC for **Multaq** (dronedarone) from Sanofi-Aventis to introduce a warning that concomitant use of dronedarone and dabigatran is not recommended.

Other information on the centralised procedure

Cessation of supply of Regranex

The Committee has been informed by Janssen-Cilag International NV of its intention to end the supply of **Regranex** (becaplermin) in Europe from 30 June 2011 onwards. Healthcare professionals will receive a letter from the company informing them of the cessation of supply and advising them to refer to the SmPC regarding the safe and appropriate use of Regranex for the management of patients currently treated with this medicine.

Regranex is a medicine for the treatment of long-term neuropathic skin ulcers (ulcers caused by a nerve problem) in people with diabetes.

More information is available in a separate question-and-answer document on the Agency's website.

Lists of Questions

The Committee adopted seven Lists of Questions on initial applications (including four under the mandatory scope, two under the optional scope as per Regulation (EC) No. 726/2004 and one under Article 31 of Regulation (EC) No. 1901/2006), together with four Lists of Questions on "line extension" applications (in accordance with Annex I of Commission Regulation (EC) No. 1234/2008).

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 April 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 April 2011 CHMP plenary meeting are provided in **Annex 3**.

Referral procedures

Review of celecoxib concluded

The Committee finalised its review on the use of the COX-2 inhibitor **celecoxib**[1] in the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis (FAP). The CHMP concluded that existing evidence of safety and efficacy does not support the use of celecoxib in FAP patients.

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

[1] The review of celecoxib was conducted in the context of a formal review under Article 5(3) of Regulation (EC) No 726/2004.

Review of buflomedil-containing medicinal products ongoing

The Committee recommended that the supply of oral **buflomedil-containing medicines**[2] be suspended in all EU Member States where it is currently authorised. A review of buflomedil solution for injection is still ongoing. The CHMP will adopt a full opinion once this review is finalised.

Buflomedil, a vasoactive agent, is used to treat peripheral arterial occlusive disease.

The review of buflomedil was initiated following the decision of the French regulatory authority in February 2011 to suspend the marketing authorisation, because serious and sometimes fatal neurological and cardiac side effects continued to occur, mainly related to accidental or intentional overdose, despite risk minimisation measures being put in place by regulatory authorities previously.

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

Update on the review of the safety of somatropin-containing medicines

The Committee finalised the first round of its review of the safety of **somatropin-containing medicines**[3,4] and agreed on further questions to be sent to the marketing authorisation holders.

While this review is ongoing, the CHMP confirms that the benefit-risk balance of these medicines continues to be positive in the approved therapeutic indications and doses. Prescribers are reminded not to exceed the maximum recommended dose for each approved indication.

The Agency will provide updates as new information becomes available.

Review on trimetazidine-containing medicines started

The Committee has begun looking at the benefit-risk balance of **trimetazidine-containing medicines**[5], currently used for the prophylactic treatment of angina pectoris crisis, the ancillary symptomatic treatment of vertigo and tinnitus and the ancillary treatment of visual acuity decrease and visual field disturbances due to vascular reasons.

The review was initiated by France following concerns over the benefit-risk balance of trimetazidine-containing medicines in all authorised indications due to the insufficient demonstration of efficacy and the risk of serious adverse events, in particular the occurrence and worsening of Parkinson syndrome.

The Committee will now review all available data to assess the balance of benefits and risks of these medicines.

Review on cilostazol-containing medicines started

The Committee has begun looking at the benefit-risk balance of **cilostazol-containing medicines**[6], currently used to improve the maximal walking distance and maximal pain-free walking distances in patients with intermittent claudication.

[2] The review of buflomedil-containing medicines is being conducted in the context of a formal review under Article 107 of Directive 2001/83/EC.
[3] The reviews of the centrally authorised somatropin-containing medicines NutropinAq, Omnitrope and Valtropin are being conducted in the context of formal reviews under Article 20 of Regulation (EC) No 726/2004.
[4] The review of nationally authorised somatropin-containing medicines is being conducted in the context of a formal review under Article 107 of Directive 2001/83/EC.
[5] The review on trimetazidine-containing medicines is being conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.
[6] The review on cilostazol-containing medicines is being conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.

This review was triggered by Spain following the review of all safety reports during the first 18 months of marketing of these medicines. The safety review showed an increased risk of cardiovascular and haemorrhagic reactions. This increased risk has to be assessed in the light of a modest clinical efficacy mainly shown in a population younger than the population receiving these medicines in daily practice.

The Committee will now review all available data to assess the balance of benefits and risks of these medicines.

Harmonisation procedure concluded

The Committee recommended the harmonisation of the prescribing information for the anti-emetic **Kytril**[7] (granisetron), from Roche group of companies. This medicine is used to prevent nausea and vomiting in patients who receive treatments for cancer such as chemotherapy and radiotherapy.

This review was initiated because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where this product is marketed.

A question-and-answer document with more information about this procedure is available on the Agency's website.

Update on review of Baxter's dialysis solutions

While an in-depth review of the problem of the presence of endotoxins in Baxter's dialysis solutions[5] manufactured at the Castlebar plant in Ireland is ongoing[8], the Committee recommended that the manufacturing site located in the United States of America is included into the existing marketing authorisations of Baxter's peritoneal dialysis solutions, in order to ensure the supply of endotoxin-free solutions in Europe. This follows an initial opinion last month to include sites located in Canada, Poland and Turkey.

The Committee will continue to investigate the root cause of the problem and the changes in the manufacturing process at Castlebar that are needed to ensure production of endotoxin-free products from this plant.

Review of Norditropin solution for injection started

The Committee started a referral procedure[9] for **Norditropin SimpleXx**, **Norditropin NordiFlex** and **Norditropin FlexPro** (somatropin), solution for injection, 5mg and 10mg and 15mg/1.5ml, from Novo Nordisk group of companies. The procedure was initiated because of disagreements regarding a new indication in children with Prader-Willi syndrome.

Review on manufacturing process of vaccines started

The Committee started a review to advise Member States on the handling of a manufacturing process issue[10] identified with vaccines marketed by GlaxoSmithKline and Novartis. The vaccines concerned are used to protect against diseases such as diphtheria, tetanus or pertussis. The investigation of this manufacturing process issue has no immediate impact on supply of these products to patients.

[7] The harmonisation procedure for Kytril was conducted in the context of a formal review under Article 30 of Directive 2001/83/EC, as amended.
[8] The referral for Baxter's dialysis solutions is being conducted under Article 31 of Directive 2001/83/EC, as amended.
[9] The review of Norditropin solution for injection is being conducted in the context of a formal review, initiated by Denmark under Article 13 of Regulation (EC) No 1234/2008.
[10] The review on manufacturing process of vaccines is being conducted in the context of a formal review under Article 5(3) of Regulation (EC) No 726/2004.

Mutual-recognition and decentralised procedures - Human

The CHMP noted the report from the 62nd CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-18 May 2011. 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 26-28 April 2011. For further details, please see **Annex 4**.

Documents adopted during the May 2011 CHMP meeting are listed in **Annex 5**.

Upcoming meetings following the May 2011 CHMP plenary meeting

- The 78th meeting of the CHMP will be held at the Agency on 20-23 June 2011.
- The next Name Review Group meeting will be held at the Agency on 24 May 2011.
- The 63rd CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 20-22 June 2011.

Organisational matters

The main topics addressed during the May 2011 CHMP meeting related to:

- The appointment of Dr Jan Schellens as Chair and Dr Jonas Bergh as Vice-Chair of Scientific Advisory Group on Oncology.
- The adoption of the mandate of the Joint CHMP/CVMP/CMDh/CMDv Active Substance Master File Working Group. The group has been created to deal with the procedural aspects of ASMF assessments and to consider the development of a guidance paper for efficient worksharing on ASMF assessment.
- An update was provided to the Committee on the activities of the EMA Task Force on Dialogue with HTA/payer groups, in particular with EUnetHTA, in the context of Drug Regulation and Health Technology Assessment. The objective of the Task Force is to maintain the overall co-ordination of activities related to such dialogue. Since its establishment in 2009 in response to the recommendations of the High Level Pharmaceutical Forum, namely, that the European Medicines Agency should continue their efforts to consider how the European Public Assessment Report (EPAR) can further contribute to relative effectiveness assessments, the areas for interaction with HTA/payer groups have increased. Current topics include exchange on scientific and methodological guidelines as well as reflection on areas of common interest in the design of drug development programmes including post-licensing data generation.
- The Committee has endorsed the establishment of a multi-disciplinary CHMP ad hoc working group for the topic phosphate buffers as excipients in eye drops. The adopted remit of this group will be to assess the risk of corneal calcification in association with the use of phosphate buffers as excipients in eye drop formulations, the need for consequential changes to the product information or replacement of these excipients, and data requirements for such variations, if warranted. The outcome of the group will be a report to the CHMP.

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 May 2011

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
N/A		

Opinion for renewals of conditional Marketing Authorisation		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
INTELENCE (etravirine), Janssen-Cilag International N.V.	Positive opinion	Marketing Authorisation remains under conditional approval

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
ATryn (antithrombin Alfa), GTC Biotherapeutics UK Limited	Positive opinion	Recommending additional renewal Marketing Authorisation remains under exceptional circumstances
Exjade (deferasirox), Novartis Europharm Ltd.	Positive opinion	Recommending additional renewal
Intrinsa (testosterone), Warner Chilcott UK Ltd.	Positive opinion	Recommending additional renewal
Livensa (testosterone), Warner Chilcott Deutschland GmbH	Positive opinion	Recommending additional renewal
Crixivan (indinavir), Merck Sharp & Dohme Ltd.	Positive opinion	Unlimited validity
Gardasil (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)), Sanofi Pasteur MSD, SNC	Positive opinion	Unlimited validity
Silgard (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)), Merck Sharp & Dohme Ltd.,	Positive opinion	Unlimited validity
Savene (dexrazoxane), **Orphan**, SpePharm Holding BV	Positive opinion	Unlimited validity

Accelerated Assessment Procedures			
Substance (Chemical/ Biological)	**Intended Indication(s)**	**Accelerated Assessment Requests**	
		Accepted	Rejected
Biological	Prevention and treatment of hepatic veno-occlusive disease following haematopoietic stem-cell transplantation	X	

Annex 2 to CHMP Monthly Report May 2011

Medicinal products granted a community marketing authorisation under the centralised procedure since the April 2011 CHMP Monthly Report

Invented name	**Rasilamlo**
INN	Aliskiren and amlodipine
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09XA53
Indication	Treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone
CHMP Opinion date	17/02/2011
Marketing Authorisation Date	14/04/2011

Invented name	**Riprazo HCT**
INN	Aliskiren hemifumarate and hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09XA52
Indication	Treatment of essential hypertension in adults
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	13/04/2011

Invented name	**Hizentra**
INN	Human normal immunoglobulin (SCIg)
Marketing Authorisation Holder	CSL Behring GmbH
Proposed ATC code	J06BA01
Indication	Replacement therapy in adults and children in primary immunodeficiency syndromes such as: - congenital agammaglobulinaemia and hypogammaglobulinaemia - common variable immunodeficiency - severe combined immunodeficiency - IgG subclass deficiencies with recurrent infections Replacement therapy in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections.
CHMP Opinion date	17/02/2011
Marketing Authorisation Date	14/04/2011

Annex 3 to CHMP Monthly Report May 2011

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

Update since the April 2011 CHMP meeting

Active substance	Invented name	Sponsor/applicant	EU designation number	Designated orphan indication
Axitinib	INLYTA	Pfizer Limited	EU/3/10/844	Treatment of renal cell carcinoma

Annex 4 to CHMP Monthly Report May 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	108	1476
Follow-up to Scientific Advice	320	28	348
Protocol Assistance	297	22	319
Follow-up to Protocol Assistance	133	10	143
	2118	**168**	**2286**

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	5	14
Ongoing	0	0	0
Foreseen	0	3	3
	9	**8**	**17**

Outcome of the May 2011 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of type 1 diabetes mellitus.	*x*				*x*	*x*	*x*	
Biological	Treatment of type 2 diabetes mellitus.	*x*						*x*	
Chemical	Treatment of gastro-oesophageal reflux disease, duodenal and gastric ulcers and Helicobacter eradication in children.	*x*					*x*	*x*	
Biological	treatment of hypercholesterolaemia.	*x*					*x*	*x*	
Chemical	Treatment of obesity.	*x*						*x*	
Chemical	Treatment of castration-resistant prostate cancer.	*x*						*x*	
Biological	Treatment of hidradenitis suppurativa.			*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 rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn´s disease.	*x*				*x*	*x*	*x*	
Biological	Treatment of Cryopyrin-Associated Periodic Syndromes.	*x*						*x*	
Biological	Treatment of Cryopyrin-Associated Periodic Syndromes.	*x*				*x*	*x*		
Chemical	Treatment of Juvenile myelomonocytic leukaemia and Relapsed/Refractory Acute Myeloid Leukaemia in paediatric patients.		*x*					*x*	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.	*x*				*x*	*x*	*x*	
Biological	Treatment of CD30-positive cutaneous T cell lymphoma.	*x*						*x*	
Biological	Treatment of Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, moderate to severe plaque psoriasis.	*x*				*x*	*x*		
Biological	Treatment of metastatic breast carcinoma.	*x*					*x*	*x*	
Biological	Treatment of Palmoplantar Pustulosis.	*x*						*x*	
Biological	Treatment of Plaque Psoriasis.	*x*						*x*	
Biological	Treatment of Ankylosing spondylitis.	*x*					*x*	*x*	
Biological	Treatment of Psoriatic arthritis.	*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 locally advanced or metastatic pancreatic cancer.				*x*			*x*	
Advanced therapy	Treatment of metastatic androgen dependent prostate cancer.	*x*						*x*	
Biological	Treatment of Rheumatoid Arthritis.	*x*					*x*		
Chemical	Prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection.	*x*				*x*	*x*	*x*	
Chemical	Treatment of advanced renal cell carcinoma.				*x*	*x*	*x*	*x*	
Biological	Treatment and prophylaxis of bleeding (including surgeries) in hemophilia A.			*x*		*x*	*x*	*x*	
Biological	Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	*x*				*x*			
Chemical	Intended for the secondary prevention cardiovascular events and for slowing the progression of atherosclerosis.			*x*				*x*	
Chemical	Intended for the secondary prevention cardiovascular events.	*x*						*x*	
Chemical	Treatment of Open Heart Surgery.	*x*					*x*	*x*	
Chemical	Treatment of chronic hepatitis C.			*x*				*x*	
Biological	Intended for the prevention of invasive meningococcal disease caused by N. meningitidis serogroup B.			*x*				*x*	
Chemical	Treatment of Hereditary Haemorrhagic Telangiectasia (HHT).		*x*				*x*	*x*	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Bone marrow intended for the treatment of non-union fractures.	*x*						*x*	
Chemical	Treatment of generalised tonic-clonic seizures in adults and adolescents 12 years and older with idiopathic generalised epilepsy.	*x*					*x*	*x*	
Advanced therapy	Treatment of childhood cerebral adrenoleukodytrophy.	*x*				*x*	*x*	*x*	
Chemical	Treatment of Schizophrenia.	*x*						*x*	
Chemical	Treatment of Huntington disease.				*x*			*x*	
Chemical	Treatment of asthma.	*x*				*x*		*x*	
Biological	Treatment of diabetes mellitus.	*x*						*x*	
Biological	Treatment of type 1 or type 2 diabetes mellitus.	*x*						*x*	
Chemical	Treatment of iron overload due to hereditary hemochromatosis.				*x*			*x*	*x*

SA: scientific advice
PA: protocol assistance

The above-mentioned 30 Scientific Advice letters, 2 Protocol Assistance letters, 5 Follow-up Scientific Advice and 4 Follow-up Protocol Assistance letters were adopted at the 16 – 19 May 2011 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 26 – 28 April 2011. The new requests are divided as follows: 35 Initial Scientific Advice, 10 Follow-up Scientific Advice, 6 Initial Protocol Assistance and 0 Follow-up Protocol Assistance.

Annex 5 to CHMP Monthly Report May 2011

Documents adopted during the May 2011 CHMP meeting

Biologics Working Party (BWP)

Reference number	Document	Status[11]
EMA/CHMP/BWP/25360/ 2011	Concept paper on process validation of medicinal products containing biotechnology derived proteins as active substance	**3-month public consultation**

Infectious Diseases Working Party

Reference number	Document	Status[11]
EMA/CHMP/822851/ 2010	Infectious Diseases Working Party Work Programme 2011	**adopted**

Pharmacogenomics Working Party (PGWP)

Reference number	Document	Status[11]
EMA/CHMP/PGxWP/ 250429/2010	Amended PGWP Work Programme 2011	**adopted**

Quality Working Party (QWP)

Reference number	Document	Status[11]
EMA/CHMP/CVMP/QWP/ 180157/2011	Quality guideline on the pharmaceutical development of medicines for paediatric use	**6-month public consultation**

ICH

Reference number	Document	Status[11]
EMA/CHMP/ICH/425213/ 2011	Q11 Draft No. Step 2 - Development and Manufacture of Drug Substances (chemical entities and biotechnological/biological entities)	**public consultation until 30/09/2011**

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