European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
MAY 2008 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its May plenary meeting from 27-30 May 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted two positive opinions by consensus on initial marketing authorisation:

- **Bridion** (sugammadex), from N.V. Organon, for the reversal of neuromuscular block induced by rocuronium or vecuronium. EMEA review began on 20 July 2007 with an active review time of 203 days.

- **Doribax** (doripenem), from Janssen-Cilag International NV, for the treatment of adult patients with nosocomial pneumonia, complicated intra-abdominal infections and complicated urinary tract infections. EMEA review began on 20 July 2007 with an active review time of 202 days.

Summaries of opinion for these medicinal products are available on the EMEA website http://www.emea.europa.eu/htms/human/opinion/opinion.htm. Further information will be included in the European Public Assessment Report (EPAR) once the European Commission has granted final approval.

Negative opinion

The CHMP adopted a negative opinion by consensus recommending the refusal of a marketing authorisation for **Ramelteon** (ramelteon), from Takeda Global Research & Development Centre (Europe) LTD. Ramelteon was intended to be used for the treatment of primary insomnia in patients aged 18 years or older. EMEA review began on 21 March 2007 with an active review time of 210 days.

A separate question-and-answer document with more detailed information on the grounds for the negative opinion is available here.

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

Following the re-examination of the negative opinion adopted in February 2008, the CHMP confirmed its previous position and adopted a final negative opinion by consensus for **Lenalidomide Celgene Europe** (lenalidomide), from Celgene Europe. Lenalidomide Celgene Europe was to be used for the treatment of anaemia due to myelodysplastic syndromes. It was designated orphan medicine.

A separate question and answer document with more information about the re-examination procedure is available here.

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Withdrawals

The EMEA has been formally notified by Sanofi-Aventis of its decision to withdraw the application for a centralised marketing authorisation for the medicine **Aquilda** (satavaptan) 5 and 25 mg film-coated tablets. Aquilda was intended to be used for the treatment of euvolaemic and hypervolaemic dilutional hyponatraemia, a metabolic condition in which the body's blood sodium level falls below normal. A separate press release with more information and a question-and-answer document are available.

The EMEA has been formally notified by Bristol-Myers Squibb Pharma EEIG of its decision to withdraw its application for a centralised marketing authorisation for the medicine **DuoCover** (fixed-dose combination tablets of 75 mg clopidogrel/75 mg acetylsalicylic acid and 75 mg clopidogrel/100 mg acetylsalicylic acid). DuoCover was expected to be used by patients already taking clopidogrel and acetylsalicylic acid for the approved indication of prevention of atherothrombotic events in acute coronary syndrome. A separate press release with more information and a question-and-answer document are available.

The EMEA has been formally notified by Sanofi Pharma Bristol-Myers Squibb SNC of its decision to withdraw its application for a centralised marketing authorisation for the medicine **DuoPlavin** (fixed-dose combination tablets of 75 mg clopidogrel/75 mg acetylsalicylic acid and 75 mg clopidogrel/100 mg acetylsalicylic acid). DuoPlavin was expected to be used by patients already taking clopidogrel and acetylsalicylic acid for the approved indication of prevention of atherothrombotic events in acute coronary syndrome. A separate press release with more information and a question-and-answer document are available.

The EMEA has been formally notified by DOR BIOPHARMA UK Ltd of its decision to withdraw the application for a centralised marketing authorisation for the medicine **orBec** (beclomethasone dipropionate) 1 mg tablets and 1 mg gastro-resistant tablets. orBec was expected to be used for the treatment of gastrointestinal graft-versus-host disease. It was designated orphan medicine on 13 March 2002. A separate press release with more information and a question-and-answer document are available.

Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP adopted three positive opinions by consensus on applications for extension of indication, adding new treatment options for the following previously approved medicines:

- **Erbitux** (cetuximab), from Merck KGaA, to update the current indication for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in combination with chemotherapy and to add an indication for the use as a single agent in KRAS wild-type metastatic colorectal cancer patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. Erbitux is currently indicated in combination therapy for the treatment of patients with metastatic colorectal cancer expressing EGFR after failure of irinotecan, and in combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck.

- **Gardasil** (human papilloma virus vaccine), from Sanofi Pasteur MSD, and **Silgard** (human papilloma virus recombinant vaccine), from Merck Sharp & Dohme to extend the indication to include the prevention of high-grade vaginal dysplastic lesions. Gardasil and Silgard are currently indicated for the prevention of high-grade cervical dysplasia, cervical carcinoma, high-grade vulvar dysplastic lesions and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18.

Summaries of opinions for all mentioned products, including their full indication, can be found here

Changes to contraindications

Considering the use of Zometa in life-threatening diseases and taking into account the discussion paper on contraindications in pregnancy (CPMP/3833/03), the CHMP recommended the removal of the absolute contraindication during pregnancy for **Zometa** (zoledronic acid) from Novartis Europharm Ltd in section 4.3 of the SPC. However the statement in section 4.6 of the SPC mentioning that "Zometa should not be used during pregnancy" was maintained. Zometa is currently authorised for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone and treatment of tumour-induced hypercalcaemia.

Withdrawal

Following the withdrawal by the Marketing Authorisation Holder of the application for an extension of indication for the centrally authorised medicine **Tygacil** (tigecycline) which was expected to be used for the treatment of community-acquired pneumonia and announced in the April CHMP Monthly Report, a question-and-answer document is now available.

Updated safety information

The CHMP recommended updating the product information of **Revlimid** (lenalidomide) from Celgene Europe Ltd with results from a nonclinical study. These results show that lenalidomide is teratogenic in monkeys. Lenalidomide is therefore expected to be teratogenic in humans. Prior to these findings, Revlimid was already considered as a potential teratogen and a thorough Pregnancy Prevention Programme was already in place with the objective of providing guidance to healthcare professionals and patients on how to prevent foetal exposure. The CHMP and the MAH (Celgene Europe Limited) agreed on a Direct Healthcare Professional Communication concerning these new nonclinical teratogenicity findings. Patients' organisations have been informed of the outcome of the CHMP opinion.

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) and one List of Questions on "line extensions" applications (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 April 2008 is provided in **Annex 3.**

Applications for marketing authorisation for orphan medicinal products

There were no orphan medicinal products that have been subject of a centralised application for marketing authorisation since the April 2008 CHMP plenary meeting.

REFERRAL PROCEDURES

Referral procedure concluded

The CHMP concluded a re-examination procedure for a referral under Article 29(2) of the Community code on human medicinal products (Directive 2001/83/EC, as amended) for **Coxtral gel**, 3% gel, (nimesulide) from Zentiva A.S., indicated for the symptomatic relief of pain associated with sprains and

acute traumatic tendinitis. The procedure was initiated because of disagreement in relation to efficacy concerns. The CHMP confirmed the negative opinion adopted in February 2008 and recommended the refusal of the granting of marketing authorisations and the suspension of the granted marketing authorisations, where appropriate.

Arbitrations under Article 29 are 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 CHMP finalised a harmonisation referral under Article 30 of the Community code on human medicinal products (Directive 83/2001/EC as amended) for **Zyrtec/Reactine and associated names** (cetirizine), from UCB, used as antiallergic and antihistaminic agent. The CHMP recommended the harmonisation of the product information across the European Union (EU). The procedures were initiated by the European Commission.

Article 30 referrals are initiated with a view to harmonising the product information across the EU for medicinal products authorised at Member State level.

Referral procedures started

The CHMP started a referral procedure under Article 29(2) of Directive 2001/83/EC as amended for **Salbutamol Easyhaler "Orion" inhalation powder 100 mcg/ dose and 200 mcg/dose** (salbutamol) from Orion Corporation, intended for the treatment of asthma. The procedure was initiated because of disagreement in relation to therapeutic equivalence with the reference medicine.

The CHMP started a referral procedure under Article 36 for **Forair/Atimos modulite 12 µg** (formoterol) and associated medicinal products, from Chiesi Farmaceutici SPA, intended for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient. The procedure was initiated by the United Kingdom and the Netherlands because of concerns that therapeutic equivalence of these medicines with the reference medicine is not established for children aged 5 years of age and above. Article 36 procedures are initiated where a Member State considers that there are public health issues relating to a product that may require regulatory action.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended for **Topamax** (topiramate), from Janssen-Cilag, used as an anticonvulsant, at the request of the European Commission, with a view to harmonising the product information for this medicine across the EU.

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**.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 29th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 27-28 May 2008. 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 6 – 8th May 2008. For further details, please see **Annex 5**. Documents prepared by the CHMP Working Parties adopted during the April 2008 CHMP meeting are listed in **Annex 6**.

UPCOMING MEETINGS FOLLOWING THE MAY 2008 CHMP PLENARY MEETING

- The 45th meeting of the CHMP will be held at the EMEA on 23-26 June 2008.
- The next Name Review Group meeting will be held at the EMEA on 29th July 2008.
- The 30th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 23-24 June 2008.

ORGANISATIONAL MATTERS

The main topics addressed during the April 2008 CHMP meeting related to:

- The election of Dr. Pfleiderer as Chair of the Vaccine Working Party and Dr. Neels as Vice-Chair.
- Preliminary discussion with regard to the definition of Gene Therapy Medicinal Porduct.
- Follow-on discussion regarding the classification of haemostatic products/sealants.
- Preliminary discussion related to request for Compassionate Use at National level.
- A CMD(h) request to the Quality Working Party concerning the inclusion of appropriate recommendation for storage orientation in the product information for suspension formulations for inhalation using pressurised metered dose inhalers.
- A CMD(h) request to the Efficacy Working Party and Safety Working Party concerning dosing of Cilazapril in patients with severe renal failure including dosing and information in patients with haemodialysis.
- A CMD(h) request to ask the PK subgroup of the Efficacy Working Party regarding the qualification of C_{min} in steady-state studies as primary criterion for decision.
- Follow-on discussion regarding coordination of tasks identified in the CHMP Work Programme. Projects with high and moderate priorities were defined as well as the next steps forwards.
- The adoption of the draft Mandate, objectives and composition of a CHMP multidisciplinary ad-Hoc group regarding HIV prevention strategies (prophylactic vaccines and microbicides).
- Follow-on discussion regarding the pilot phase for Benefit-Risk assessment in the context of the evaluation of Marketing Authorisation Application and the use of an appropriate template for Rapporteurs and assessors while preparing the various assessment reports.
- A presentation from Pr. Phillips (visiting Professor of Decision Science at the London School of Economics) regarding Benefit-Risk Methodology project.
- Preliminary discussion regarding the proposal for standardisation of timelines for submission of written responses at Day 180.
- Follow-on discussion regarding the guideline on the use of statistical signal detection methods in the Eudravigilance data analysis system and the overview of comments received during the public consultation phase. These documents will be adopted in June 2008.
- Follow-on discussion regarding the management of pharmacovigilance signals across the European Union.
- Appointment of the two outstanding CHMP/ Committee for Advanced Therapies (CAT) Rapporteurs. Dr. Thirstrup (Denmark) and Dr. Silva Lima (Portugal) were appointed and now join the full team of five CHMP/CAT Rapporteurs. Dr Sol (Spain), Dr Schneider (Germany) and Dr. Maciulaitis (Lithunia) who were previously appointed.
- The adoption of the agenda for the Informal CHMP meeting to be held on the 9-11th June 2008 in Slovenia.

PROCEDURAL ANNOUNCEMENT

There is no procedural announcement this month.

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

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2008								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	14	3	0	1	5	3	4	30	698
Positive opinions	10	2	0	0	7	3	3	25	454
Negative opinions[1]	1	0	0	0	0	0	2	3	21
Withdrawals prior to opinion	4	0	0	0	3	0	2	9	125
Marketing authorisation granted by the Commission	6	3	0	2	3	0	2	16	433

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2008	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	5
PMF (Click here for a list of PMF certifications)	1	12
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 MAY 2008 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

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

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

Activity	2008	Overall total 1995 onwards
Type I Variations (positive notifications)	503	5705
Type II Variations (positive opinions)	197	4041
Type II Variations (negative opinions)	1	11
Annex II Applications (positive opinions)	19	188
Annual Re-assessment (positive opinions)	14	-
Opinion for renewals of conditional MA's (positive opinions)	0	2
5 Year Renewals (positive opinions)	21	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
3 Extensions of indication	3 Positive opinion
38 SPC changes	38 Positive opinions
53 Quality changes	53 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Revatio (sildenafil citrate) Pfizer Limited	Positive Opinion adopted	exceptional circumstances are being lifted
Prialt (ziconotide) Elan Pharma International Ltd	Positive Opinion adopted	remaining under exceptional circumstances
Trisenox (arsenic trioxide) Cephalon UK Ltd	Positive Opinion adopted	remaining 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**
Avandamet (rosiglitazone/metformin) SmithKline Beecham plc	Positive Opinion adopted	requiring 2nd Renewal
Evista (raloxifene) Eli Lilly Nederlands B.V	Positive Opinion adopted	unlimited validity
Optruma (raloxifene) Eli Lilly Nederlands B.V	Positive Opinion adopted	unlimited validity
Novonorm (repaglinide) Novo Nordisk	Positive Opinion adopted	unlimited validity
Prandin (repaglinide) Novo Nordisk	Positive Opinion adopted	unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT MAY 2008

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE APRIL 2008 CHMP MONTHLY REPORT

Invented Name	Prepandrix
INN	Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14
Marketing Authorisation Holder	GlaxoSmithKline Biologicals S.A
Proposed ATC code	J07BB02
Indication	Active immunisation against H5N1 subtype of Influenza A virus. This indication is based on immunogenicity data from healthy subjects aged 18-60 years following administration of two doses of vaccine prepared from A/VietNam/1194/2004 NIBRG-14 (H5N1).
CHMP Opinion date	21.02.2008
Marketing Authorisation Date	14.05.2008

Invented Name	Pandemrix
INN	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14
Marketing Authorisation Holder	GlaxoSmithKline Biologicals S.A
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.
CHMP Opinion date	21.02.2008
Marketing Authorisation Date	20.05.2008

Invented Name	Extavia
INN	interferon beta-1b
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	L03AB08
Indication	Extavia is indicated for the treatment of: • Patients with a single demyelinating event with an active inflammatory process, if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis (see section 5.1). • Patients with relapsing-remitting multiple sclerosis and two or more relapses within the last two years. • Patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses.
CHMP Opinion date	19.03.2008
Marketing Authorisation Date	20.05.2008

ANNEX 4 TO CHMP MONTHLY REPORT MAY 2008

INVENTED NAME REVIEW GROUP (NRG)

	May 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names[1]	35	27	104	94
Justification for retention of invented name *[2]	0	2	6	4

*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.

[1] None of the proposed invented name requests have been postponed to the July 2008 NRG meeting

[2] One of the justifications for retention of a proposed invented name has been postponed to the July NRG meeting

	May 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	53	24	80	73
Criterion - Safety concerns				
Similarity with other Invented name	51	21	111	72
Conveys misleading therapeutic/pharmaceutical connotations		1	1	1
Misleading with respect to composition	0	0	0	1
Criterion - INN concerns				
Similarity with INN	1	1	4	2
Inclusion of INN stem	1		4	1
Criterion - Other public health concerns				
Unacceptable qualifiers	0	0	10	8
Conveys a promotional message	0	1	2	11
Appears offensive or has a bad connotation	0	0	0	0
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0	1	0
Similarity between name of prodrug and related active substance	0	0	0	0

See *Guideline on the Acceptability of Invented names for human medicinal products processed through the Centralised procedure (CPMP/328/98)* for detailed explanations of criteria used.

ANNEX 5 TO CHMP MONTHLY REPORT MAY 2008

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

	1995 - 2007	2008	Overall Total
Scientific Advice	887	85	972
Follow-up to Scientific Advice	171	19	190
Protocol Assistance	198	20	218
Follow-up to Protocol Assistance	90	7	97
	1346	**131**	**1478**

OUTCOME OF THE MAY 2008 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Final Scientific Advice Procedures

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 Systemic Lupus Erythematosus			X		X	X		
Chemical	Treatment of non-small cell lung cancer	X					X	X	
Chemical	Treatment of endometrial cancer	X						X	
Chemical	Treatment of gastrointestinal stromal tumours	X						X	
Biological	Treatment of chronic lymphocytic leukaemia	X						X	
Chemical	Treatment of melanoma	X						X	
Biological	Treatment of chronic renal failure			X				X	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharma-ceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Prevention of venous thromboembolism	X				X	X	X	
Biological	Prevention of influenza virus infection			X				X	
Chemical	Treatment of HIV infection	X						X	
Biological	Treatment of osteonecrosis		X			X	X	X	
Biological	Treatment of Alzheimer's disease	X					X		
Chemical	Treatment of symptomatic neurogenic orthostatic hypotension		X					X	
Chemical	Treatment of acute migraine			X				X	
Chemical	Reduction of alcohol consumption	X						X	
Chemical	Treatment of open angle glaucoma and ocular hypertension	X				X			
Chemical	Detection of alpha v beta 3-associated tumour angiogenesis	X					X	X	
Biological	Treatment of haemophilia B		X					X	X

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 11 Scientific Advice letters, 3 Protocol Assistance letters and 4 Follow-up Scientific Advice letters were adopted at the 27-30 May CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 53 new Requests for which the procedure started at the SAWP meeting held on 6-8 May. The new requests are divided as follows: 32 Initial Scientific Advice, 12 Follow-up Scientific Advice, 8 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE FEBRUARY 2008 CHMP MEETING

VACCINES WORKING PARTY (VWP)

Reference number	Document	Status[3]
CHMP/VEG/4717/03 Rev. 1	Revised Guideline on dossier structure and content of pandemic influenza vaccine marketing authorisations	Adopted for 3-month public consultation
CHMP/VWP/125444/2008	Core SPC for Influenza vaccines prepared from viruses with a pandemic potential and intended to be used outside of the core dossier context.	Adopted for 6-month public consultation

GENE THERAPY WORKING PARTY (GTWP)

Reference number	Document	Status[3]
CHMP/GTWP/125491/ 2006	Guideline on the Scientific Requirements for the Environment Risk Assessment of gene therapy medicinal products	Adopted
CHMP/GTWP/564874/ 2007	Overview of comments received on the Guideline on Scientific Requirements for the Environmental Risk Assessment of gene therapy medicinal products (EMEA/CHMP/GTWP/564874/2007	Adopted
CHMP/GTWP/60436/2007	Draft Guideline on follow-up of patients administered with gene therapy/medicinal products	Adopted for 6-month public consultation
CHMP/GTWP/125459/ 2006	Guideline on the non-clinical studies required before first clinical use of gene therapy medicinal products	Adopted
CHMP/GTWP/65260/2008	Overview of comments received on the Guideline on the non-clinical studies required before first clinical use of gene therapy medicinal products	Adopted

WORKING PARTY ON CELL BASED PRODUCT (CPWP)

Reference number	Document	Status[3]
CHMP/410869/2006	Guideline on Cell-Based Medicinal Products	Adopted
CHMP/CPWP/57885/2008	Overview of comments received Guideline on Cell-Based Medicinal Products	Adopted

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

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
CHMP/CVMP/QWP/ 139037/2008	Question-and-Answer document on the process validation	Adopted
CHMP/CVMP/QWP/ 136351/2008	Concept Paper on the Development of a Guideline on Setting Specifications for Related Impurities in Antibiotics	Adopted for 3-month public consultation

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CHMP/EWP/9147/2008	Guideline on the Clinical Development of Medicinal Products for the Treatment of Cystic Fibrosis	Adopted for 6-month public consultation
CHMP/EWP/176348/2008	Concept Paper on the Need for Revision of the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus	Adopted
CHMP/EWP/110540/2007	Guideline on the Clinical and non Clinical Evaluation during the consultation procedure on Medicinal Substances contained in Drug-Eluting (Medicinal Substance-Eluting) coronary stents	Adopted
EMEA/255210/2008	Concept Paper on need for Revision of (CHMP) Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders	Adopted