29 April 2011
EMA/CHMP/814037/2010 - Corr[1]

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

13 – 16 December 2010

Centralised procedure

Review of benefits and risks of Avastin concluded

Finalising a review[2] of **Avastin** (bevacizumab), from Roche Registration Ltd, the Committee confirmed that the benefits of Avastin in combination with paclitaxel outweigh its risks and that this combination remains a valuable treatment option for patients suffering from metastatic breast cancer.

The CHMP also concluded by majority that Avastin in combination with docetaxel should no longer be used in the treatment of metastatic breast cancer. Patients who are currently being treated with this combination should discuss their ongoing treatment with their doctor.

Avastin is an anticancer medicine which contains the active substance bevacizumab. It is used in combination with other anticancer treatments to treat cancers of the colon, rectum, lung, kidney or breast. The CHMP's review was restricted to the use of Avastin in breast cancer and does not affect its use in the other indications.

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

Initial applications for marketing authorisation

New medicinal products

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

[1] The document has been revised to correct statistical figures contained in Annex 3 (page 12).
[2] The review of Avastin was conducted under Article 20 of Regulation (EC) No 726/2004.

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- **Esbriet** (pirfenidone), an orphan medicine from InterMune Europe Ltd, intended for the treatment of idiopathic pulmonary fibrosis. The review for Esbriet began on 24 March 2010 with an active review time of 180 days.
- **Orphacol** (cholic acid), an orphan medicine from Laboratoires CTRS, intended for the treatment of inborn errors in primary bile acid synthesis due to 3β-Hydroxy-Δ5-C27-steroid oxidoreductase deficiency or Δ4-3-Oxosteroid-5β-reductase deficiency. The review for Orphacol began on 18 November 2009 with an active review time of 210 days.
- **Teysuno** (tegafur/gimeracil/oteracil), an orphan medicine from Taiho Pharma Europe Ltd, intended for the treatment of advanced gastric cancer in adults when given in combination with cisplatin. The review for Teysuno began on 18 November 2009 with an active review time of 210 days.
- **Xeplion** (paliperidone) from Janssen-Cilag International N.V., for the treatment of schizophrenia. The review for Xeplion began on 23 December 2009 with an active review time of 180 days.
- **Xiapex** (collagenase clostridium histolyticum), from Pfizer Ltd, intended for the treatment of Dupuytren's contracture in adult patients with a palpable cord. The review for Xiapex began on 21 January 2010 with an active review time of 210 days.

Positive opinions for informed consent applications adopted

The Committee adopted positive opinions by consensus recommending the granting of marketing authorisations for the informed consent applications **Daliresp** and **Libertek** (roflumilast), from Nycomed GmbH, intended for the maintenance treatment of severe chronic obstructive pulmonary disease associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add-on to bronchodilator treatment. The reviews for Daliresp and Libertek began on 17 October 2010 with an active review time of 60 days. These applications were informed consent applications referring to the dossier of the authorised medicine Daxas.

Generic medicinal products

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

- **Ifirmacombi** (irbesartan hydrochloride/hydrochlorothiazide), from Krka, d.d., Novo mesto, intended for the treatment of adult patients with essential hypertension, whose blood pressure is not adequately controlled with irbesartan or hydrochlorothiazide alone. Ifirmacombi is a generic of CoAprovel.
- **Leflunomide Teva** (leflunomide), from Teva Pharma B.V., intended for the treatment of adult patients with active rheumatoid arthritis. Leflunomide Teva is a generic of Arava.
- **Repso** (leflunomide), from Teva Pharma B.V., intended for the treatment of adult patients with active rheumatoid arthritis and active psoriatic arthritis. Repso is a generic of Arava.

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

Withdrawals

The European Medicines Agency has been formally notified by Sanofi Pasteur of its decision to withdraw its application for a centralised marketing authorisation for **Emerflu**, a pandemic influenza vaccine (split virion, inactivated, adjuvanted) A/Vietnam/1194/2004 NIBRG-14, 30 µg of

haemagglutinin + aluminium hydroxide adjuvant, suspension for injection. This medicine was intended to be used for prophylaxis of influenza in an officially declared pandemic situation. A core pandemic dossier was submitted in the context of prevention of influenza in an officially declared pandemic situation, according to the mock-up vaccine procedure. The application for the marketing authorisation for Emerflu was submitted to the Agency on 27 April 2007. Emerflu received a negative opinion from the Committee for Medicinal Products for Human Use (CHMP) on 19 March 2009 and at the time of withdrawal a European Commission decision was pending. A separate press release and a question-and-answer document with more information are available.

The European Medicines Agency has been formally notified by Novartis Europharm Ltd. of its decision to withdraw its application for an extension of indication for the centrally authorised medicine **Zometa** (zoledronic acid) 4 mg powder and solvent for solution for infusion and 4 mg/5 ml concentrate for solution for infusion. On 22 December 2009, Novartis Europharm Ltd. submitted an application to extend the marketing authorisation for Zometa to include the adjuvant treatment of hormone receptor-positive early breast cancer (EBC) in premenopausal women for whom hormonal therapy is recommended. At the time of withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP). A separate press release with more information is available.

Update on the withdrawal of Thelin

The Committee has reviewed the data on liver toxicity, including three cases of fatal liver injury, that had prompted the marketing authorisation holder, Pfizer, to withdraw the marketing authorisation for **Thelin** worldwide and to discontinue all ongoing clinical trials. A separate press release with more information is available.

Post-authorisation procedures

Extensions of indications and other recommendations

The Committee adopted a positive opinion by consensus for an application for extension of the therapeutic indication, adding a new treatment option for a medicine already authorised in the European Union, for:

- **Simponi** (golimumab), from Centocor B.V., to include adult patients with severe, active and progressive rheumatoid arthritis (RA) not previously treated with methotrexate and to include reduction in the rate of progression of joint damage in all RA populations.

The summary of opinion for the mentioned medicine, including the full indication, can be found here.

Negative opinion for extension of therapeutic indication adopted

The Committee adopted a negative opinion for **Avastin** (bevacizumab), from Roche Registration Ltd, recommending that the current indication should not be extended to include first-line combination therapy with capecitabine in patients with metastatic breast cancer. The review of benefits and risks of Avastin (see above) was triggered by data submitted in the context of this application.

Additional safety information

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal products **Rasilez**, **Sprimeo**, **Riprazo** (aliskiren) and **Rasilez**

HCT (aliskiren/hydrochlorothiazide) from Novartis Europharm Ltd. This worksharing (type IB) variation concerns an update of sections 4.3, 4.4 and 4.8 of the Summary of Product Characteristics (SmPC), upon request by CHMP following a review by the PhVWP of the risk of angioedema with aliskiren, to add the new contraindication 'hereditary or idiopathic angioedema' and to add further information about the risk of angioedema with aliskiren administration.

The CHMP adopted by consensus amendments to sections 4.4 and 4.8 of the SmPC of **Enbrel** (etanercept) from Wyeth Europa Ltd. Sections 4.4 and 4.8 of the SmPC were amended with information regarding reports of inflammatory bowel disease (IBD) in patients with juvenile idiopathic arthritis treated with Enbrel. The package leaflet was updated accordingly. The evidence for a potential association between etanercept treatment and IBD derives predominantly from spontaneous reports and case reports from the literature.

The Committee adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Multaq** (dronedarone) from Sanofi Aventis. Sections 4.3, 4.4, 4.5 and 5.2 of the SmPC were amended following results from interaction studies. In particular erythromycin was included in section 4.3 as an example of oral macrolides. The package leaflet was updated accordingly.

Other information on the centralised procedure

Lists of Questions

The Committee adopted five Lists of Questions on initial applications (including three under the mandatory scope, and two 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 November 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

Review of the safety of somatropin-containing medicines started

The Committee has started a review[3,4] of the safety of somatropin-containing medicines authorised centrally or by national procedures in the European Union. The CHMP will look into all available data on somatropin to reassess the benefit-risk balance of these medicines.

[3] The reviews of the centrally authorised somatropin-containing medicines NutropinAq, Omnitrope and Valtropin are being conducted under Article 20 of Regulation (EC) No 726/2004.
[4] The reviews of nationally authorised somatropin-containing medicines is being conducted under Article 107 of Directive 2001/83/EC.

While this review is ongoing, the CHMP confirms that there is no immediate concern. However, prescribers are reminded to strictly follow the indications and the approved doses. The maximum recommended dose of 50µg/kg weight/day for somatropin-containing medicines should not be exceeded.

More information about this review is available in a separate press release on the Agency's website.

Review of potential presence of endotoxins in peritoneal dialysis solutions concluded

The Committee concluded by consensus a review[5] on the potential presence of endotoxins in the peritoneal dialysis solutions **Dianeal**, **Extraneal** and **Nutrineal**, from Baxter. These are sterile solutions used in patients who have to undergo peritoneal dialysis because of kidney failure.

Although the number of batches affected is likely to be low, the CHMP concluded that current stocks should be replaced, because it is not possible to identify which bags are affected and there is a risk that patients who receive peritoneal solutions which contain endotoxins may develop aseptic peritonitis. The replacement of batches should be handled in such a way that vulnerable patients who rely on a particular type of solution are not put at risk. The CHMP has therefore recommended an action plan so that patients who are most in need continue to have access to treatment.

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

Arbitration concluded

The Committee completed an arbitration procedure initiated[6] because of disagreement among EU Member States regarding the authorisation of the generic isotretinoin-containing medicine **Isotretinoin Ranbaxy (UK) Limited**, from Ranbaxy (UK) Ltd. This medicine is indicated for treatment of severe acne that has not responded to standard treatments.

This procedure was initiated because of concerns that bioequivalence of this medicine to the reference product Roaccutane had only been shown under fasting conditions but not under fed conditions, and that this could thus result in suboptimal dosing. The Committee concluded that bioequivalence with the reference product has not been shown according to current requirements and that the benefit-risk balance of this medicine is negative.

The CHMP therefore recommended by consensus that marketing authorisations should not be granted in the concerned Member States and it should be suspended in the United Kingdom where it is already authorised.

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

Harmonisation referral concluded

The Committee recommended by consensus harmonisation of the prescribing information for the medicine **Tienam** (imipenem/cilastatin), from Merck Sharp & Dohme and associated companies by consensus. This medicine is an antibiotic authorised to treat complicated intra-abdominal infections, severe pneumonia, intra- and post-partum infections, complicated urinary tract infections, complicated skin and soft-tissue infections and the treatment of bacteraemia associated with these infections.

[5] The review of peritoneal dialysis solutions was conducted under Article 5(3) of Regulation (EC) No 726/2004, at the request of the UK Medicines and Healthcare products Regulatory Agency.
[6] The review of Isotretinoin Rabaxy (UK) Limited was conducted under Article 29 of Directive 2001/83/EC.

This review was initiated[7] because of differences in the summaries of product characteristics, labelling and package leaflets in the countries where the product is marketed.

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

Mutual-recognition and decentralised procedures - Human

The CHMP noted the report from the 57th CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 13-14 December 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 30 November to 2 December 2010. For further details, please see **Annex 4**.

Documents adopted during the December 2010 CHMP meeting are listed in **Annex 5**.

Upcoming meetings following the December 2010 CHMP plenary meeting

- The 73rd meeting of the CHMP will be held at the Agency on 17-20 January 2011.
- The next Name Review Group meeting will be held at the Agency on 25 January 2011.
- The 58th CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 17-18 January 2011.

Organisational matters

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

- The election of Dr Skovlund as new Chair of the Biostatistics Working Party and the nomination of Dr Vilceanu as CHMP representative to PDCO.
- A report on the experience with grouping and worksharing of variations. Until 31 October 2010 the Agency has received 394 grouped applications and 73 worksharing applications. Based on experience, the Agency established principles for acceptable grouping and worksharing which are currently being applied and are reflected in the Post-authorisation procedural advice, available on the Agency's website.

[7] The harmonisation referral on Tienam was conducted under Article 30 of Directive 2001/83/EC, as amended.

Procedural Announcement

Information required in Cover Letter for Submissions related to Medicinal Products for Human Use in the Centralised Procedure

The European Medicines Agency is standardising the administrative information required in cover letters for any submissions concerning centralised procedures. This is in line with future changes to the internal financial system and quality improvements to distribution workflows.

These changes will be applicable to any future submission.

The **Summary Table** should be incorporated in each cover letter.

TEMPLATE FOR COVER LETTER SUMMARY TABLE

1*	**Applicant/MAH Name**					
2*	**Customer Account Number**					
3*	**Customer Reference / Purchase Order Number**					
4	**Product Name**					
5*	**Procedure Number**					
6	**INN / Active substance**					
7*	**Application Type**		**P**	☐	**Q**	☐
8*	**Description of Submission**					
9*	**eCTD sequence**		**Related sequence**			
10*	**Checksum**					
11*	**Contact Persons' details (include email address)**	**A) Regarding the content of the submission:** **B) Regarding eCTD technical questions:** **C) Regarding financial queries:**				

** please see explanatory notes*

1) MAH: Marketing Authorisation Holder

2) This field is mandatory if the submission concerns a fee related application. Please quote your EMA designated customer account number. To request an EMA customer account number or for any other accounts query please email your request to accountsreceivable@ema.europa.eu.

3) This is a reference number provided by the applicant (i.e. PO – purchase order number). It will be quoted on the invoice issued by the Agency. If not applicable, please state clearly 'NOT APPLICABLE'.

*5) eg: EMEA/H/C/00…/IB/xxxx (if already assigned by EMA and known); **for new submissions of application, please refrain from inserting this number**, as it is sequentially generated by the EMA internal database upon receipt of submission.*

7) Type of procedure (e.g. PSUR [periodic safety update report], FUM [follow up measures], Variation Type [IA,IB, II], WS [worksharing], G [grouped], T [transfer], N [notification 61.3], etc). In case of variation,

*please indicate if it affects quality changes **Q**. In case this submission is made on grounds of usage patent(s) pertaining to indication(s) and/or dosage form(s) please indicate **P**.*

8) Description of submission (specify if it is an initial submission). In case of a variation application, give details of the scope, in particular, indicate if it is an extension of indication, or if it is addressing a FUM.

Specify whether the application contains any of the following: Responses / Supplementary information; Re-Submission of variation; Replacement sequence [due to negative technical report]; S.OB.s [specific obligations]; Specify PSUR number and/or period covered / FUM number / Commitments / Study Reports / Risk Management Reports; Translations; Product information; Withdrawal; Corrigendum, etc)

9) eCTD sequence number (electronic common technical document)

10) The unique number as it appears in eCTD index-md. Note that this information is required in the printed version of the cover letter only, as it is not possible to have it included beforehand in the PDF version included in the sequence. This information is not mandatory and it is at the discretion of the applicant.

11) A) Contact person as specified in section 2.4.2 (for initial application) or 2.4.3 (for post-authorisation applications) in Part IA/Module 1 Application Form.

C) Please provide details of a contact person for matters related to settlement of invoices, statements of account, etc. The Agency will send an invoice to the billing address it has on file at the time of receipt of the present application. For queries on billing addresses please send an email to accountsreceivable@ema.europa.eu. Please note that EMA fees are payable net of all bank charges, withholding taxes and any other deduction imposed on the customer by legislation of the country of residence.

Change to procedure concerning submissions of opinion and related documents to Applicant and Marketing Authorisation Holder

The European Medicines Agency is implementing improvements which aim to streamline various process outputs by switching to electronic format only.

From 1st of February 2011, the European Medicines Agency will send the opinions adopted by the Committee for Human Medicinal Products (CHMP) to the Applicant/Marketing Authorisation Holder in electronic format only including the signed opinion pages and relevant correspondence in PDF format and the related Annexes in MS-Word format.

This opinion package will be sent via a secure mail distribution platform (Eudralink). It will be the replica of the electronic copy sent simultaneously to the European Commission and of the electronic copy retained at the Agency, marked as un-modifiable according to the Agency's Records Management Policy.

As no paper version will follow by postal mail/courier, the Applicant/Marketing Authorisation Holder should acknowledge download of the package and safe receipt of the message received by Eudralink to ensure compliance with Articles 9 and 10 of Regulation (EC) No 726/2004 of 31 March 2004.

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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 December 2010

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Ilaris (canakinumab), Novartis Europharm Ltd.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Replagal (agalsidase alfa), Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

Opinion for renewals of conditional Marketing Authorisation		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
N/A		

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Kaletra ((lopinavir / ritonavir), Abbott Laboratories Ltd.	Positive Opinion	Unlimited validity
Myozyme (alglucosidase alfa), Genzyme Europe B.V.	Positive Opinion	Unlimited validity
Omnitrope (somatropin), Sandoz GmbH	Positive Opinion	Unlimited validity
Prevenar (pneumococcal saccharide conjugated vaccine, adsorbed), Wyeth Lederle Vaccines S.A.	Positive Opinion	Unlimited validity
Vaniqa (eflornithine), Laboratorios Almirall, S.A.	Positive Opinion	Unlimited validity

Accelerated Assessment Procedures			
Substance	**Intended Indication(s)**	**Accelerated Assessment Requests**	
		Accepted	Rejected
Biological	Replacement therapy in patients with a confirmed diagnosis of Gaucher disease		X

Annex 2 to CHMP Monthly Report December 2010

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

Invented name	**Leflunomide Ratiopharm**
INN	leflunomide
Marketing Authorisation Holder	ratiopharm GmbH
Proposed ATC code	L04AA13
Indication	Treatment of adult patients with active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD)
CHMP Opinion date	23.09.2010
Marketing Authorisation Date	29.11.2010

Invented name	**AFLUNOV**
INN	Prepandemic Influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted).
Marketing Authorisation Holder	Novartis Vaccines and Diagnostics S.r.l.
Proposed ATC code	J07BB02
Indication	Active immunisation against H5N1 subtype of Influenza A virus
CHMP Opinion date	23.09.2010
Marketing Authorisation Date	29.11.2010

Invented name	**Prepandemic Influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostics**
INN	Prepandemic Influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted).
Marketing Authorisation Holder	Novartis Vaccines and Diagnostics S.r.l.
Proposed ATC code	J07BB02
Indication	Active immunisation against H5N1 subtype of Influenza A virus
CHMP Opinion date	23.09.2010
Marketing Authorisation Date	29.11.2010

ANNEX 3 to CHMP Monthly Report December 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	30	46	**247**	**302**
Justification for retention of invented name *	***1***	***6***	2	4	0	3	2	4	0	3	1	5	**6**	**25**

*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 Oct 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	139	85	144	45	99	56	**665**	**332**
Criterion - Safety concerns														
Similarity with other Invented name	73	21	90	31	90	62	98	59	128	38	69	28	**548**	**239**
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	1	0	0	8	2	1	1	1	4	**12**	**8**
Misleading with respect to composition	0	0	0	1	0	0	6	0	2	0	5	0	**13**	**1**
Criterion - INN concerns														
Similarity with INN	5	3	6	8	5	3	4	3	7	3	3	4	**30**	**24**
Inclusion of INN stem	3	6	3	1	2	3	2	6	5	3	2	8	**17**	**27**
Criterion - Other public health concerns														
Unacceptable qualifiers	0	1	0	2	0	0	5	2	0	0	11	3	**16**	**8**
Conveys a promotional message	0	1	1	4	0	0	10	9	1	0	5	5	**17**	**19**
Appears offensive or has a bad connotation	0	0	1	1	0	0	3	1	0	0	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	0	2	**2**	**3**
Similarity between name of prodrug and related active substance	0	0	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 4 to CHMP Monthly Report December 2010

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

	1995 - 2009	2010	Overall total
Scientific Advice	1134	234	1368
Follow-up to Scientific Advice	232	88	320
Protocol Assistance	245	52	297
Follow-up to Protocol Assistance	109	24	133
	1720	**398**	**2118**

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 December 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 type 2 diabetes.	*x*				*x*		*x*	
Chemical	Treatment of type 2 diabetes.			*x*				*x*	
Chemical	Treatment of type 2 diabetes mellitus.			*x*				*x*	
Chemical	Treatment of acute ulcerative colitis.				*x*			*x*	*x*
Chemical	Treatment type 2 diabetes mellitus.	*x*					*x*	*x*	
Chemical	Treatment of primary biliary cirrhosis.		*x*			*x*		*x*	
Chemical	Intended for weight loss.	*x*						*x*	
Biological	Reduction of neutropenia.	*x*				*x*	*x*	*x*	
Biological	Reduction of neutropenia.	*x*				*x*	*x*	*x*	
Chemical	Treatment of hepatocellular carcinoma.	*x*				*x*	*x*		

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of peripheral T-cell lymphoma.	x				x			
Biological	Treatment of peripheral T-cell lymphoma.			x			x	x	
Chemical	Treatment of soft-tissue sarcoma.	x						x	
Chemical	Treatment of basal cell carcinoma in patients with Gorlin syndrome.	x					x	x	
Chemical	Treatment of relapsing-remitting multiple sclerosis.	x				x	x	x	
Biological	First-line treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of prostate cancer.			x				x	
Chemical/ Biological	Treatment of breast cancer.	x					x		
Biological	Treatment of sickle cell disease.		x				x	x	
Advanced therapy	Treatment of thromboangiitis obliterans (Buerger's disease).		x					x	x
Chemical	Treatment of hypercholesterolaemia.	x						x	
Advanced therapy	Treatment of critical limb ischaemia.	x				x	x	x	
Biological	Treatment of acute heart failure.	x					x	x	
Chemical	Treatment of pulmonary arterial hypertension.		x					x	
Biological	Prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and invasive diseases caused by H. influenzae Type b and Meningococcal serogroup C.			x				x	
Chemical	Treatment of HIV-1 infection.			x				x	
Biological	Prophylaxis of influenza.	x						x	
Biological	Prophylaxis of influenza.	x				x			
Chemical	Treatment of skin and skin structure infections.	x					x	x	
Biological	Treatment of Peyronie's disease.	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	Treatment of schizophrenia.	*x*						*x*	
Chemical	Treatment of severe pain.	*x*						*x*	
Chemical	Treatment of Parkinson's disease.	*x*					*x*	*x*	
Chemical	Treatment of cystic fibrosis.		*x*				*x*	*x*	
Other innovative	Treatment of moderate to severe dry eye.	*x*				*x*	*x*	*x*	
Biological/ Other innovative	Aid to smoking cessation and long term abstinence.			*x*			*x*	*x*	
Biological/ Other innovative	Aid to smoking cessation and long term abstinence.	*x*				*x*			

SA: scientific advice
PA: protocol assistance

The above-mentioned 24 Scientific Advice letters, 5 Protocol Assistance letters, 7 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letters were adopted at the 13 - 16 December 2010 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 37 new Requests for which the procedure started at the SAWP meeting held on 30 November – 2 December 2010. The new requests are divided as follows: 26 Initial Scientific Advice, 7 Follow-up Scientific Advice, 3 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

Annex 5 to CHMP Monthly Report December 2010

Documents adopted during the December 2010 CHMP meeting

Biosimilar Medicinal Products Working Party (BMWP)

Reference number	Document	Status[7]
EMA/CHMP/BMWP/572297/2010	BMWP Work Programme 2011	**adopted**

Blood Products Working Party (BPWP)

Reference number	Document	Status[8]
EMA/CHMP/BPWP/761007/2010	Concept paper on revision of note for guidance on the clinical investigation of human normal immunoglobulin for subcutaneous and intramuscular use (CPMP/BPWG/283/00)	**3-month public consultation**

Biostatistics Working Party (BSWP)

Reference number	Document	Status[7]
EMA/676305/2010	BSWP Work Programme 2011	**adopted**
EMA/CHMP/EWP/117211/2010	Concept Paper on the Need for a Guideline on the Use of Subgroup Analyses in Randomised Controlled Trials	**adopted**

Central Nervous System Working Party (CNS WP)

Reference number	Document	Status[7]
EMA/CHMP/761049/2010	CNS WP Work Programme 2011	**adopted**

Infectious Diseases Working Party

Reference number	Document	Status[7]
EMA/644581/2010	Infectious Disease WP Work Programme 2011	**adopted**

[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").

Oncology Working Party (ONCWP)

Reference number	Document	Status[7]
EMA/CHMP/ONCWP/644147/2010	Oncology Working Party Work Programme 2011	**adopted**

Pharmacogenomics Working Party (PGWP)

Reference number	Document	Status[7]
EMA/CHMP/PGxWP/250429/2010	PGWP Work Programme 2011	**adopted**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status[7]
EMA/CHMP/697445/2010	PKWP Work Programme 2011	**adopted**

Quality Working Party (QWP)

Reference number	Document	Status[7]
EMA/CHMP/CVMP/QWP/696270/2010	Template for the Qualified Person's declaration	**3-month public consultation**

Scientific Advice Working Party (SAWP)

Reference number	Document	Status[7]
EMEA/CHMP/SAWP/69686/04 Rev 8	Revised mandate, objectives and rules of procedure of the Scientific Advice Working Party	**adopted**

CHMP Drafting Groups

Reference number	Document	Status[7]
EMA/CHMP/711449/2010	Urology Drafting Group Work Programme 2011	**adopted**
EMA/758102/2010	Respiratory Drafting Group Work Programme 2011	**adopted**
EMA/CHMP/774753/2010	Gastroenterology Drafting Group Work Programme 2011	**adopted**
EMA/774372/2010	Radiopharmaceuticals Drafting Group Work Programme 2011	**adopted**

ICH

Reference number	Document	Status[7]
EMA/CHMP/ICH/645469 /2008	Q4B Annex 7 (R2) – Dissolution Test	**adopted**
EMA/CHMP/ICH/265145 /2009	Q8, Q9 and Q10 – Questions and Answers Volume 4	**adopted**