European Medicines Agency
Evaluation of Medicines for Human Use

London, 3rd July 2009
EMEA/CHMP/389326/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
JUNE 2009 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its June plenary meeting on 22-25 June 2009.

The CHMP welcomed Dr. Jean-François Baurain as the new alternate member from Belgium replacing Pr. Bruno Flamion.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP has adopted its first positive opinion by consensus for an advanced therapy medicinal product, recommending that **ChondroCelect**, from TiGenix NV, be granted a marketing authorisation. The CHMP adopted its opinion on the basis of a draft opinion prepared by the Agency's new Committee for Advanced Therapies (CAT).

ChondroCelect is a cell-based medicine consisting of chondrocytes (cartilage-forming cells) expanded *in vitro*. The chondrocytes are taken from a small biopsy of healthy cartilage from the patient, grown outside the body, and then re-implanted during surgery. ChondroCelect is used to repair single symptomatic cartilage defects of the femoral condyle (the end of the thighbone) in the knee.

More information is available in a separate press release.

The CHMP adopted three positive opinions by consensus and one by majority (Javlor) on initial marketing authorisation applications.

New medicinal products

- **Cimzia** (certolizumab pegol), from UCB Pharma SA, intended for the treatment of rheumatoid arthritis. The review began on 25 June 2008, with an active review time of 205 days.
- **Javlor** (vinflunine ditartrate), from Pierre Fabre Medicament, intended for the treatment of carcinoma of the urothelial tract. The review began on 27 February 2008, with an active review time of 196 days.
- **Onglyza** (saxagliptin), from Bristol-Myers Squibb/AstraZeneca EEIG, intended for the treatment of type 2 diabetes mellitus. The review began on 23 July 2008, with an active review time of 205 days.
- **Simponi** (golimumab), from Centocor BV, intended for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. The review began on 26 March 2008, with an active review time of 177 days.

Generic medicinal products

The Committee adopted 15 positive opinions by consensus for the following generic medicines, for which a reference medicine is already authorised in the European Union. The medicines concerned are:

- **Vizarsin** (sildenafil), from Krka, d.d., Novo mesto, a generic of Viagra, intended to treat erectile dysfunction.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

- **Topotecan Teva** (topotecan hydrochloride), from Teva Pharma B.V., a generic of Hycamtin, intended for the treatment of ovarian carcinoma, carcinoma of the cervix and small cell lung cancer.
- **Clopidogrel Acino Pharma** (clopidogrel, as besilate), **Clopidogrel Acino Pharma GmbH** (clopidogrel, as besilate), **Clopidogrel ratiopharm** (clopidogrel, as besilate), **Clopidogrel Sandoz** (clopidogrel, as besilate), all from Acino Pharma GmbH.
- **Clopidogrel Krka** (clopidogrel, as hydrochloride), from Krka, d.d., Novo mesto, **Clopidogrel DURA** (clopidogrel, as hydrochloride), from Mylan dura GmbH, **Clopidogrel HCS** (clopidogrel, as hydrochloride), from HCS bvba, **Clopidogrel Mylan** (clopidogrel, as hydrochloride), from Mylan S.A.S., **Clopidogrel Qualimed** (clopidogrel, as hydrochloride), from Qualimed, **Clopidogrel TAD** (clopidogrel, as hydrochloride), from Tad Pharma GmbH, **Zopya** (clopidogrel, as hydrochloride), from Norpharm Regulatory Services Ltd.
- **Zyllt (**clopidogrel, as hydrogen sulphate) and **Zylagren** (clopidogrel, as hydrogen sulphate), both from Krka, d.d., Novo mesto.

All of the clopidogrel-containing medicines mentioned are generics of Plavix and are intended for the prevention of atherothrombotic events.

Summaries of opinion for these medicinal products are available here. Further information will be included in the European Public Assessment Reports (EPARs) once the European Commission has granted final approval.

Re-examination procedures (new applications) under Article 9(2) of Regulation (EC) No. 726/2004

The CHMP adopted a final positive opinion by majority recommending the granting of a conditional marketing authorisation for **Cayston** (aztreonam lysine), from Gilead Sciences International Ltd, following a re-examination of its previous negative opinion, adopted in March 2009. Cayston is intended for the suppressive therapy of chronic pulmonary infection caused by *Pseudomonas aeruginosa* bacteria in adults with cystic fibrosis.

More information on the re-examination procedure is available in a separate question-and-answer document.

Post-authorisation procedures

Extensions of indication and other recommendations

The Committee gave one positive opinion by consensus (Xolair) and four by majority for applications for the extension of indication, adding a new treatment option, for the following medicines:

- **Avastin** (bevacizumab), from Roche Registration Ltd., to extend the indication to add combination therapy with docetaxel chemotherapy to the first-line treatment of metastatic breast cancer. Avastin is already authorised in this indication in combination with paclixatel. It is also authorised for first-line combination therapy of patients with certain types of cancer of the colon or rectum, the kidney and non-small cell lung cancer.
- **Januvia** (sitagliptin), **Tesavel** (sitagliptin) and **Xelevia** (sitagliptin), all from Merck Sharp & Dohme, to extend the indication to allow the use of sitagliptin as monotherapy in patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. Januvia, Tesavel and Xelevia are currently only authorised as combination therapy.
- **Xolair** (omalizumab), from Novartis Europharm Ltd., to extend the existing indication to paediatric patients from 6 to less than 12 years of age. Xolair currently is used as add-on therapy to improve the control of severe persistent allergic asthma in adult and adolescent patients 12 years of age and over.

Summaries of opinion for these extensions of indication are available here. Further information will be included in the EPARs once the European Commission has granted final approval.

Withdrawals

The EMEA has been formally notified by Menarini International Operations Luxembourg S.A. of its decision to withdraw its application for a centralised marketing authorisation for **Factive** (gemifloxacin mesilate) 320 mg film-coated tablets. Factive was expected to be used for the treatment of bacterial infections causing mild to moderate community-acquired pneumonia and acute exacerbation of chronic bronchitis. A separate press release document and a question-and-answer document with more information are available.

The question-and-answer document on the withdrawal of application for **Biferonex** (interferon-beta-1a), from BioPartners GmbH which was originally announced in the May CHMP monthly report, is now available on the EMEA website.

Special warnings and precautions for use

The CHMP adopted several amendments to sections 4.4 and 4.8 of the Summary of Product Characteristics (SPC) of **Revlimid** (lenalidomide) from Celgene Europe Limited, to add warnings on allergic reactions (including hypersensitivity reactions and cross-allergy with thalidomide) and on severe skin reactions following the assessment of the 3rd Periodic Safety Update Report (PSUR). In addition, the existing warning concerning the use of erythropoietic agents was updated with the currently approved threshold of the haemoglobin target level (i.e. 12 g/dl). Hypersensitivity reactions and tumour lysis syndrome were also added as rare adverse reactions in section 4.8 of the SPC. The Package Leaflet has been updated accordingly.

The CHMP adopted amendments to sections 4.4 and 4.8 of the SPC of **Tasigna** (nilotinib) from Novartis Europharm Limited, further to cases of sudden death. Following a cumulative review, it was identified that uncommon cases of sudden death have been reported in patients receiving Tasigna with a past medical history of cardiac disease or significant cardiac risk factors. Comorbidities in addition to the underlying malignancy were also frequently present, as were concomitant medications. Ventricular repolarisation abnormalities may have been contributory factors. The Package Leaflet has been updated accordingly.

Lifting of conditions for suspension for Optison

The Committee recommended lifting the conditions for the suspension of the marketing authorisation for **Optison** (perflutren) from GE Healthcare, which was suspended in June 2008 following serious findings during an inspection of the manufacturing facility in the United States of America. This had led the Norwegian Competent Authority, which was supervising the import of Optison into the EU and European Economic Area, to suspend parts of the manufacturing licence of the importer prohibiting further import of Optison.
On 30 April 2008, the marketing authorisation holder (MAH) informed the Agency that the programme of improvements to the manufacturing process had been successfully completed. On 25 June 2009, following a request from the MAH, the CHMP recommended the lifting of the suspension of the marketing authorisation for Optison. A separate public statement document with more information is available.

Other information – supply shortage

The CHMP has recommended that patients who are in greatest need of treatment are given priority access to **Cerezyme** (imiglucerase) and **Fabrazyme** (agalsidase beta) during the expected supply shortage of these two medicines over the next few months. A separate press release document with more information is available.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted six Lists of Questions on initial applications (including one under the mandatory scope and five under the optional scope).

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in May 2009 is provided in **Annex 3.**

REFERRAL PROCEDURES

Referral procedures concluded

The CHMP concluded a number of referral procedures under **Article 29** of Directive 2001/83/EC, as amended. This type of procedure is initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual-recognition procedure or the decentralised procedure. The medicinal products concerned are:

- **Fentrix and associated names** (fentanyl), 25, 50, 75 and 100 µg/h transdermal patches from Helm Pharmaceuticals GmbH, indicated for severe chronic pain. The procedure was initiated because of disagreements regarding the safety of the product. The CHMP concluded that the transdermal patch does not pose a risk to public health. The CHMP recommended by majority the granting of the Marketing Authorisation in the Concerned Member States for Fentrix and associated names.
- **Teicoplanin Hospira and associated names** (teicoplanin), 200 mg and 400 mg powder and solvent for injection or infusion, from Hospira UK Limited, indicated for the treatment of specific bacterial infections. The procedure was initiated because of concerns that bioequivalence to the reference medicinal product had not been adequately demonstrated. The CHMP concluded that sufficient evidence was not presented to demonstrate that Teicoplanin Hospira was a generic of the reference product. The CHMP recommended by consensus the refusal of the granting of the Marketing Authorisation in the Concerned Member States for Teicoplanin Hospira and associated names.
- **Avalox** and associated names (moxifloxacin hydrochloride), 400 mg solution for infusion, and **Octegra** and associated names (moxifloxacin hydrochloride), 400 mg solution for infusion, both from Bayer Vital GmbH, indicated for the second-line treatment of community-acquired pneumonia and complicated skin and skin structure infections. Both procedures were initiated because of potentially serious public health concerns related to the use of these medicines. The CHMP concluded that these medicines are approvable but that their benefit-risk balance is only positive when used as a second-line indication. The Committee recommended the granting of the marketing authorisations.

The CHMP concluded a number of referral procedures under Article 30 of Directive 2001/83/EC, as amended. This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level. The CHMP recommended the amendment of the SPCs, labelling and package leaflets for the following medicinal products:

- **Augmentin and associated names** (amoxicillin and clavulanic acid), from GSK group of companies and associated companies, used as an anti-infective. The CHMP adopted harmonised Product Information by consensus.

- **Topamax and associated names** (topiramate), from Johnson & Johnson group of companies and associated companies, used as an anticonvulsant. The CHMP adopted harmonised Product Information by consensus.

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

The CHMP concluded a referral procedure under **Article 31** of Regulation (EC) 83/2001, as amended, for **dextropropoxyphene-containing medicines**, concluding that the risks of these medicines, particularly the risk of potentially fatal overdose, are greater than their benefits. The CHMP therefore recommended that the marketing authorisations for these medicines be withdrawn across the European Union. The withdrawal will be gradual to allow time for the safe transfer of patients to appropriate alternative therapies, in line with national recommendations.
Dextropropoxyphene-containing medicines are painkillers used to treat acute and chronic pain. They have been available as prescription-only medicines for about 40 years, containing either dextropropoxyphene on its own or in combination, primarily with paracetamol, as tablets, capsules, suppositories and solutions for injection.

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

Referral procedures started

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended for **Tazocin and associated names** (piperacillin/tazobactam), from Wyeth group of companies and associated companies, used as an anti-infective.

Re-examination procedure

The EMEA has been formally requested by International Drug Licensing to re-examine the negative opinion adopted during the CHMP meeting on 20–23 April 2009 for **Ciclosporine IDL and associated names** (ciclosporin), 25, 50 and 100 mg capsules. The CHMP had concluded during a referral procedure under Article 29 of Directive 2001/83/EC, as amended, that the data and justification presented were not adequate to confirm the bioequivalence of this medicine with the reference medicine. The CHMP had recommended by majority the refusal of the granting of the Marketing Authorisation in the Concerned Member States and the suspension of the Marketing Authorisation for Ciclosporin IDL in the Member States.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 41st CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 22-23 June 2009. 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 2-4 June 2009. For further details, please see **Annex 4**.

Documents prepared by the CHMP Working Parties adopted during the June 2009 CHMP meeting are listed in **Annex 5**.

UPCOMING MEETINGS FOLLOWING THE JUNE 2009 CHMP PLENARY MEETING

- The 57th meeting of the CHMP will be held at the Agency on 20-23 July 2009.
- The next Name Review Group meeting will be held at the Agency on 28 July 2009.
- The 42nd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 20-21 July 2009.

ORGANISATIONAL MATTERS

The main topics addressed during the June 2009 CHMP meeting related to:

- Discussion on revision of the CHMP Assessment Report template relating to the risk/benefit section. It was proposed that the revised template will be rolled out for use from October 2009 for new applications only.
- Preliminary discussion regarding the profile of the fifth CHMP co-opted member following the announcement that Dr. Persson will be leaving the Committee in the course of the autumn.
- Discussion with regards to the EMEA policy on transparency that was released for a 3-month public consultation on 19th June 2009. Members were asked to provide comments on this policy alongside the general public.
- The re-election of Dr. Barbara Bannister as Chair of the SAG Anti-infectives and Dr. Jaap T. van Dissel as Vice-Chair.
- A general update regarding the International Conference on Harmonisation (ICH) meeting held in Yokohama in early June 2009.
- The co-adoption by the CHMP together with the PDCO of the Guideline on the Investigation of Medicinal Products in the Term and Preterm Neonate (EMEA/536810/2008) which will shortly be published on the Agency's website.
- A follow-on discussion on the latest developments regarding EMEA activities concerning the novel influenza virus (H1N1).

Noël Wathion
Head of Unit
Post-Authorisation Evaluation of Medicines for Human Use, Tel. (+44-20) 74 18 85 92

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

ANNEX 1 TO CHMP MONTHLY REPORT JUNE 2009

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2009								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	8	2	0	31	2	1	3	47	845
Positive opinions	8	9	0	27	5	3	3	55	548
Negative opinions[1]	0	0	0	0	1	0	1	2	23
Withdrawals prior to opinion	2	0	0	1	2	2	1	8	147
Marketing authorisation granted by the Commission	10	10	0	3	8	1	4	36	521

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2009	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	6
PMF (Click here for a list of PMF certifications)	1	14
VAMF	0	0

[1] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[2] Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/104/EC

OUTCOME OF THE JUNE 2009 CHMP MEETING IN RELATION TO ACCELERATED ASSESSMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Chemical	N/A	N/A	N/A
Biological	N/A	N/A	N/A

ANNEX 2 TO CHMP MONTHLY REPORT JUNE 2009

POST-AUTHORISATION: TYPE I AND II VARIATIONS, ANNEX II, RENEWALS AND ANNUAL RE-ASSESSMENT APPLICATIONS

Activity	2009	Overall total 1995 onwards
Type I Variations (positive notifications)	568	6937
Type II Variations (positive opinions)	564	5107
Type II Variations (negative opinions)	1	17
Annex II Applications (positive opinions)	40	223
Annual Re-assessments (positive opinions)	11	-
Opinions for renewals of conditional MA's (positive opinions)	2	8
5-year Renewals (positive opinions)	39	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
5 Extension of indication	5 Positive opinions
72 SPC changes	72 Positive opinions
41 Quality changes	41 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Onsenal (celecoxib) Pfizer Limited	Positive opinion	Marketing Authorisation remains under exceptional circumstance
Orfadin (nitisinone) Swedish Orphan International AB	Positive opinion	No remaining grounds for the Marketing Authorisations to remains under exceptional circumstances
Trisenox (arsenic trioxide) Cephalon UK Ltd	Positive opinion	Marketing Authorisation remains under exceptional circumstance
Elaprase (idursulfase) Shire Human Genetic Therapies	Positive opinion	Marketing Authorisation remains under exceptional circumstance

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	N/A	N/A

Opinions for 5-Year Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
AZILECT (rasagiline) Teva Pharma GmbH	Positive Opinion adopted	Unlimited validity
Alimta (pemetrexed) Eli Lilly Nederland B.V.,	Positive Opinion adopted	Unlimited validity
Emselex (darifenacin hydrobromide) Novartis Europharm Ltd.,	Positive Opinion adopted	Unlimited validity
Ferriprox (deferiprone) Apotex Europe BV,	Positive Opinion adopted	Unlimited validity
Mimpara (cinacalcet) Amgen Europe B.V.,	Positive Opinion adopted	Unlimited validity
Tasmar (tolcapone) Meda AB	Positive Opinion adopted	Recommending additional renewal

ANNEX 3 TO CHMP MONTHLY REPORT JUNE 2009

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE MAY 2009 CHMP MONTHLY REPORT

Invented Name	Renvela
INN	sevelamer carbonate
Marketing Authorisation Holder	Genzyme Europe B.V
Proposed ATC code	V03A E02
Indication	Renvela is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Renvela is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. Renvela should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.
CHMP Opinion date	19.03.2009
Marketing Authorisation Date	10.06.2009

Invented Name	Pantozol Control
INN	pantoprazole
Marketing Authorisation Holder	Nycomed GmbH
Proposed ATC code	A02BC02
Indication	Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
CHMP Opinion date	24.04.2009
Marketing Authorisation Date	12.06.2009

Invented Name	Controloc Control
INN	pantoprazole
Marketing Authorisation Holder	Nycomed GmbH
Proposed ATC code	A02BC02
Indication	Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
CHMP Opinion date	24.04.2009
Marketing Authorisation Date	12.06.2009

Invented Name	Somac Control
INN	pantoprazole
Marketing Authorisation Holder	Nycomed GmbH
Proposed ATC code	A02BC02
Indication	Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
CHMP Opinion date	24.04.2009
Marketing Authorisation Date	12.06.2009

Invented Name	Pantecta Control
INN	pantoprazole
Marketing Authorisation Holder	Nycomed GmbH
Proposed ATC code	A02BC02
Indication	Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
CHMP Opinion date	24.04.2009
Marketing Authorisation Date	12.06.2009

Invented Name	Pantoloc Control
INN	pantoprazole
Marketing Authorisation Holder	Nycomed GmbH
Proposed ATC code	A02BC02
Indication	Short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
CHMP Opinion date	24.04.2009
Marketing Authorisation Date	12.06.2009

ANNEX 4 TO CHMP MONTHLY REPORT JUNE 2009

PRE-AUTHORISATION: SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE EMEA CENTRALISED PROCEDURES

	1995 - 2008	2009	Overall Total
Scientific Advice	887	**125**	**1012**
Follow-up to Scientific Advice	171	**22**	**193**
Protocol Assistance	198	**19**	**217**
Follow-up to Protocol Assistance	90	**10**	**100**
	1346	**176**	**1522**

OUTCOME OF THE JUNE 2009 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 type 2 diabetes mellitus	X						X	
Chemical	Treatment of type 2 diabetes mellitus			X				X	
Chemical	Treatment of metabolic disorders and Type II diabetes complications	X					X		
Chemical	Treatment of Gaucher disease		X				X		
Biological	Preservation of residual beta cell function in patients with autoimmune type 1 diabetes mellitus			X			X	X	
Chemical	Treatment of advanced renal cell carcinoma	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 Acute Myleogenous Leukemia		X					X	
Biological	Treatment of neutropenia	X				X	X	X	
Biological	Treatment of early-stage breast cancer	X						X	
Chemical	Treatment of Neuroblastoma, Wilms Tumors, Rhabdo-myosarkoma, Ewing's Sarcoma	X						X	
Biological	Treatment of rheumatoid arthritis and psoriasis	X					X		
Biological	Treatment of melanoma	X				X		X	
Chemical	Treatment of mantle cell lymphoma	X						X	
Biological	Treatment of neutropenia	X				X	X	X	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis	X				X	X	X	
Biological	Treatment of rheumatoid arthritis	X						X	
Chemical	Treatment of Prostate Cancer	X				X			
Biological	Treatment and prophylaxis of bleeding in haemophilia B	X				X		X	
Biological	Treatment and prophylaxis of bleeding in patients with haemophilia A	X				X	X	X	
Chemical	Treatment of Pulmonary Arterial Hypertension	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 chronic heart failure	X					X	X	
Chemical	Prevention of post-coronary artery bypass graft atrial fibrillation	X						X	
Chemical	Prevention of venous thromboembolic events	X						X	
Chemical	Prevention of cardiovascular events	X						X	
Chemical	Treatment of Hepatitis C Virus infection	X				X	X	X	
Chemical	Treatment of severe sepsis	X				X			
Biological	Treatment of cystic fibrosis				X			X	
Chemical	Treatment of Mycoses, visceral leishmaniasis, empirical treatment of febrile neutropenia	X				X	X	X	
Biological	Prophylaxis of influenza	X					X	X	
Chemical	Treatment of endometriosis	X					X	X	
Chemical	Treatment of dysmenorrhoea	X				X	X	X	
Chemical	Treatment of Duchenne Muscular Dystrophy				X		X	X	
Biological	Treatment of chronic low back pain	X						X	
Biological	Remyelination of quadriplegia originated by chronic lesions of the spinal cord	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 attention-deficit hyperactivity disorder	X					X	X	
Chemical	Treatment of attention-deficit hyperactivity disorder	X					X	X	
Chemical	Treatment of Spinal Muscular Atrophy		X			X	X	X	
Chemical	Treatment of refractory partial onset seizures			X				X	
Chemical	Treatment of Alzheimer's disease	X						X	
Chemical	Treatment of idiopathic Parkinson's Disease	X					X	X	
Biological	Treatment of Chronic Obstructive Pulmonary Disease	X				X	X	X	
Chemical	Prevention of corneal graft rejection				X			X	
Chemical	Prevention of corneal graft rejection		X				X		
Biological	Treatment of non-infectious uveitis	X				X	X	X	
Advanced Therapy	Treatment of corneal lesion due to ocular burn		X			X	X	X	
Chemical	Treatment of intraocular pressure in open angle glaucoma or ocular hypertension	X					X	X	
Chemical	Broader advice on interpretation of fixed dose combinations	X						X	
Advanced Therapy	Treatment of anal fistula				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 methaemo-globinaemia	X				X	X	X	
Biological	Treatment of anovulation	X						X	
Biological	Broader advice on quality issues for parenteral drug products	X				X			

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 39 Scientific Advice letters, 5 Protocol Assistance letters, 3 Follow-up Scientific Advice and 4 Follow-up Protocol Assistance letters were adopted at the 22-25 June 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 34 new Requests for which the procedure started at the SAWP meeting held on 2-5 June 2009. The new requests are divided as follows: 23 Initial Scientific Advice, 7 Follow-up Scientific Advice, 3 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

ANNEX 5 TO CHMP MONTHLY REPORT JUNE 2009

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE JUNE 2009 CHMP MEETING

SICENTIFIC ADVICE WORKING PARTY (SAWP)

Reference number	Document	Status[3]
EMEA/CHMP/SAWP/ 69686/04/Rev 7	Amendment of the SAWP mandate	Adopted

BIOLOGIC WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CHMP/BWP/ 134153/2009	Concept Paper on the Need to revise the Guideline on the Use of Transgenic Animals in the Manufacture of Biological Medicinal Products for Human Use (3AB7A of July 1995)	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/CVMP/ QWP/380883/2009	Question and answer document on the Determination of Limits for Impurities.	Adopted

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/618604/2008	Questions & Answers: Positions on specific questions addressed to the EWP therapeutic subgroup on Pharmacokinetics Document updated following questions on generic application for Clopidogrel raised by CHMP to the PK and CVS EWP subgroups.	Adopted

PHARMACOVIGILANCE WORKING PARTY (PhVWP)

Reference number	Document	Status[3]
EMEA/395110/2009	Revised CHMP Recommendations for the Pharmacovigilance Plan as part of the Risk Management Plan to be submitted with the Marketing Authorisation Application for a Pandemic Influenza Vaccine in light of H1N1 virus pandemic.	Adopted