European Medicines Agency
Evaluation of Medicines for Human Use

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

The Committee for Medicinal Products for Human Use (CHMP) held its March plenary meeting from 16-19 March 2009.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

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

New medicinal products

- **Ellaone** (ulipristal acetate), from Laboratoire HRA Pharma, indicated for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. EMEA review began on 25 June 2008, with an active review time of 203 days.
- **Modigraf** (tacrolimus), from Astellas Pharma Europe B.V., indicated for the prophylaxis and treatment of transplant rejection in adult and paediatric kidney, liver or heart allograft recipients. EMEA review began on 26 December 2007, with an active review time of 205 days.
- **Qutenza** (capsaicin), from NeurogesX UK Ltd, indicated for the treatment of peripheral neuropathic pain in non-diabetic adults, either alone or in combination with other medicinal products for pain. EMEA review began on 27 September 2007, with an active review time of 202 days.
- **Renvela (**sevelamer carbonate), from Genzyme Europe B.V., indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis, and for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. EMEA review began on 26 March 2008, with an active review time of 204 days

Generic medicinal products

- The Committee adopted a positive opinion for **Nimvastid (**rivastigmine), from Krka, d.d., Novo mesto, intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Nimvastid is a generic of Exelon, which has been authorised in the European Union (EU) since 12 May 1998. EMEA review began on 25 June 2008, with an active review time of 198 days.

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.

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

Negative opinions

The CHMP adopted two negative opinions by majority recommending the refusal of a marketing authorisation for:

- **Cayston** (aztreonam lysine), from Gilead Sciences International Ltd, intended for use in the management of adult cystic fibrosis patients with chronic airway infection caused by *Pseudomonas aeruginosa* bacteria, to improve their pulmonary function and respiratory symptoms. The medicine was designated as an orphan medicine in June 2004. EMEA review began on 26 March 2008, with an active review time of 204 days.
- **Emerflu** (H5N1 split antigen influenza vaccine Alum adjuvanted), from Sanofi Pasteur. The vaccine was intended for use during an influenza pandemic. EMEA review began on 23 May 2007, with an active review time of 204 days.

Separate question-and-answer documents with more detailed information about the negative opinions for Cayston and for Emerflu are available.

Withdrawals

- The EMEA has been formally notified by SP Europe of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Cylatron** (peginterferon alfa-2b), 200 micrograms /0.5 ml, 300 micrograms /0.5 ml and 600 micrograms/0.5 ml. Cylatron was expected to be used for the adjuvant treatment of patients with stage III melanoma as evidenced by microscopic, non-palpable nodal involvement. A separate press release and a question-and-answer document with more information are available.
- The EMEA has been formally notified by Bristol-Myers Squibb Pharma EEIG of its decision to withdraw the application for a centralised marketing authorisation for **Ixempra** (ixabepilone), 2 mg/ml powder and solvent for concentrate for solution for infusion. Ixempra was expected to be used to treat locally advanced or metastatic breast cancer after failure of previous cytotoxic chemotherapy treatments. It was to be used in combination with capecitabine. A separate press release document with more information is available and a question-and-answer document will be available following the April 2009 CHMP plenary meeting.

Post-authorisation procedures

Extensions of indication and other recommendations

- The CHMP gave a positive opinion by consensus for an application for the extension of indication, adding a new treatment option for **Glivec** (imatinib), from Novartis Europharm Ltd, to extend the indications to include the adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117) positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. Glivec is currently indicated for the treatment of adult and paediatric patients with Philadelphia chromosome (bcr-abl) positive chronic myeloid leukaemia, adult patients with Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL), adult patients with myelodysplastic/myeloproliferative diseases (MD/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangements, adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant GIST, and adult patients with dermatofibrosarcoma protuberans (DFSP).

Withdrawals

- The European Medicines Agency (EMEA) has been formally notified by Orion Corporation of its decision to withdraw its application for an extension of indication for the centrally authorised medicine **Stalevo** (levodopa/carbidopa/entacapone) film-coated tablets. On 10 April 2008, Orion Corporation submitted an application to extend the marketing authorisation for Stalevo to use in the

initiation of levodopa therapy in early Parkinson's disease. At the time of withdrawal, the application was under review by the CHMP. A separate press release document with more information and a question-and-answer document with more information are available.

Other information

The CHMP adopted several amendments to update sections 4.4 and 4.8 of the SPC for **BeneFIX** (nonacog alfa) from Wyeth Europa Ltd, with information concerning the risk of thrombotic events in patients receiving BeneFIX via continuous infusion. Furthermore, the information that continuous infusion is not a recommended method of administration was reinforced in section 4.2. An update of section 4.4 of the SPC to add "bronchospasm and laryngospasm" as symptoms of hypersensitivity reactions was also made. Finally section 4.8 was amended with information on inadequate therapeutic response and inadequate factor IX recovery observed with the post-marketing use of BeneFIX. The Package Leaflet has been updated accordingly.

The CHMP has received information on **Myozyme** from Genzyme regarding the resolution of the supply situation which had led to the temporary treatment recommendations for the adult patients with Pompe disease (see EMEA press release from January 2009). As the supply of Myozyme has returned to normal, the prescribers were advised to revert to treatment regimens in accordance with the approved Product Information for all patient treatments.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted nine Lists of Questions on initial applications under the optional scope and eight List of Questions on "line extension" application (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

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 February 2009 is provided in **Annex 3.**

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 February 2009 CHMP plenary meeting are provided in **Annex 4**.

Name Review Group (NRG)

The outcome of the NRG meeting that took place on 17th March 2009 will be published in the April 2009 CHMP Monthly Report.

REFERRAL PROCEDURES

Referral procedures concluded

The CHMP concluded two 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 medicines concerned are:

- **Betavert N and associated names**, 8/16 mg, tablets (betahistine dihydrochloride), from Henning Arzneimittel GmbH&Co. KG, used as an anti-vertigo drug in Menière's disease. The procedure was initiated as a result of disagreements regarding the bioequivalence with the reference medicinal product. The CHMP concluded that the product can be considered as bioequivalent to the originator, and concluded that the benefit-risk balance is positive. The CHMP recommended the granting of a marketing authorisation.
- **Gluscan 500,** 500 MBq/ml, solution for injection (fluorodeoxyglucose(^{18}F)), from Advanced Accelerator Applications SA, used as a medical imaging product. The procedure was initiated because of disagreements regarding one of the proposed indications (infectious or inflammatory diseases). The CHMP concluded that the use of Gluscan in the proposed indication is well established and that the benefit-risk balance is positive. The CHMP recommended the granting of a marketing authorisation.

The CHMP concluded a referral procedure 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 SPC, labelling and package leaflet for the following medicine:

- **Diovan Comp and associated names** (valsartan/hydrochlorothiazide), from Novartis group of companies and associated companies, intended for the treatment of hypertension.

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

Referral procedures started

The CHMP started a referral procedure under Article 6(12) of Regulation (EC) 1084/2003, as amended for V**alproat-ratiopharm chrono 300/500 mg Retardtabletten** from Ratiopharm Nederland B.V., used as an antiepileptic drug. Procedures under article 6(12) are initiated in cases of disagreement between Member States in the context of the mutual recognition procedure in relation to applications to change the marketing authorisation. In this particular case the procedure was initiated because of disagreements between Member States regarding the addition of "acute treatment of manic episode and prevention of recurrence in patients with bipolar disorder" as a new indication.

Benefit-risk review for Regranex started

The CHMP started a review of overall benefits and risks of **Regranex** (becaplermin), from Janssen-Cilag International, in the light of concerns over the safety profile, especially with respect to the possible risk of cancer. Regranex is indicated, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers ≤ 5 cm^2. The review was initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 38th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-17 March 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 23-25 February 2009. For further details, please see **Annex 6**.

Documents prepared by the CHMP Working Parties adopted during the March 2009 CHMP meeting are listed in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE MARCH 2009 CHMP PLENARY MEETING

- The 54th meeting of the CHMP will be held at the EMEA on 20-23 April 2009.
- The next Name Review Group meeting will be held at the EMEA on 12 May 2009.
- The 39th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 20-21 April 2009.

ORGANISATIONAL MATTERS

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

- An update on the EMEA/CHMP/National Competent Authorities participation in the next SANCO Pandemic Simulation Exercise scheduled later in 2009.
- Discussion on the proposed list of activities to be undertaken within the context of the 7th Framework Programme. The top 3 priority topics were the following: study of long-term effects in children and in young adults of medicines used to treat attention-deficit-hyperactivity disorder (ADHD) (methylphenidate), study of long-term adverse effects of immunomodulators and study on long-term adverse skeletal effects of bisphosphonates. A number of other topics were also listed with lesser priority. The proposed list of activities will be transmitted to the European Commission for consideration.
- Preliminary discussion on the experience obtained following the recent suspension / withdrawal of marketing authorisations.
- Follow-up discussion on the procedural advice on evaluation of advanced-therapy medicinal products with adoption of the document for a pilot period of operation.
- An update on the multidisciplinary ad-hoc group on HIV prevention strategies following a meeting held on 10th December 2008.
- The report from the joint EMEA/ European Centre for Disease Prevention and Control gap analysis and presentation of the results of the pipeline search for anti-bacterials in clinical development. The recommendations from the think tank group were to make tailor-made requirements to encourage development of new antimicrobials but also to propose initiatives for incentives for developing old antimicrobials or niche products.
- The adoption of the SAWP peer review process for CHMP peer review groups (EMEA/83948/2009).

PROCEDURAL ANNOUNCEMENT

Adjusted fees for application to the EMEA to come into effect on 1st April 2009

Applicants are reminded that the European Commission is in the process of adopting a regulation adjusting the fees payable to the EMEA in line with inflation and amending Council Regulation (EC) No 297/95. It is expected that the adopted Commission Regulation will be published shortly.
Details of the revised fees will be published shortly thereafter, in the section Guidelines on fees payable to EMEA

Duplicates/multiple applications

Applicants are reminded that multiple/duplicate or informed consent applications from the same or different marketing authorisation holder for a specific medicinal product with an active substance(s) already authorised via the centralised procedure, have automatic access to the centralised procedure. Nevertheless in all cases, the eligibility of a medicinal product for evaluation via the centralised procedure needs to be requested and confirmed by the applicant by submitting an eligibility request to the EMEA. This has to be done prior to submission of any dossier. In addition agreement from the European Commission should be sought in the context of the Article 82 of Regulation (EC) 726/2004.

Further information can be found under the pre-submission procedural advice.

EMEA Recommendations on the Classification of Unforeseen Variations

The EMEA has developed, in cooperation with the CMD(h) and the CMD(v), a "Procedural Advice on recommendation on the classification of unforeseen variations, according to Article 5 of Commission Regulation (EC) No 1234/2008". This procedural advice will be published on the EMEA website in the near future – Regulatory and Procedural Guidance webpage – Post-Marketing Authorisation.

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 MARCH 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	4	2	0	16	2	1	3	28	798
Positive opinions	4	8	0	3	3	0	0	18	511
Negative opinions[1]	1	0	0	0	2	0	1	4	25
Withdrawals prior to opinion	0	0	0	0	1	1	1	3	142
Marketing authorisation granted by the Commission	6	2	0	1	6	1	3	19	504

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)	0	13
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 MARCH 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 MARCH 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)	221	6590
Type II Variations (positive opinions)	262	4805
Type II Variations (negative opinions)	0	16
Annex II Applications (positive opinions)	25	208
Annual Re-assessments (positive opinions)	4	-
Opinions for renewals of conditional MA's (positive opinions)	1	7
5-year Renewals (positive opinions)	19	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
1 Extension of indication	1 Positive opinion
41 SPC changes	41 Positive opinions
30 Quality changes	30 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Ventavis (iloprost) Bayer Schering Pharma AG	Positive Opinion adopted	The marketing authorisation remains under exceptional circumstances.
Zavesca (miglustat) Actelion Ltd	Positive Opinion adopted	The marketing authorisation remains under exceptional circumstances.

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**
Lyrica (pregabalin) Pfizer Limited	Positive Opinion adopted	Unlimited validity
Telzir (fosamprenavir) Glaxo Group Limited	Positive Opinion adopted	Unlimited validity
Ziagen (abacavir sulfate) Glaxo Group Limited	Positive Opinion adopted	Recommending additional renewal
TachoSil* (human fibrinogen / human thrombin) Nycomed Austria GmbH	Positive Opinion adopted	Unlimited validity

***** From CHMP February 2009

ANNEX 3 TO CHMP MONTHLY REPORT MARCH 2009

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

Invented Name	Mepact
INN	mifamurtide
Marketing Authorisation Holder	IDM Pharma, S.A
Proposed ATC code	L03AX15
Indication	MEPACT is indicated in children, adolescents and young adults for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection. It is used in combination with post-operative multi-agent chemotherapy. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis.
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	06.03.2009

Invented Name	Intanza
INN	Influenza Vaccine (split virion, inactivated)
Marketing Authorisation Holder	Sanofi Pasteur MSD, SNC
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in adults up to 59 years of age, especially in those who run an increased risk of associated complications.
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	24.02.2009

Invented Name	IDflu
INN	Influenza Vaccine (split virion, inactivated)
Marketing Authorisation Holder	Sanofi Pasteur SA
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in adults up to 59 years of age, especially in those who run an increased risk of associated complications.
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	24.02.2009

Invented Name	Fablyn
INN	lasofoxifene
Marketing Authorisation Holder	Pfizer Limited
Proposed ATC code	Not yet assigned
Indication	FABLYN is indicated for the treatment of osteoporosis in postmenopausal women at increased risk of fracture. A significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. When determining the choice of FABLYN or other therapies, including estrogens, for a postmenopausal woman, consideration should be given to menopausal symptoms, effects on uterine and breast tissues, and cardiovascular risks and benefits
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	24.02.2009

Invented Name	Celvapan
INN	Whole virion influenza vaccine, inactivated containing antigen of pandemic strain
Marketing Authorisation Holder	Baxter AG
Proposed ATC code	J07BB01
Indication	Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance. CELVAPAN has been evaluated in adults 18-59 years of age and in elderly 60 years of age and above.
CHMP Opinion date	18.12.2008
Marketing Authorisation Date	04.03.2009

Invented Name	Fertavid
INN	follitropin beta
Marketing Authorisation Holder	Schering-Plough Europe
Proposed ATC code	G03G A06
Indication	*In the female:* Fertavid is indicated for the treatment of female infertility in the following clinical situations: • Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomifene citrate. • Controlled ovarian hyperstimulation to induce the development of multiple follicles in medically assisted reproduction programs [e.g. *in vitro* fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)]. *In the male:* • Deficient spermatogenesis due to hypogonadotrophic hypogonadism.
CHMP Opinion date	22.01.2009
Marketing Authorisation Date	19.03.2009

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE FEBRUARY 2009 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Treprostinil sodium (inhalation use)	United Therapeurics Europe Ltd	EU/3/04/197	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
Ofatumumab	Glaxo Group Limited	EU/3/08/581	Treatment of chronic lymphocytic leukaemia

ANNEX 5 TO CHMP MONTHLY REPORT MARCH 2009

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

	1995 - 2008	2009	Overall Total
Scientific Advice	887	41	928
Follow-up to Scientific Advice	171	6	177
Protocol Assistance	198	5	203
Follow-up to Protocol Assistance	90	0	90
	1346	**73**	**1419**

OUTCOME OF THE MARCH 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				
Biological	Treatment of Crigler-Najjar syndrome		X				X		
Biological	Treatment diabetes mellitus.	X				X	X	X	
Chemical	Treatment of type 2 diabetes mellitus.	X					X	X	
Chemical	Treatment of type 2 diabetes mellitus.	X					X	X	
Chemical	Treatment of hormone refractory prostate cancer	X				X			
Chemical	Treatment of pancreatic cancer.	X				X			
Chemical	Treatment of breast cancer			X				X	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of relapsed/refractory indolent/follicular Non Hodgkin Lymphoma	X						X	
Chemical	Intended for the reduction of cardiovascular mortality			X				X	
Chemical	Treatment of lipoprotein lipase deficiency				X	X			
Chemical	Treatment of tuberculosis		X				X	X	X
Chemical	Treatment of hepatitis C	X					X	X	
Biological	treatment of idiopathic overactive bladder			X			X	X	
Biological	Treatment of Alzheimer's disease	X				X	X	X	
Broader Advice	inpatient reported outcomes in chronic obstructive pulmonary disease	X						X	
Chemical	Treatment of asthma and chronic obstructive pulmonary disease	X						X	
Innovative Product	Treatment of Pseudomonas aeruginosa infection	X				X	X	X	
Biological	Treatment of growth hormone deficiency	X					X	X	
Biological	Treatment of cartilage injuries	X					X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 13 Scientific Advice letters, 2 Protocol Assistance letters, 3 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letters were adopted at the 16-19 March 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 23 new Requests for which the procedure started at the SAWP meeting held on 23-25 Feb 2009. The new requests are divided as follows: 19 Initial Scientific Advice, 4 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

ANNEX 6 TO CHMP MONTHLY REPORT MARCH 2009

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

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/CHMP/BWP/269/95	Draft Revision 4 of the Guideline on Plasma-derived Medicinal Products (EMEA/CHMP/BWP/269/95	Adopted for 6-month public consultation
EMEA/CHMP/BWP/133895/2009	Ad-hoc Influenza Working party: EU Strain selection for the Influenza Vaccines for the season 2009/2010	Adopted

GENE THERAPY WORKING PARTY (GTWP)

Reference number	Document	Status[3]
EMEA/CHMP/GTWP/587488/2007	Reflection Paper on Quality, Non-clinical and Clinical Issues relating specifically to Recombinant Adeno-Associated Viral Vectors	Adopted for 6-month public consultation

BIOSIMILAR WORKING PARTY (BMWP)

Reference number	Document	Status[3]
EMEA/CHMP/BMWP/118264/2007	Guideline on Non-clinical and Clinical Development of Similar Biological Medicinal Products containing low-molecular-weight-heparins	Adopted
EMEA/CHMP/BMWP/114720/2009	Concept paper on Immunogenicity Assessment of Monoclonal Antibodies intended for in vivo clinical use	Adopted for 3-month public consultation

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/QWP/160238/2009	Questions-and-Answers document on the Need for in vitro Dissolution Studies with Alcohol for modified-release oral opioids products	Adopted
EMEA/CHMP/CVMP/QWP/160263/2009	Questions-and-Answers document on Endotoxin/Sterility testing during and at the end of shelf-life	Adopted subject to adoption by CVMP