EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2010
EMA/CHMP/256110/2010 - Corr[1]

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

19-22 April 2010

CENTRALISED PROCEDURE

Update on pandemic medicines

The Committee reviewed further results from clinical studies and post-marketing experience for the centrally authorised pandemic influenza vaccines **Celvapan**, **Focetria** and **Pandemrix**. Marketing authorisations for these vaccines had been given under specific conditions. The Committee concluded that the additional data from clinical and non-clinical studies, from post-marketing surveillance and from the use of these vaccines in at least 40 million people in the European Economic Area since September 2009 was sufficient to allow these vaccines to be given full marketing authorisations that allow their use outside a declared influenza pandemic. Under the terms of their current authorisations ('exceptional circumstances') they can only be used in the context of a WHO-declared pandemic. The Committee will continue to keep the vaccines under close surveillance. The product information of the three vaccines has been updated accordingly.

For **Focetria**, the CHMP recommended further changes to the product information to include data on the immunogenicity and safety in children aged 6 to 35 months and in children aged 3 to 7 years. The available data indicate that a single full dose of Focetria vaccine triggered a good immune response in children aged 6 to 35 months, but that the second dose further increased the immune response. Furthermore, immunogenicity data in children aged 3 to 7 years old suggests that a single dose may be sufficient.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary. The most recent pandemic influenza pharmacovigilance update report was published on 21st April 2010 and can be found here.

[1] The document has been revised to correct information on annual re-assessment applications contained in Annex 1 (page 9).

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Initial applications for marketing authorisation

New medicinal product

The Committee adopted a positive opinion by majority, recommending the granting of a marketing authorisation for **Daxas** (roflumilast), from Nycomed GmbH, intended for maintenance treatment of severe chronic obstructive pulmonary disease associated with chronic bronchitis in adult patients as add-on to bronchodilator treatment. The review for Daxas began on 27 May 2009 with an active review time of 210 days.

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

Revised positive opinion

The Committee adopted a revised positive opinion by majority, recommending the granting of a conditional marketing authorisation for **Votrient** (pazopanib hydrochloride), 200 and 400 mg for oral use from Glaxo Group Ltd, intended for the treatment of advanced renal cell carcinoma. The revision was triggered by the removal of Votrient from the Community register of orphan medicinal products, on the applicant's request. As a consequence, the CHMP considered that Votrient still fell within the scope of Regulation (EC) No 507/2006, i.e. under Article 2(1) – medicinal product which aims at the treatment, the prevention or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and issued a revised opinion recommending the granting of conditional marketing authorisation.

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

Withdrawals

The European Medicines Agency has been formally notified by Novartis Europharm Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Joulferon** (albinterferon alfa-2b) solution for injection. This medicine was intended for treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and who have not been previously treated with interferon. A separate question-and-answer document with more information is available.

The European Medicines Agency has been formally notified by Sun Pharmaceutical Industries B.V. of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product **Repaglinide SUN** (repaglinide) 0.5 mg, 1 mg and 2 mg film-coated tablets. This medicine was developed as a generic medicine to be used for the treatment of patients with type 2 diabetes whose hyperglycaemia can no longer be satisfactory controlled by diet, weight reduction and exercise. It was also intended as combination treatment with metformin of type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone. The reference medicinal product for Repaglinide SUN is NovoNorm, which has been authorised in the European Union since 1998. A separate press release and question-and-answer document with more information are available.

Post-authorisation procedures

Extensions of indications and other recommendations

The CHMP adopted two positive opinions, one by majority (**Reyataz**) and another by consensus (**RoActemra**) for applications for extension of indications of the existing therapeutic indication, adding new treatment options for the following previously approved medicines:

- **Reyataz** (atazanavir), from Bristol Myers Squibb Pharma EEIG, to extend the therapeutic indication to include the treatment of HIV-1 infected paediatric patients above 6 years of age.
- **RoActemra** (tocilizumab), from Roche Registration Ltd, to extend the therapeutic indication to include a statement that RoActmera has been shown to reduce the rate of progression of joint damage and to improve physical function, when given in combination with methotrexate.

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

No safety concern with Myozyme

The CHMP was informed by Genzyme Europe B.V. of a production problem at one of its manufacturing sites, the Flanders facility in Geel, Belgium, for **Myozyme** (alglucosidase alfa). During routine maintenance Genzyme discovered a faulty pump seal that could have potentially contaminated Myozyme batches with hydraulic oil. After reviewing all available data, including results of the analysis of samples of the concerned batches using enhanced analytical methods that did not reveal any contamination, the Committee concluded that there was no concern about the safety of Myozyme. The production problem has now been corrected and production is resuming. While currently no shortage of Myozyme is expected, the CHMP will be monitoring the availability of Myozyme on the market. Myozyme is used to treat patients with Pompe disease, a rare, inherited enzyme-deficiency disorder.

New temporary treatment recommendations for Fabrazyme

The CHMP was informed that the supply shortages for Genzyme's medicinal products, Cerezyme and Fabrazyme, are continuing for longer than expected and that Genzyme has not yet resumed full production. The supply shortages are likely to continue at least until the end of September 2010.

For Fabrazyme, the CHMP decided to revise the recommendations made on 25 September 2009, since, based on information supplied by the manufacturer, at least 12% of patients on the reduced Fabrazyme dose regimen have already experienced a worsening of their disease. For Cerezyme the interim recommendations made by the Committee on 22 October 2009 remain valid.

More information about the continued shortage of these products and the new treatment recommendations for Fabrazyme is available in a separate press release.

Additional safety information

F. Hoffmann-La Roche Ltd. (Roche Registration Ltd.) notified the European Medicines Agency on the 22 February 2010 of the cessation of the 10,000 IU and 20,000IU cartridge presentations of **NeoRecormon** 10,000 IU and 20,000 IU lyophilisate and solvent for solution for injection in cartridges (EU/1/97/031/021-022 and EU/1/97/031/023-024) and **Reco-Pen**. Following earlier communication on this matter from the British Association of Paediatric Nephrology and the Kidney Alliance, the Agency issued a letter on the 26 February to the Marketing Authorisation Holder (MAH), expressing concerns regarding the withdrawal of these presentations, as they had been found to be the most appropriate treatment option for a small group of children with renal insufficiency. In this letter, the

CHMP requested that the MAH consider the re-introduction of the aforementioned presentations. The CHMP regrets that Roche has decided to cease the placement of Reco-Pen and cartridges on the EU market, after having investigated the feasibility of reinstating their manufacture. Instead, Roche is offering to supply a finer 30.5G needle with the 2000 IU pre-filled syringes for better tolerability in children and a reference guide to assist patients with the switch from pen to pre-filled syringes.

Sanofi-Aventis Deutschland GmBH, MAH for **Lantus/Optisulin** (insulin glargine) submitted to the Agency final study protocols of epidemiological studies regarding the conduct of clinical trials investigating the possible association between insulin glargine and cancer. These study protocols have now been adopted by the CHMP.

The CHMP adopted amendments to section 4.2, 4.3, 4.4 and 4.8 of the Summary of Product Characteristics (SPC) of **Thelin** (sitaxentan) from Encysive (UK) Ltd. The MAH submitted further safety data regarding the hepatotoxic potential of sitaxentan, triggered by a fatal outcome reported in a young female patient with PAH following a hepatotoxic reaction associated with the use of sitaxentan. Based on this information, a new contra-indication was added for patients with elevated direct bilirubin of > 2 x ULN prior to initiation of treatment in section 4.3 of the SPC. Consequently, elevated direct bilirubin as a potential marker of hepatotoxicity was introduced in section 4.2, 4.4 and 4.8 of the SPC. The Package Leaflet has been updated accordingly.

The CHMP agreed on a Direct Healthcare Professional Communication for **Avastin** (bevacizumab) from Roche Registration Limited informing healthcare professionals that a risk for Avastin-treated patients experiencing hypersensitivity reactions/infusion reactions has been identified in up to 5 % of patients. In order to minimize the risk of adverse reactions, the following advice is given to healthcare professionals "*Close observation of the patient during and following the administration of bevacizumab is recommended as expected for any infusion of a therapeutic humanized monoclonal antibody. If a reaction occurs, the infusion should be discontinued and appropriate medical therapies should be administered. A systematic premedication is not warranted".* Furthermore the CHMP agreed, on the basis of these findings, to update section 4.4 and 4.8 of the SPC. The Package Leaflet has been updated accordingly.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted seven Lists of Questions on initial applications (including one under the mandatory scope, and six under the optional scope) as per Regulation (EC) No. 726/2004, together with three List of Questions on "line extension" applications (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

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 March 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 March 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

Harmonisation referrals concluded

The Committee recommended harmonisation of the prescribing information for three medicinal products. The reviews were initiated because of differences in the Summaries of Product Characteristics, labelling and package leaflets in the countries where the products are marketed. The products reviewed are:

- **Famvir** and associated names (famciclovir), from Novartis and associated companies. The medicine is authorised to treat herpes zoster and acute genital herpes simplex and to suppress recurrent genital herpes.
- **Valtrex** and associated names (valaciclovir) from GlaxoSmithKline and associated companies. The medicine is authorised to treat herpes zoster, herpes simplex and genital herpes and to prevent cytomegalovirus infections and disease.
- **Vascace** (cilazapril), from Roche and associated companies. The medicine is authorised to treat hypertension and heart failure.

Question-and-answer documents with more information about these referrals can be found here

Review of bufexamac concluded

Finalising a review of medicinal products for topical use containing **bufexamac**, a non-steroidal anti-inflammatory drug (NSAID), and the risk of contact allergic reactions, the Committee concluded that the benefits of these medicines do not outweigh their risks for patients in all indications and therefore recommended that the marketing authorisations be revoked.

More information about this review is available in a separate press release and a question-and-answer document.

Arbitration on Seroquel XR concluded

The Committee completed an arbitration procedure initiated at the request of the marketing authorisation holder following the refusal of an extension of the therapeutic indications of **Seroquel XR** prolonged release tablets (quetiapine), from AstraZeneca AB, in a mutual recognition procedure. The CHMP concluded that the benefit-risk profile of this medicine was positive as an add-on medication for major depressive episodes in major depressive disorder patients who have had sub-optimal response to treatment with other antidepressants, and recommended that an extension of the therapeutic indication should be granted.

More information about this review is available in a separate question-and-answer document.

Review of live attenuated vaccines started

The Committee has begun looking at the overall impact of the detection of genomic fragments of viral origin in batches of live attenuated vaccines. This follows the publication of an article in which a highly sensitive new polymerase chain reaction technique was used to detect these genomic fragments. The review was started upon request of the Executive Director of the European Medicines Agency under Article 5(3) of Council Regulation 726/2004. The CHMP will give an Opinion on whether there is any potential public health concern arising from the findings and whether new test methods should be considered for the development and routine testing of live attenuated vaccines. The Committee will also review the need to update existing guidance on this matter and the need for appropriate guidance for other vaccines and other biological products. This review will be conducted in close co-operation with the EDQM (European Directorate of Quality of Medicines & Healthcare) and international partners.

MUTUAL-RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 50th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 19-20 April 2010. For further details, please see the relevant press release on the CMD(h) 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 22-24 March 2010. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the April 2010 CHMP meeting are listed in **Annex 6**.

UPCOMING MEETINGS FOLLOWING THE APRIL 2010 CHMP PLENARY MEETING

- The 66th meeting of the CHMP will be held at the Agency on 17-20 May 2010.
- The next Name Review Group meeting will be held at the Agency on 25 May 2010.
- The 51st CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 17-18 May 2010.

ORGANISATIONAL MATTERS

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

- The endorsement of the Vaccine Working Party recommendation regarding the proposal to appoint Pr. Robert Cohen as a new VWP Core member.
- The adoption of revised Rapporteurs and CHMP assessment report templates.

- The release for three months public consultation of a guideline on Duplicate Detection and Management of Individual Cases and Individual Case Safety Report (ICSRs).

PROCEDURAL ANNOUNCEMENT

Recommended submission dates for Type IB variations requiring linguistic review of product information

In order to facilitate the linguistic review process of product information for certain variations which have been downgraded from Type II to Type IB, the Agency has published recommended submission dates for Type IB variations requiring linguistic review.

The Agency considers that despite the "downgrading" of certain variations to Type IB it is important from a public health protection point of view to continue to ensure high quality and consistent product information of centrally authorised medicinal products in all Member States.

Some examples of Type IB variations where a linguistic review will be performed are listed bellow:

- C.I.3.a) *Implementation of change(s) requested by the Agency following the assessment of an Urgent Safety Restriction, class labelling, a Periodic Safety Update report, Risk Management Plan, Follow up Measure/Specific Obligation, data submitted under Article 45/46 of Regulation (EC) No 1901/2006, or amendments to reflect a competent authority Core SPC*.
- *Other default safety and efficacy Type IB variations affecting the product information.*

The linguistic review process will be normally performed within the 30 day timeframe for assessment of Type IB variations with translations submitted at the start of the procedure.

The recommended submission dates for Type IB variations requiring linguistic review are available on the European Medicines Agency website, under submission deadlines/procedural timetables http://www.ema.europa.eu/pdfs/human/submission/TypeIBLinguisticReview.pdf

These submission dates are not applicable for type IB variations included in a worksharing submission or for Type IB variations submitted as part of a group including Type II variations and/or extensions

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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

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ANNEX 1 TO CHMP MONTHLY REPORT APRIL 2010

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Xigris (drotrecogin alfa (activated)), Eli Lilly Nederland B.V.	Positive Opinion	Marketing authorisation remains under exceptional circumstances

Opinion for renewals of conditional MA's		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
INTELENCE (etravirine), Janssen-Cilag International N.V.	Positive Opinion	The Committee recommended the renewal of the conditional Marketing Authorisation

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Myocet (doxorubicin hydrochloride), Cephalon Europe	Positive Opinion	Unlimited validity
Tarceva (erlotinib), Roche Registration Ltd.	Positive Opinion	Unlimited validity
NovoMix (insulin aspart), Novo Nordisk A/S	Positive Opinion	Unlimited validity

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ANNEX 2 TO CHMP MONTHLY REPORT APRIL 2010

Medicinal products granted a community marketing authorisation under the centralised procedure since the March 2010 CHMP monthly report

Invented name	**Arzerra**
INN	ofatumumab
Marketing Authorisation Holder	Glaxo Group Ltd
Proposed ATC code	L01XC10
Indication	Treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab
CHMP Opinion date	21/01/2010
Marketing Authorisation Date	19/04/2010

Invented name	**Tepadina**
INN	thiotepa
Marketing Authorisation Holder	ADIENNE S.r.l.
Proposed ATC code	L01AC01
Indication	In combination with other chemotherapy medicinal products: 1) with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients; 2) when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.
CHMP Opinion date	17/12/2009
Marketing Authorisation Date	15/03/2010

Invented name	**Menveo**
INN	Meningococcal Group A, C, W135 and Y conjugate vaccine
Marketing Authorisation Holder	Novartis Vaccines and Diagnostics S.r.l.
Proposed ATC code	Not yet assigned
Indication	Active immunization of adolescents (from 11 years of age) and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease.
CHMP Opinion date	17/12/2009
Marketing Authorisation Date	15/03/2010

Invented name	DuoCover
INN	clopidogrel and acetylsalicylic acid
Marketing Authorisation Holder	Bristol Myers Squibb Pharma EEIG
Proposed ATC code	B01AC30
Indication	Prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). DuoCover is a fixed-dose combination medicinal product for continuation of therapy in: • Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention • ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy
CHMP Opinion date	17/12/2009
Marketing Authorisation Date	15/03/2010

ANNEX 3 TO CHMP MONTHLY REPORT APRIL 2010

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

UPDATE SINCE THE MARCH 2010 CHMP MEETING

Active substance	Sponsor/applicant	EU designation number & Date of orphan designation	Designated orphan indication
Human C1 inhibitor	ViroPharma SPRL	EU/3/09/668	Treatment of angioedema caused by C1 inhibitor deficiency
Pirfenidone	Intermune Europe Limited	EU/3/04/241	Treatment of idiopathic pulmonary fibrosis

ANNEX 4 TO CHMP MONTHLY REPORT APRIL 2010

Name Review Group

	NRG meeting 26 Jan 2010		NRG meeting 23 Mar 2010		NRG meeting 26 May 2010		NRG meeting 27 Jul 2010		NRG meeting 6 Sep 2010		NRG meeting 23 Nov 2010		2010	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	*25*	35	48	46									**73**	**81**
Justification for retention of invented name *	*1*	*6*	2	4									**3**	**10**

*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 Sep 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									**185**	**77**
Criterion - Safety concerns														
Similarity with other Invented name	73	21	90	31									**163**	**52**
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	1									**2**	**1**
Misleading with respect to composition	0	0	0	1									**0**	**1**
Criterion - INN concerns														
Similarity with INN	5	3	6	8									**11**	**11**
Inclusion of INN stem	3	6	3	1									**6**	**7**
Criterion - Other public health concerns														
Unacceptable qualifiers	0	1	0	2									**0**	**3**
Conveys a promotional message	0	1	1	4									**1**	**5**
Appears offensive or has a bad connotation	0	0	1	1									**1**	**1**
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	0	0									**1**	**0**
Similarity between name of prodrug and related active substance	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 APRIL 2010

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

	1995 - 2009	2010	Overall total
Scientific Advice	1134	70	1204
Follow-up to Scientific Advice	232	31	263
Protocol Assistance	245	16	261
Follow-up to Protocol Assistance	109	8	117
	1720	**125**	**1845**

Outcome of the March 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				
Chemical	Treatment of moderate to severe asthma.	*x*						*x*	
Chemical	Treatment of opioid induced constipation.	*x*						*x*	
Biological	Treatment of acute lymphoblastic leukemia.	*x*						*x*	
Chemical	Reduction of albuminuria in type 2 diabetic patients with macroalbuminuria.	*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 patients with advanced prostate cancer, breast cancer, endometriosis, endometrial thinning, preoperative Treatment of uterine fibroids to reduce their size and associated bleeding, assisted reproduction and idiopathic or central gonadotropin-dependent precocious puberty in paediatric patients.	*x*						*x*	
Chemical	Treatment of metastatic colorectal cancer.	*x*				*x*	*x*	*x*	
Chemical	Treatment of acute lymphoblastic leukaemia.				*x*	*x*	*x*	*x*	
Chemical	Treatment of BRAF V600E mutation positive metastatic melanoma.	*x*				*x*	*x*	*x*	
Chemical	Treatment of non complicated malaria caused by Plasmodium falciparum.	*x*				*x*	*x*	*x*	
Chemical	Treatment of Chronic Lymphatic Leukemia.	*x*					*x*	*x*	
Biological	Prevention of bleeding in patients with Congenital FXIII A-subunit deficiency.				*x*			*x*	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological/ Other innovative	Reduction/prevention of AHR in pre-sensitized patients undergoing Living Related Donor or Diceased Donor kidney transplantation.	*x*						*x*	
Biological	Treatment and prophylaxis of bleeding in haemophilia B.				*x*			*x*	
Chemical	Treatment of naevoid basal cell carcinoma syndrome (Gorlin syndrome).		*x*			*x*	*x*	*x*	
Biological	Broader advice on general issues concerning transfer of production of several authorised drug products containing biotech active substance.			*x*		*x*			
Biological	Treatment of patients with primary immunodeficiency diseases associated with defects in humoral immunity including, but not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.	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	Treatment of adults with chronic HCV infection.			x				x	
Chemical	Treatment of vaginal atrophy in postmenopausal women.			x			x	x	
Biological	Treatment of Hypophosphatasia.	x					x	x	
Chemical	Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency.	x					x	x	
Biological	Treatment of spinal cord injury.		x			x	x	x	
Chemical	Treatment of Parkinson's disease.	x					x	x	
Chemical	Treatment of asthma and COPD as currently approved for the reference product, Symbicort Turbuhaler.			x				x	
Chemical	Treatment of asthma and COPD.	x				x			
Chemical	Treatment of asthma and COPD.			x				x	
Chemical	Positron emission tomography imaging of amyloid deposits in the brain.	x						x	
Chemical	In vitro radio-labelling of pharmaceutical substances (specific carriers), such as monoclonal antibodies, peptides amminoacids, hormones a or other chemical vectors for diagnostic Pet imaging.	x					x	x	

SA: scientific advice
PA: protocol assistance

The above-mentioned 17 Scientific Advice letters, 2 Protocol Assistance letters, 5 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 19 - 22 April 2010 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 42 new Requests for which the procedure started at the SAWP meeting held on 22 - 24 March 2010. The new requests are divided as follows: 18 Initial Scientific Advice, 10 Follow-up Scientific Advice, 11 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

ANNEX 6 TO CHMP MONTHLY REPORT APRIL 2010

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

BIOLOGICS WORKING PARTY

Reference number	Document	Status [2]
EMEA/410/01 Rev 4	Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products	Adopted and will now be transmitted to the European Commission
EMA/CPMP/BWP/125/04 EMA/CHMP/BWP/ 174129/2009	Revision of the Guideline on Epidemiological Data on Blood Transmissible Infections ▪ Appendices to the Revision of the Guideline on Epidemiological Data on Blood Transmissible Infections ▪ Overview of comments received	Adopted

PHARMACOGENETICS WORKING PARTY

Reference number	Document	Status [1]
EMA/CHMP/37646/2009	Guideline on the Use of Pharmacogenetic Methodologies in the Pharmacokinetic Evaluation of medicinal products	Adopted for 6-month public consultation

QUALITY WORKING PARTY

Reference number	Document	Status [1]
EMA/CHMP/CVMP/QWP/ 242647/2010	Question-and-Answer document on Harmonisation of Policies on Setting Specifications for High Risk Impurities	Adopted

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

EFFICACY WORKING PARTY

Reference number	Document	Status [1]
EMA/CHMP/EWP/82574/2009	Concept Paper on the Update of Guideline on the Clinical Development of Medicinal Products for the Treatment of Hepatitis C	Adopted for 3-month public consultation
CHMP/EWP/1343/01 Rev. 1	Guideline on the Clinical Evaluation of Antifungal Agents for the Treatment and Prophylaxis of Invasive Fungal Disease ▪ Overview of comments	Adopted
EMA/CHMP/EWP/17936/2010	Concept Paper on the Need for Revision of the Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Schizophrenia	Adopted for 3-month public consultation
EMA/CHMP/EWP/11721/2010	Concept Paper on the Need for a Guideline on the Use of Subgroup Analyses in Randomised Controlled Trials	Adopted for 3-month public consultation
CPMP/EWP/18/01 EMA/CHMP/EWP/68523/2010	Concept Paper on the Revision of the Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence	Adopted for 3-month public consultation
EMA/CHMP/EWP 125211/2010	Guideline on the Investigation of Drug Interactions	Adopted for 6-month public consultation
EMA/CHMP/EWP/82259/2010	Concept Paper on the Need to Develop an Appendix to the Guideline on Bioequivalence Regarding the Presentation of Biopharmaceutical and Bioanalytical Data in Application Dossiers	Adopted for 3-month public consultation